



COUNTYCARE HEALTH PLAN PRIOR AUTHORIZATION GUIDELINES

Administered by



April 1, 2026

Specialty Guideline Management

Actemra and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Actemra	tocilizumab
Avtozma	tocilizumab-anoh
Tofidence	tocilizumab-bavi
Tyenne	tocilizumab-aazq
tocilizumab-aazg (unbranded Tyenne)	tocilizumab-aazg
tocilizumab-anoh (unbranded Avtozma)	tocilizumab-anoh

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻⁶

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs)
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA)
- Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA)
- Adult patients with giant cell arteritis (GCA)
- Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function

- Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
- Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

Compendial Uses^{7,20}

- Unicentric Castleman disease
- Multicentric Castleman disease
- Oligoarticular juvenile idiopathic arthritis
- Immune checkpoint inhibitor-related toxicity
- Acute graft versus host disease
- Cytokine release syndrome (other than severe or life-threatening CAR T cell-induced CRS)
- Polymyalgia rheumatica
- Moderate to severe rheumatoid arthritis with no previous treatment failure

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving treatment for COVID-19 will be managed according to the member's inpatient benefit.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Articular juvenile idiopathic arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic juvenile idiopathic arthritis (sJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Immune checkpoint inhibitor-related toxicity, and acute graft versus host disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

Initial requests

Result of a chest high-resolution computed tomography (HRCT) study.

Polymyalgia rheumatica and immune checkpoint inhibitor-related inflammatory arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, and polymyalgia rheumatica: rheumatologist
- Systemic sclerosis-associated interstitial lung disease: rheumatologist or pulmonologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Cytokine release syndrome, unicentric Castleman disease, multicentric Castleman disease, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Coverage Criteria

Rheumatoid arthritis (RA)^{1-6,8,9,16,18-20}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when either of the following criteria is met:

- Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
- Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Articular juvenile idiopathic arthritis^{1-6,12,21}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:

- Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
- Presence of erosive disease or enthesitis
- Delay in diagnosis
- Elevated levels of inflammation markers
- Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

Systemic juvenile idiopathic arthritis (sJIA)^{1-6,11,21}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Giant cell arteritis (GCA)^{1-6,13}

Authorization of 12 months may be granted for adult members for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- Temporal artery biopsy or cross-sectional imaging
- Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP]).

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)^{1,17,23,24}

Authorization of 12 months may be granted for adult members for treatment of sclerosis-associated interstitial lung disease when the diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Cytokine release syndrome^{1,7}

Authorization of 1 month may be granted for the prophylaxis or treatment of cytokine release syndrome (CRS).

Unicentric Castleman disease⁷

Authorization of 12 months may be granted for treatment of unicentric Castleman disease when all of the following criteria are met:

- The member is human immunodeficiency virus (HIV)-negative.
- The member is human herpesvirus-8-negative.

- The requested medication will be used as a single agent.
- The disease has progressed following treatment of relapsed/refractory disease or has surgically unresectable disease.

Multicentric Castleman disease⁷

Authorization of 12 months may be granted for treatment of multicentric Castleman disease when either of the following criteria is met:

- The member meets both of the following:
 - The requested medication will be used as a single agent.
 - The disease has progressed following treatment of relapsed/refractory or progressive disease.
- The requested medication is being used as a substitute for siltuximab when there is a shortage of siltuximab or it is not available.

Immune checkpoint inhibitor-related toxicity⁷

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Acute graft versus host disease⁷

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Polymyalgia rheumatica (PMR)⁷

Authorization of 12 months may be granted for treatment of polymyalgia rheumatica (PMR) when any of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has had a disease flare during a taper with systemic corticosteroids.
- Member has had an inadequate response to methotrexate.

- Member has had an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

Continuation of Therapy

Rheumatoid arthritis (RA)^{1-6,8,9,16,18-19}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Articular juvenile idiopathic arthritis^{1-6,12,21}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Systemic juvenile idiopathic arthritis (sJIA)^{1-6,11,21}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for sJIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Giant cell arteritis (GCA)^{1,14}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for GCA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Headaches
- Scalp tenderness
- Tenderness and/or thickening of superficial temporal arteries

- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)¹

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for SSc-ILD when the member is currently receiving treatment with Actemra or Tyenne.

Immune checkpoint inhibitor-related inflammatory arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Cytokine release syndrome, acute graft versus host disease, and immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Unicentric Castleman disease and Multicentric Castleman disease

Authorization of 12 months may be granted for continued treatment in members (including new members) who are using the requested medication for Unicentric Castleman disease or Multicentric Castleman disease when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Polymyalgia rheumatica (PMR)

Authorization of 12 months may be granted for continued treatment in members who are using the requested medication for PMR and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Morning stiffness
- Hip or shoulder pain
- Hip or shoulder range of motion
- C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Other^{1-6,15}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate²²

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis²¹

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.

2. Avtozma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2025.
3. tocilizumab-aazg [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC; May 2025.
4. tocilizumab-anoh [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2025.
5. Tofidence [package insert]. Cambridge, MA: Biogen MA Inc.; March 2025.
6. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA LLC; February 2025.
7. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed January 23, 2025.
8. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
9. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
10. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
11. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013;65:2499-2512.
12. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *American College of Rheumatology*. 2019;1-18.
13. Stone JH, Tuckwell K, Dimonaco S, et al. Efficacy and safety of tocilizumab in patients with giant cell arteritis: Primary and secondary outcomes from a phase 3, randomized, double-blind, placebo-controlled trial. 2016 ACR/ARHP Annual meeting. Abstract number 911.
14. Hellmich B, Agueda A, Monti S, et al. 2018 Update of the EULAR recommendations for the management of large vessel vasculitis. *Ann Rheum Dis*. 2020;79(1):19-30.
15. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 22, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.
16. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
17. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2020 Oct;8(10):e75 [published correction appears in *Lancet Respir Med*. 2021 Mar;9(3):e29]. *Lancet Respir Med*. 2020;8(10):963-974. doi:10.1016/S2213-2600(20)30318-0.
18. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis disease activity and physical function. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed January 23, 2025.
19. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2021;0:1-16.
20. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 23, 2025.

21. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
22. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6): 1445-86.
23. Rahaghi FF, Hsu VM, Kaner RJ, et al. Expert consensus on the management of systemic sclerosis-associated interstitial lung disease. *Respir Res.* 2023;24(1):6-16.
24. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Ann Rheum Dis.* 2024;0:1-12.

Initial Prior Authorization Actinic Keratosis Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Carac	fluorouracil
Klisyri	tirbanibulin
Tolak	fluorouracil
Zyclara	imiquimod

Indications

FDA-approved Indications

Carac

Carac is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

Klisyri

Klisyri is indicated for the topical field treatment of actinic keratosis on the face or scalp.

Tolak

Tolak (fluorouracil) cream is indicated for the topical treatment of actinic keratosis lesions of the face, ears, and/or scalp.

Zyclara

Actinic Keratosis

Reference number(s)
1378-A

Zyclara, 2.5% and 3.75% are indicated for the topical treatment of clinically typical, visible or palpable actinic keratoses (AK) of the face or balding scalp in immunocompetent adults.

External Genital Warts

Zyclara, 3.75% is indicated for the topical treatment of external genital and perianal warts (EGW) in immunocompetent patients 12 years of age and older.

Coverage Criteria

Actinic Keratosis (AK)

Authorization may be granted for the treatment of actinic keratosis (AK) when ONE of the following criteria is met:

- The request is for Carac, Tolak, OR Zyclara.
- The request is for Klisyri AND the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, OR has a contraindication to ANY of the following: imiquimod 5 percent cream, fluorouracil cream or solution.

External Genital Warts (EGW)

Authorization may be granted for the treatment of external genital warts (EGW) when the following criteria is met:

- The request is for Zyclara.

Continuation of Therapy

Actinic Keratosis (AK)

Authorization may be granted for the treatment of actinic keratosis (AK) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of actinic keratosis lesions cleared, patient/prescriber satisfaction, etc.).

External Genital Warts (EGW)

Authorization may be granted for the treatment of external genital warts (EGW) when ALL of the following criteria are met:

Reference number(s)
1378-A

- The request is for Zyclara.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of warts cleared).

Duration of Approval (DOA)

- 1378-A: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

1. Carac [package insert]. Bridgewater, NJ: Bausch Health US, LLC; May 2021.
2. Klisyri [package insert]. Malvern, PA: Almirall, LLC; June 2024.
3. Tolak [package insert]. Sanford, FL: Hill Dermaceuticals, Inc.; August 2022.
4. Zyclara [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2024.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 28, 2025.
6. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 28, 2025.
7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/28/2025).
8. Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85:e209-e233.
9. Eisen DB, Dellavalle RP, Frazer-Green L, et al. Focused update: Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2022;87:374.e1-374.e5.
10. Steeb T, Wessely A, Petzold A, et al. How to Assess the Efficacy of Interventions for Actinic Keratosis? A Review with a Focus on Long-Term Results. J Clin Med. 2021 Oct 15;10(20):4736.

Specialty Guideline Management

Adbry

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adbry	tralokinumab-ldrm

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Atopic Dermatitis^{1,4}

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Dupixent, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when both of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Continuation of Therapy^{1,2}

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products³

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%

Reference number(s)
5125-A

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; June 2024.
2. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
3. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
4. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Specialty Guideline Management

Adempas

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adempas	riociguat

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Pulmonary Arterial Hypertension (PAH)

Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH), (World Health Organization [WHO] Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening. Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II-III and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Adempas is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH to improve exercise capacity and WHO functional class.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)^{1,3-5}

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by right heart catheterization with all of the following pretreatment results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)^{1-4,6,7}

Authorization of 12 months may be granted for treatment of CTEPH when ALL of the following criteria are met:

- Member has CTEPH defined as WHO Group 4 class of pulmonary hypertension (refer to Appendix).
- Member has either of the following:
 - Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA)
 - Inoperable CTEPH with diagnosis confirmed by BOTH of the following:
 - Computed tomography (CT)/magnetic resonance imaging (MRI) angiography or pulmonary angiography
 - Pretreatment right heart catheterization with all of the following results:
 - mPAP > 20 mmHg
 - PCWP ≤ 15 mmHg
 - PVR > 2 Wood units

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁴

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)
 - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
 - Non-malignant tumors (e.g., uterine leiomyoma)
 - Arteritis without connective tissue disease
 - Congenital pulmonary artery stenoses
 - Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; January 2023.
2. Jenkins D, Mayer E, Screaton N, Madani M. State-of-the-art chronic thromboembolic pulmonary hypertension diagnosis and management. *Eur Respir Rev.* 2012;21(123):32-39.
3. Simonneau G, Montani D, Celermajor DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J.* 2019;53(1):1801913. doi: 10.1183/13993003.01913-2018
4. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J.* 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
5. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
6. Kim NH, D'Armini AM, Delcroix M, et al. Chronic thromboembolic pulmonary disease. *Eur Respir J.* 2024;64(4):2401294. doi: 10.1183/13993003.01294-2024
7. Rajagopal S, Bogaard HJ, Elbaz MSM, et al. Emerging multimodality imaging techniques for the pulmonary circulation. *Eur Respir J.* 2024;64(4):2401128. doi: 10.1183/13993003.01128-2024

Prior Authorization Policy

Non-Methylphenidate ADHD Agents (Amphetamine Class) and Select Non-Stimulant Agents

Products Referenced by this document

Brand Name	Generic Name
Adzenys®	amphetamine
Dyanavel®	amphetamine
Evekeo®	amphetamine
Adderall®	amphetamine-dextroamphetamine
Mydayis®	amphetamine-dextroamphetamine
Dexedrine®	dextroamphetamine
Dextroamphetamine	dextroamphetamine
Procentra®	dextroamphetamine
Xelstrym®	dextroamphetamine
Zenzedi®	dextroamphetamine
Arynta®	lisdexamfetamine
Vyvanse®	lisdexamfetamine
Desoxyn®	methamphetamine
Methamphetamine	methamphetamine
Atomoxetine	atomoxetine
Strattera®	atomoxetine
Qelbree®	viloxazine
Clonidine ER 12-hour	clonidine ER
Intuniv®	guanfacine ER
Onyda XR®	clonidine ER suspension

Required Documentation

To support review of a prior authorization request, documentation should clearly identify:

- Member diagnosis
- Member age
- Requested medication, strength, and formulation
- Relevant chart notes supporting the clinical need for therapy
- Documentation of positive clinical response for continuation requests
- Documentation of cardiac risk screening when applicable
- Documentation supporting quantity requests when exceeding plan limits

Coverage Criteria by Indication

ADHD / ADD — Adults (≥18 years)

Authorization of 12 months may be granted when:

- ADHD/ADD diagnosis is documented using DSM-5 evaluation methods, or
 - The member is stable on therapy, and interruption may result in harm.
-

ADHD / ADD — Pediatrics (<18 years)

Under age 6

Authorization of 12 months may be granted when:

- Persistent symptoms despite evidence-based behavioral therapy, AND
- Medication use is FDA-approved or compendia-supported for age.

Age 6–17

Authorization of 12 months may be granted with DSM-5 diagnostic documentation.

Binge-Eating Disorder (lisdexamfetamine, Vyvanse®, Arynta® only)

Authorization of 12 months may be granted when:

- Member is ≥18 years old
 - Diagnosis of binge-eating disorder is documented
 - Cardiac risk screening is documented
-

Narcolepsy

Authorization of 12 months may be granted when:

- Diagnosis of narcolepsy is confirmed by sleep study
- Prescribed by or in consultation with a sleep specialist
- Cardiac risk screening is documented

Idiopathic Hypersomnia / Klein-Levin Syndrome / Secondary Hypersomnia

Authorization of 12 months may be granted when:

- Diagnosis is confirmed by sleep study
- Member is ≥18 years old
- Cardiac risk screening is documented
- Positive clinical response* is documented for continuation

Formulary Exception Criteria

Non-Preferred Stimulant Agents (ADHD/ADD)

Authorization of 12 months may be granted when:

- ADHD/ADD diagnosis is documented
- Previous trial of at least 1 preferred product
- For continuation requests, documentation shows positive clinical response and reassessment within the past year

Non-Preferred Non-Stimulants

Authorization of 12 months may be granted when:

- ADHD/ADD diagnosis is documented
- For continuation requests, positive clinical response* and reassessment are documented

Formulation Exceptions (ODT, chewable, solution, patch)

Authorization of 12 months may be granted when:

- Documentation shows difficulty swallowing or medical need for alternate formulation

Quantity Limit Override

Authorization of 12 months for the requested quantity may be granted when:

- The requested dose is within FDA-approved dosing
- Supported by clinical literature or recognized treatment guidelines

Authorization Duration

All authorizations are issued for 12 months.

*Positive Clinical Response: **ADD/ADHD Examples:** Improvement in hyperactivity, impulsivity, inattention, organization skills, time management, sleep patterns, emotional management, or self-esteem. **Narcolepsy Examples:** improvement in excessive daytime sleepiness, improvement in work/school performance/attendance, improvement in quality of life.

Specialty Guideline Management ambrisentan-Letairis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Letairis	ambrisentan

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) in adults:

- To improve exercise ability and delay clinical worsening.
- In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Compendial Uses⁶⁻⁷

- PAH (WHO Group I) in pediatric members.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)¹⁻⁷

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by either of the following criteria:
 - Pretreatment right heart catheterization with all of the following results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units. For pediatric members, pulmonary vascular resistance index (PVRI) > 3 Wood units x m² is also acceptable.
 - For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁴

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)

- Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
- Non-malignant tumors (e.g., uterine leiomyoma)
- Arteritis without connective tissue disease
- Congenital pulmonary artery stenoses
- Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2025.
2. Ambrisentan [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; January 2024.
3. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. Eur Respir J. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018
4. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. Eur Respir J. 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
5. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. Eur Respir J. 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
6. Ivy D, Rosenzweig EB, Abman SH, et al. Embracing the challenges of neonatal and paediatric pulmonary hypertension. Eur Respir J. 2024;64(4):2401345. doi: 10.1183/13993003.01345-2024
7. Abman SH, Hansmann G, Archer SL, et al. Pediatric Pulmonary Hypertension: Guidelines From the American Heart Association and American Thoracic Society. Circulation. 2015 Nov 24;132(21):2037-99. doi: 10.1161/CIR.0000000000000329

CountyCare IL: ARANESP (darbepoetin alfa)

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CountyCare.

CRITERIA FOR APPROVAL

1. What is the diagnosis?
 - a. Anemia due to chronic kidney disease (CKD)
 - b. Anemia due to myelosuppressive chemotherapy
 - c. Anemia in myelodysplastic syndrome (MDS)
 - d. Anemia in patients whose religious beliefs forbid blood transfusions
 - e. Anemia in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
 - f. Anemia due to cancer
 - g. Other, please specify. _____
2. Does the patient have a documented inadequate response or intolerable adverse event with ONE of the following preferred products, Epogen or Procrit?
 - a. Yes
 - b. No
3. Will the requested medication be used concomitantly with other erythropoiesis stimulating agents (ESAs)?
 - a. Yes
 - b. No
4. Has the patient received erythropoiesis stimulating agent (ESA) therapy in the previous month (within 30 days of request)?
 - a. Yes
 - b. No
5. Has the patient completed at least 12 weeks of ESA therapy? Indicate therapy start date and number of weeks completed. _____
 - a. Yes
 - b. No
6. At any time since the patient started ESA therapy, has the patient's hemoglobin (Hgb) increased by 1 g/dL or more?
 - a. Yes
 - b. No
7. At any time since the patient started ESA therapy, has the patient's hemoglobin (Hgb) increased by 1 g/dL or more?
 - a. Yes
 - b. No
8. Has the patient been assessed for iron deficiency anemia?
 - a. Yes
 - b. No
9. What is the most recent serum transferrin saturation (TSAT) level? Indicate percentage.
 - a. Less than 20%, _____
 - b. Greater than or equal to 20%, _____
 - c. Unknown

10. Was the most recent serum transferrin saturation (TSAT) level obtained within the prior 3 months?
Indicate date lab was drawn. _____
a. Yes
b. No
11. Is the patient receiving iron therapy?
a. Yes
b. No
12. What is the patient's diagnosis?
a. Anemia due to chronic kidney disease (CKD)
b. Anemia due to myelosuppressive chemotherapy
c. Anemia in myelodysplastic syndrome (MDS)
d. Anemia in patients whose religious beliefs forbid blood transfusions
e. Anemia in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
f. Anemia due to cancer
13. Does the patient have a non-myeloid malignancy?
a. Yes
b. No
14. What is the patient's current hemoglobin (Hgb) level (exclude values due to a recent transfusion)?
a. Less than 12 g/dL
b. Greater than or equal to 12 g/dL
c. No
15. Was the patient's current hemoglobin (Hgb) level drawn within 30 days of the request (exclude values due to a recent transfusion)? Indicate date lab was drawn.
a. Yes, _____
b. No, _____
c. Unknown
16. Is the patient undergoing palliative treatment?
a. Yes
b. No
17. Has the patient been assessed for iron deficiency anemia?
a. Yes
b. No
18. What is the most recent serum transferrin saturation (TSAT) level? Indicate percentage.
a. Less than 20%, _____
b. Greater than or equal to 20%, _____
c. Unknown
19. Was the most recent serum transferrin saturation (TSAT) level obtained within the prior 3 months? Indicate date lab was drawn.
a. Yes, _____
b. No, _____
20. Is the patient receiving iron therapy?
a. Yes
b. No
21. What is the patient's diagnosis?

Reference number(s)
C28992-A

- a. Anemia due to chronic kidney disease (CKD)
- b. Anemia due to myelosuppressive chemotherapy
- c. Anemia in myelodysplastic syndrome (MDS)
- d. Anemia in patients whose religious beliefs forbid blood transfusions
- e. Anemia in primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis
- f. Anemia due to cancer

22. Does the patient have a non-myeloid malignancy?

- a. Yes
- b. No

23. What is the patient's pretreatment serum erythropoietin (EPO) level?

- a. Less than 500 mU/mL
- b. Greater than or equal to 500 mU/mL
- c. Unknown

24. What is the patient's pretreatment hemoglobin (Hgb) level (exclude values due to a recent transfusion)?

- a. Less than 10 g/dL
- b. Greater than or equal to 10 g/dL
- c. Unknown

25. Was the patient's pretreatment hemoglobin (Hgb) level drawn within 30 days of the request (exclude values due to a recent transfusion)? Indicate date lab was drawn.

- a. Yes, _____
- b. No, _____
- c. Unknown

26. Is the patient undergoing palliative treatment?

- a. Yes
- b. No

REFERENCE

1. Aranesp 1616-A SGM 2024 Policy.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Adbry

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adbry	tralokinumab-ldrm

Indications

This program applies to Adbry for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Adbry. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase [JAK] inhibitors, topical phosphodiesterase-4 [PDE-4] inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Ebglyss, Dupixent, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 180 days.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when both of the following criteria are met:^{1-5,7}

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁶

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%

Reference number(s)
5520-A

Potency	Drug	Dosage form	Strength
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%

Reference number(s)
5520-A

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Adbry [package insert]. Madison, NJ: LEO Pharma Inc.; June 2024.
2. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
3. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
4. Fishbein AB, Silverberg JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. J Allergy Clin Immunol Pract. 2020;8(1):91-101.
5. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020;34(12):2717-2744.
6. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
7. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Cibinqo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cibinqo	abrocitinib

Indications

This program applies to Cibinqo for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Cibinqo. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:

- Chart notes or medical record documentation showing affected area(s) and affected body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase [JAK] inhibitors, topical phosphodiesterase-4 [PDE-4] inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).

Continuation requests:

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has had an inadequate response or intolerance to at least one biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Rinvoq) in the past 180 days.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:^{1-6,9}

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).
- Member has had an inadequate response or intolerance to treatment with a biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Rinvoq) indicated for the treatment of atopic dermatitis.

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other^{1,7}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁸

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%

Reference number(s)
5521-A

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Cibirgo [package insert]. New York, NY: Pfizer Inc.; December 2023.
2. Simpson EL, Sinclair R, Forman S, et al. Efficacy and safety of abrocitinib in adults and adolescents with moderate-to-severe atopic dermatitis (JADE MONO-1): a multicentre, double-blind, randomised, placebo-controlled, phase 3 clinical trial. Lancet. 2020;396:255-266.

Reference number(s)
5521-A

3. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014;70:338-351.
4. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
5. Fishbein AB, Silverberg, JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. J Allergy Clin Immunol Pract. 2020;8(1):91-101.
6. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020;34(12):2717-2744.
7. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 15, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
8. Topical Corticosteroids. *Drug Facts and Comparisons*. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
9. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Dupixent

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Dupixent	dupilumab

Indications

This program applies to Dupixent for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Dupixent. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase [JAK] inhibitors, topical phosphodiesterase-4 [PDE-4] inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 6 months of age or older who have previously received a biologic (e.g., Adbry, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 180 days.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 6 months of age or older when both of the following criteria are met:^{1-7,9}

- Affected body surface area is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Continuation of Therapy

Authorization of 12 months may be granted for members 6 months of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁸

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%

Reference number(s)
1743-A

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2024.
2. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014;70:338-351.

Reference number(s)
1743-A

3. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
4. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016;375:2335-2348.
5. Fishbein AB, Silverberg JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. J Allergy Clin Immunol Pract. 2020;8(1):91-101.
6. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020;34(12):2717-2744.
7. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03346434. Safety, Pharmacokinetics and Efficacy of Dupilumab in Patients ≥ 6 months to < 6 years with Moderate-to-Severe Atopic Dermatitis (Liberty AD PRESCHOOL) 2022 Jun 10. Available from: <https://clinicaltrials.gov/ct2/show/NCT03346434>.
8. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
9. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Ebglyss

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ebglyss	lebrikizumab-lbkz

Indications

This program applies to Ebglyss for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Ebglyss. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase [JAK] inhibitors, topical phosphodiesterase [PDE-4] inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 12 years of age or older weighing at least 40 kg who have previously received a biologic (e.g., Adbry, Dupixent, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 180 days.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older weighing at least 40 kg when both of the following criteria are met:¹⁻⁶

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) weighing at least 40 kg who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁷

Potency	Drug	Dosage form	Strength
I.Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I.Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I.Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I.Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I.Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II.High potency (group 2)	Amcinonide	Ointment	0.1%

Potency	Drug	Dosage form	Strength
II.High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II.High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II.High potency (group 2)	Clobetasol propionate	Cream	0.025%
II.High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II.High potency (group 2)	Desoximetasone	Gel	0.05%
II.High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II.High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II.High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II.High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III.High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III.High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III.High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III.High potency (group 3)	Betamethasone valerate	Foam	0.12%
III.High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III.High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III.High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III.High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III.High potency (group 3)	Mometasone furoate	Ointment	0.1%
III.High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV.Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%

Potency	Drug	Dosage form	Strength
IV.Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV.Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV.Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV.Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV.Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V.Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V.Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V.Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V.Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V.Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V.Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V.Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V.Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%

Potency	Drug	Dosage form	Strength
VI.Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI.Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI.Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI.Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI.Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024.
2. Silverberg JI, Guttman-Yassky E, Thaçi D, et al. Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. *N Engl J Med*. 2023;388(12):1080-1091.
3. Simpson EL, Gooderham M, Wollenberg A, et al. Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere). *JAMA Dermatol*. 2023;159(2):182-191.
4. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol*. 2014;70:338-351.
5. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
6. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024 Feb;90(2):e43-e56.

Reference number(s)
6646-A

7. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Nemluvio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nemluvio	nemolizumab-ilto

Indications

This program applies to Nemluvio for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Nemluvio. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical records showing affected area(s) and body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase (JAK) inhibitors, topical phosphodiesterase-4 (PDE-4) inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Adbry, Ebglyss, Dupixent) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past 180 days. The requested medication must be prescribed in combination with a low potency to medium potency topical corticosteroid (see Appendix) or topical calcineurin inhibitor, unless the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

- Member is prescribed the requested medication in combination with a low potency to medium potency topical corticosteroid (see Appendix) or topical calcineurin inhibitor or the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Nemluvio [package insert]. Dallas, TX: Galderma Laboratories; December 2024.
2. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
3. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
4. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.
5. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed December 23, 2024.

Enhanced Specialty Guideline Management Treatment of Atopic Dermatitis Rinvoq

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rinvoq	upadacitinib

Indications

This program applies to Rinvoq for the treatment of atopic dermatitis. For indications other than atopic dermatitis, refer to the Specialty Guideline Management program for Rinvoq. Coverage will be provided if all the approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and affected body surface area (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried (including topical calcineurin inhibitors, topical corticosteroids, topical Janus kinase [JAK] inhibitors, topical phosphodiesterase-4 [PDE-4] inhibitors, or biologics/targeted synthetic drugs) including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has had an inadequate response or intolerance to at least one biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Cibinqo) in the past 180 days.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:^{1-5,8}

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past 180 days:
 - A high potency or super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical JAK inhibitor
 - A topical PDE-4 inhibitor
 - The use of high potency or super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).
- Member has had an inadequate response or intolerance to treatment with a biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Cibinqo) indicated for the treatment of atopic dermatitis.

Continuation of Therapy

Authorization of 12 months may be granted for all members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other^{1,6}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Table. Relative potency of select topical corticosteroid products⁷

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Rinvoq [package insert]. North Chicago, IL; AbbVie, Inc.; April 2024.

Reference number(s)
5522-A

2. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014;70:338-351.
3. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
4. Fishbein AB, Silverberg, JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. J Allergy Clin Immunol Pract. 2020;8(1): 91-101.
5. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020;34(12):2717-2744.
6. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 15, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
7. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
8. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Specialty Guideline Management

Austedo-Austedo XR

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Austedo	deutetrabenazine
Austedo XR	deutetrabenazine extended release

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Treatment of chorea associated with Huntington's disease in adults
- Treatment of tardive dyskinesia in adults

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.

Reference number(s)
1746-A

- Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.

Coverage Criteria

Chorea associated with Huntington's disease^{1,2}

Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:

- Member demonstrates characteristic motor examination features.
- Member meets one of the following conditions:
 - Laboratory results indicate an expanded HTT CAG repeat sequence of at least 36
 - Member has a positive family history for Huntington's disease

Tardive dyskinesia^{1,3-5}

Authorization of 6 months may be granted for treatment of tardive dyskinesia when both of the following criteria are met:

- Member exhibits clinical manifestations of disease.
- Member's tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale [AIMS], Dyskinesia Identification System: Condensed User Scale [DISCUS]).

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Austedo [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. February 2025.
2. Frank S, Testa CM, Stamler D, et al. Effect of deutetrabenazine on chorea among patients with Huntington disease: a randomized clinical trial. JAMA. 2016;316(1):40-50.
3. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: the ARM-TD study. Neurology. 2017;88:2003-10.

Reference number(s)
1746-A

4. Anderson KE, Stamler D, Davis MD, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomized, placebo-controlled, phase 3 trial. *Lancet Psychiatry*. 2017;4:595-604.
5. American Psychiatric Association. (2021). Practice Guideline for the Treatment of Patients With Schizophrenia, third edition. <https://doi.org/10.1176/appi.books.9780890424841>.

Specialty Guideline Management

Bafiertam

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Bafiertam	monomethyl fumarate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication¹

Bafiertam is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing forms of multiple sclerosis¹

Reference number(s)
3881-A

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically isolated syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted to members who are experiencing disease stability or improvement while receiving Bafiertam.

Other Criteria

- Members will not use Bafiertam concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Reference

1. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; March 2024.

Specialty Guideline Management

Benlysta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Benlysta	belimumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Benlysta is indicated for the treatment of:

- Patients 5 years of age and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy
- Patients 5 years of age and older with active lupus nephritis who are receiving standard therapy

Limitations of Use

The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system (CNS) lupus. Use of Benlysta is not recommended in this situation.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins), or kidney biopsy supporting the diagnosis (where applicable).

Continuation requests

- Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Severe active central nervous system (CNS) lupus (including seizures that are attributed to CNS lupus, psychosis, organic brain syndrome, cerebritis, or CNS vasculitis requiring therapeutic intervention before initiation of belimumab) in a member initiating therapy with Benlysta.
- Member is using Benlysta in combination with other biologics.

Coverage Criteria

Systemic Lupus Erythematosus (SLE)^{1-4,6,8}

Authorization of 12 months may be granted for treatment of active SLE when both of the following criteria are met:

- Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins)
- The member is receiving a standard treatment for SLE with any of the following (alone or in combination):
 - Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
 - Antimalarials (e.g., hydroxychloroquine)
 - Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

Active Lupus Nephritis^{1,4-5,7-8}

Authorization of 12 months may be granted for treatment of active lupus nephritis when both of the following criteria are met:

- Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins) or lupus nephritis was confirmed on kidney biopsy.

- Member is receiving a standard therapy regimen (e.g., cyclophosphamide, mycophenolate mofetil, azathioprine, glucocorticoids).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References

1. Benlysta [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; June 2024.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2023 Update of the EULAR Recommendations for the Management of Systemic Lupus Erythematosus. *Ann Rheum Dis*. 2024;83:15-29.
3. Rovin BH, Parikh SV, Hebert LA, et al. Lupus nephritis: induction therapy in severe lupus nephritis – should MMF be considered the drug of choice? *Clin J Am Soc Nephrol*. 2013;8(1):147-153.
4. Hahn BH, McMahon MA, Wilkinson A, et al. American College of Rheumatology guidelines for screening, treatment, and management of lupus nephritis. *Arthritis Care & Research*. 2012;64(6):797-808.
5. Furie R, Rovin BH, Houssiau F, et al. Two-Year, Randomized, Controlled Trial of Belimumab in Lupus Nephritis. *N Engl J Med*. 2020;383(12):1117-1128.
6. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Ann Rheum Dis*. 2019;78:1151-1159.
7. Rovin BH, Adler SG, Barratt J, et al. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Disease Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021 Oct; 100(4S):S1-S276.
8. Gordon C, Amissah-Arthru MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. *Rheumatology (Oxford)*. 2018; 57(1):e1-e45.
9. Petri M, Orbai A-M, Alarcon GS, et al. Derivation and Validation of Systemic Lupus International Collaborating Clinics (SLICC) Classification Criteria for Systemic Lupus Erythematosus. *Arthritis Rheum*. 2012; 64:2677-2686. URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409311/>. Accessed January 21, 2025.

Specialty Guideline Management

Bimzelx

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Bimzelx	bimekizumab-bkzx

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with moderate to severe hidradenitis suppurativa (HS)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and hidradenitis suppurativa (HS)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Plaque psoriasis: dermatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- Ankylosing spondylitis and non-radiographic axial spondyloarthritis: rheumatologist

Coverage Criteria

Plaque psoriasis (PsO)^{1-5,7-9}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Psoriatic arthritis (PsA)^{1,10,13-16}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
 - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,11,12,17,18}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has had an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Hidradenitis suppurativa (HS)^{1,19,20}

Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Continuation of Therapy

Plaque psoriasis (PsO)¹

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Psoriatic arthritis (PsA)^{1,13,14}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,11,12,17}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Hidradenitis suppurativa (HS)^{1,19,20}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Other^{1,6}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide⁸

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024.
2. Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial [published correction appears in Lancet. 2021;397(10280):1182]. Lancet. 2021;397(10273):475-486.
3. Lebwohl M, Strober B, Menter A, et al. Phase 3 studies comparing brodalumab with ustekinumab in psoriasis. N Engl J Med. 2015;373(14):1318-1328.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
6. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 15, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.
7. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18(8):465-479.
8. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis

- Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
9. Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. *Lancet.* 2021;397(10273):487-498.
 10. 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.
 11. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896-904.
 12. 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):1285-1299.
 13. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum.* 2018;71:5-32.
 14. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
 15. Ritchlin CT, Coates LC, McInnes IB, et al. Bimekizumab treatment in biologic DMARD-naïve patients with active psoriatic arthritis: 52-week efficacy and safety results from the phase III, randomised, placebo-controlled, active reference BE OPTIMAL study. *Ann Rheum Dis.* 2023;82(11):1404-1414.
 16. Coates LC, Landewé R, McInnes IB, et al. Bimekizumab treatment in patients with active psoriatic arthritis and prior inadequate response to tumour necrosis factor inhibitors: 52-week safety and efficacy from the phase III BE COMPLETE study and its open-label extension BE VITAL. *RMD Open.* 2024;10(1):e003855.
 17. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82:19-34.
 18. van der Heijde D, Deodhar A, Baraliakos X, et al. Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials [published correction appears in *Ann Rheum Dis.* 2023;82(9):e213. doi: 10.1136/ard-2022-223595corr1]. *Ann Rheum Dis.* 2023;82(4):515-526. doi:10.1136/ard-2022-223595.
 19. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. *J Am Acad Dermatol.* 2019;81(1):76-90.
 20. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol.* 2019;81(1):91-101.

Specialty Guideline Management

Botox

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Botox	onabotulinumtoxin A

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults or pediatric patients 5 years of age or older who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

Reference number(s)
2247-A

- Treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Safety and effectiveness have not been established in patients under age 18.
- Treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Compendial Uses

- Achalasia
- Chronic anal fissures
- Essential tremor
- Excessive salivation (ptyalism)
- Hemifacial spasm
- Spasmodic dysphonia (laryngeal dystonia)
- Oromandibular dystonia
- Myofascial pain syndrome
- Focal hand dystonia
- Facial myokymia
- Hirschsprung disease with internal sphincter achalasia
- Orofacial tardive dyskinesia
- Painful bruxism
- Palatal myoclonus
- First bite syndrome
- Palmar or gustatory (Frey's syndrome) hyperhidrosis

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

The medication must be prescribed by, or in consultation with a provider specialized in treating the member's condition.

Exclusions

Coverage will not be provided for cosmetic use.

Coverage Criteria

Blepharospasm

Authorization of 12 months may be granted for treatment of blepharospasm when all of the following criteria are met:

- Member is 12 years of age or older
- Member is diagnosed with blepharospasm including blepharospasm associated with dystonia, benign essential blepharospasm or VII nerve disorder.

Cervical Dystonia

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when all of the following criteria are met:

- There is abnormal placement of the head with limited range of motion in the neck
- Member is 18 years of age or older.

Chronic Migraine Prophylaxis

Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:

- Member experiences headaches 15 days or more per month.
- Member experiences headaches lasting 4 hours or longer on at least 8 days per month.
- Member completed an adequate trial of (or has a contraindication to) two migraine preventative therapies coming from at least 2 of the following classes with a trial of each medication at least 60 days in duration:
 - Antidepressants (e.g., amitriptyline, venlafaxine)
 - Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium)
 - Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol)
 - Calcitonin gene-related peptide (CGRP)-targeting therapies (e.g., fremanezumab, galcanezumab, epitinezumab, rimegepant, atogepant).
- Member has signs and symptoms consistent with chronic migraine diagnostic criteria as defined by the International Headache Society (IHS).
- Member is 18 years of age or older

Overactive Bladder with Urinary Incontinence

Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence, urgency, and frequency when all of the following criteria are met:

- The member has tried and failed behavioral therapy.
- The member has had an inadequate response or experienced intolerance to two agents from either of the following classes:
 - Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
 - Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron], Gemtesa [vibegron]).
- Member is 18 years of age or older.

Primary Axillary, Palmar, and Gustatory (Frey's Syndrome) Hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary, palmar, or gustatory (Frey's syndrome) hyperhidrosis when all of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating.
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.
- Member is 18 years of age or older.

Strabismus

Authorization of 12 months may be granted for treatment of strabismus when all of the following criteria are met:

- Strabismus interference with normal visual system development is likely to occur and spontaneous recovery is unlikely.
- Member is 12 years of age or older.
- Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

Upper or Lower Limb Spasticity

Authorization of 12 months may be granted for treatment of upper or lower limb spasticity when all of the following criteria are met:

- Member is 2 years of age or older

- Member has a primary diagnosis of upper or lower limb spasticity or as a symptom of a condition causing limb spasticity (including focal spasticity or equinus gait due to cerebral palsy).

Urinary Incontinence Due to Detrusor Overactivity Associated with a Neurologic Condition (e.g., Spinal Cord Injury, Multiple Sclerosis)

Authorization of 12 months may be granted for treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) when all of the following criteria are met:

- The member has tried and failed behavioral therapy.
- The member has had an inadequate response or experienced intolerance to one agent from either of the following classes:
 - Anticholinergic medication (e.g., Vesicare [solifenacin], Enablex [darifenacin], Toviaz [fesoterodine], Detrol/Detrol LA [tolterodine], Sanctura/Sanctura XR [trospium], Ditropan XL [oxybutynin]).
 - Beta-3 adrenergic agonist (e.g., Myrbetriq [mirabegron])
- Member is 5 years of age or older.

Achalasia

Authorization of 12 months may be granted for treatment of achalasia when the member has tried and failed or is a poor candidate for conventional therapy such as pneumatic dilation and surgical myotomy.

Chronic Anal Fissures

Authorization of 12 months may be granted for treatment of chronic anal fissures when the member has not responded to first line therapy such as topical calcium channel blockers or topical nitrates.

Essential Tremor

Authorization of 12 months may be granted for treatment of essential tremor.

Excessive Salivation

Authorization of 12 months may be granted for treatment of excessive salivation (chronic sialorrhea or ptyalism) when the member has been refractory to pharmacotherapy (e.g., anticholinergics).

Hemifacial Spasm

Authorization of 12 months may be granted for treatment of hemifacial spasm.

Spasmodic Dysphonia (laryngeal dystonia)

Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

Oromandibular Dystonia

Authorization of 12 months may be granted for treatment of oromandibular dystonia.

Myofascial Pain Syndrome

Authorization of 12 months may be granted for treatment of myofascial pain syndrome when the member has tried and failed all of the following:

- Physical therapy
- Injection of local anesthetics into trigger points
- Injection of corticosteroids into trigger points

Focal Hand Dystonia

Authorization of 12 months may be granted for the treatment of focal hand dystonias.

Facial Myokymia

Authorization of 12 months may be granted for the treatment of facial myokymia.

Hirschsprung Disease with Internal Sphincter Achalasia

Authorization of 12 months may be granted for the treatment of Hirschsprung's disease with internal sphincter achalasia following endorectal pull through and the member is refractory to laxative therapy.

Orofacial Tardive Dyskinesia

Authorization of 12 months may be granted for the treatment of orofacial tardive dyskinesia when conventional therapies have been tried and failed (e.g., benzodiazepines, clozapine, or tetrabenazine).

Painful Bruxism

Authorization of 12 months may be granted for the treatment of painful bruxism when the member has had an inadequate response to a night guard and has had an inadequate response to pharmacologic therapy such as diazepam.

Palatal Myoclonus

Authorization of 12 months may be granted for the treatment of palatal myoclonus when the member has disabling symptoms (e.g., intrusive clicking tinnitus) who had an inadequate response to clonazepam, lamotrigine, carbamazepine or valproate.

First Bite Syndrome

Authorization of 12 months may be granted for the treatment of first bite syndrome when the member has failed relief from analgesics, antidepressants or anticonvulsants.

Continuation of Therapy

- All members (including new members) requesting authorization for continuation of therapy for approvable conditions other than migraine prophylaxis must meet all requirements in the coverage criteria and be experiencing benefit from therapy.
- Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the member has achieved or maintained a reduction in monthly headache frequency since starting therapy with Botox.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Adults: Dosing should not exceed a cumulative dose of 400 units every 84 days

Pediatric (patients less than 18 years of age): Dosing should not exceed the lessor of 10 units/kg or 340 units every 84 days.

References

1. Botox [package insert]. Madison, NJ: Allergan USA, Inc; November 2023.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com>. Accessed July 10, 2024.
3. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed July 10, 2024.
4. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the

- American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-45.
5. Snow V, Weiss K, Wall EM, et al. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. *Ann Intern Med*. 2002;137(10):840-849.
 6. Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine--revised report of an EFNS task force. *Eur J Neurol*. 2009;16(9):968-981.
 7. Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(2 Suppl 2):S1-59.
 8. Zesiewicz TA, Elble RJ, Louis ED et al. Evidence-based guideline update: Treatment of essential tremor: Report of the Quality Standards Subcommittee of the American Academy of Neurology: *Neurology* 2011; 77: 1752-1755.
 9. Restivo D, Panebianco M, Casabona A et al. Botulinum Toxin A for Sialorrhea Associated with Neurological Disorders: Evaluation of the Relationship between Effect of Treatment and the Number of Glands Treated. *Toxins* 2018;55:1-10.
 10. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. *Toxins* 2013, 5, 1010-1031
 11. Zoons E, Dijkgraaf M, Dijk J et al. Botulinum toxin as treatment for focal dystonia: a systematic review of the pharmaco-therapeutic and pharmaco-economic value. *J Neurol* 2012;259: 2519-2526.
 12. Conrin L, Karp BI, Alter K et al. Long Term Follow-up Botulinum Toxin Therapy for Focal Hand Dystonia: Outcome at 10 or More Years: *Mov Disord*. 2011 Mar; 26(4): 750–753.
 13. Daele D, Finnegan E, Rodnitzky R et al. Head and Neck Muscle Spasm After Radiotherapy. *Otolaryngol Head and Neck Surg* 2002;128:956-959.
 14. Han-Guerts I, Hendrix V, Blaauw I et al. Outcome after Anal Intrasphincteric Botox Injection in Children with Surgically Treated Hirschsprung Disease. *JPGN* 2014; 59: 604-607.
 15. Asutay F, Atalay Y, Asutay H, Huseyin Acar A. The Evaluation of the clinical effects of Botulinum Toxin on Nocturnal Bruxism. *Pain Research and Management* 2017;1-5.
 16. Gosain A, Frykman PK, Cowles RA, et al. Guidelines for the diagnosis and management of Hirschsprung-associated enterocolitis. *Pediatr Surg Int*. 2017; 33(5):517–521.
 17. Thuruthiath N, Arayamparambil R. Essential palatal myoclonus: A rare cause of objective tinnitus. *J Adv Med Heath Res* 2016;3:1-3.
 18. Laccourreye O, Werner A, Garcia D, Malinvaud D, Tran Ba Huy P, Bonfils P. First bite syndrome. *Euro Ann Otolaryngol Head Neck Diseases*. 2013; 130:269-273.
 19. Linkov G et al. First bite syndrome: incidence, risk factors, treatment, and outcomes. *The Laryngoscope*. 2012; 122: 1773-1778.
 20. Slotema CW;van Harten PN;Bruggeman R;Hoek HW. Botulinum toxin in the treatment of orofacial tardive dyskinesia: a single blind study. *Prog Neuropsychopharmacol Biol Psychiatry* 2008;32(2):507-509.
 21. Odderson IR. Hyperhidrosis treated by botulinum A exotoxin. *Dermatol Surg*. 1998;24(11):1237-1241.
 22. Solomon BA, Hayman R. Botulinum toxin type A therapy for palmar and digital hyperhidrosis. *J Am Acad Dermatol*. 2000;42(6):1026-1029.
 23. Naver H, Swartling C, Aquilonius SM. Palmar and axillary hyperhidrosis treated with botulinum toxin: One-year clinical follow-up. *Eur J Neurol*. 2000;7(1):55-62.

Reference number(s)
2247-A

24. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders: 3rd edition. Cephalalgia. 2018;Vol. 38(1) 1–211.
25. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. American Academy for Cerebral Palsy and Developmental Medicine Care Pathways. <https://www.aacpdm.org/publications/care-pathways/sialorrhea>. Accessed August 3, 2021.
26. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. Degener Neurol Neuromuscul Dis. 2019; 9: 19–26.
27. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. Published online March 11, 2024.
28. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. J Urol. 2024;212(1):11-20.
29. Smith C, Pariser D. Primary Focal Hyperhidrosis. Waltham, MA. UpToDate. Last Modified May 13, 2024. <https://www.uptodate.com/contents/primary-focal-hyperhidrosis>. Accessed July 22, 2024.

Initial Prior Authorization with Quantity Limit

Benign Prostatic Hyperplasia (BPH)

Chewtadzy 5 mg, Cialis 2.5 mg, 5 mg

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form	Strength
Chewtadzy	tadalafil	chewable tablets	5 mg
Cialis	tadalafil	all	2.5 mg, 5 mg

Indications

FDA-approved Indications

Chewtadzy

Erectile Dysfunction

Chewtadzy is indicated for the treatment of erectile dysfunction (ED) in adult males.

Benign Prostatic Hyperplasia

Chewtadzy is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males.

Erectile Dysfunction and Benign Prostatic Hyperplasia

Chewtadzy is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH) in adult males.

Reference number(s)
865-C

Limitations of Use

If Chewtdazy is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil beyond 26 weeks is unknown.

Chewtdazy is not indicated for once daily use for ED because dosing is not possible in such patients (the recommended dosage for this indication cannot be achieved with the lowest available strength).

Cialis

Erectile Dysfunction

Cialis is indicated for the treatment of erectile dysfunction (ED).

Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Erectile Dysfunction and Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

Limitation of Use

If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

Coverage Criteria

Benign Prostatic Hyperplasia (BPH)

Authorization may be granted when the requested drug is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH).

[NOTE: Examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency.]

Continuation of Therapy

Benign Prostatic Hyperplasia (BPH)

Authorization may be granted when the requested drug is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) when the following criteria is met:

Reference number(s)
865-C

[NOTE: Examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency.]

- The patient has achieved or maintained a positive clinical response to the requested drug.

Quantity Limits Apply

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Chewtadzy (tadalafil chewable tablets) 5 mg	30 tablets / 25 days	90 tablets / 75 days
Cialis (tadalafil) 2.5 mg, 5 mg	30 tablets / 25 days	90 tablets / 75 days

Duration of Approval (DOA)

- 865-C: DOA: 36 months

References

1. Chewtadzy [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc. June 2024.
2. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 25, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/25/2025).
5. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Part I-Initial Work-up and Medical Management. J Urol. 2021;206(4):806-817.
6. Sandhu JS, Bixler BR, Dahm P, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (BPH): AUA Guideline Amendment 2023. J Urol. 2023;211(1):11-19.
7. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: AUA Guideline. J Urol. 2018;200:633-641.
8. Ueda P, Mercer CH, Ghaznavi C, et al. Trends in Frequency of Sexual Activity and Number of Sexual Partners Among Adults Aged 18-44 Years in the US, 2000-2018. JAMA Network Open. 2020;3(6):e203833.
9. Twenge JM, Sherman RA, Wells BE. Declines in Sexual Frequency Among American Adults, 1989–2014. Arch Sex Behav. 2017;46(8):2389-2401.
10. Mark KP, Arenella K, Girard A, et al. Erectile dysfunction in the United States: report from the 2021 National Survey of Sexual Wellbeing. J Sex Med. 2024;21(4):296-303.

Specialty Guideline Management

Cabenuva

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cabenuva	cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Cabenuva is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per milliliter [mL]) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

All other indications are considered experimental/investigational and not medically necessary.

Compendial Uses

HIV-1 infection with viremia^{2,3}

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Plasma HIV-1 RNA level (viral load) within the last 6 months
- For HIV-1 infection with viremia only: laboratory results, chart notes, or medical record documentation supporting high risk of disease progression.

Coverage Criteria

Human Immunodeficiency Virus Type 1 (HIV-1) Infection¹⁻³

Authorization of 12 months may be granted for treatment of human immunodeficiency virus type 1 (HIV-1) infection when either of the following criteria is met:

- Member meets all of the following criteria:
 - Member is currently receiving a stable antiretroviral regimen.
 - Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA level (viral load) less than 50 copies per mL.
 - Member has no history of treatment failure.
 - Member has no known or suspected resistance to either cabotegravir or rilpivirine.
- Member meets all of the following criteria:
 - Member has viremia (i.e., elevated HIV-1 RNA level [viral load]).
 - Member has high risk of disease progression (e.g., cluster of differentiation 4 [CD4] count less than 200 cells per microliter, history of acquired immunodeficiency syndrome [AIDS]-defining complications).
 - Member is unable to achieve or maintain virologic suppression while on oral antiretroviral therapy (ART) despite intensive medication adherence support.
 - The prescriber attests that they have discussed the significant risk of resistance to certain drug classes (e.g., non-nucleoside reverse transcriptase inhibitors [NNRTIs], integrase strand transfer inhibitors [INSTIs]) if virologic failure is experienced while receiving treatment with the requested medication.
 - Member has no known or suspected resistance to either cabotegravir or rilpivirine.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of human immunodeficiency virus type 1 (HIV-1) infection when the member

Reference number(s)
4517-A

has not experienced a virologic failure while on the requested drug, defined as two consecutive plasma HIV-1 RNA levels (viral loads) greater than or equal to 200 copies per mL.¹⁻³

References

1. Cabenuva [package insert]. Durham, NC: ViiV Healthcare; September 2024.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed January 6, 2025.
3. Gandhi RT, Landovitz RJ, Sax PE, et al. Antiretroviral drugs for treatment and prevention of HIV in adults: 2024 Recommendations of the International Antiviral Society–USA Panel. JAMA. Published online December 1, 2024. doi: 10.1001/jama.2024.24543

CountyCare Continuous Glucose Monitors (CGM) Policy

Product List:

DEXCOM (ALL PRODUCTS)
ENLITE (ALL PRODUCTS)
EVERSENSE (ALL PRODUCTS)
FREESTYLE LIBRE (ALL PRODUCTS)
GUARDIAN (ALL PRODUCTS)
MINILINK (ALL PRODUCTS)
MINIMED (ALL PRODUCTS)
PARADIGM (ALL PRODUCTS)
SIMPLERA (ALL PRODUCTS)

Coverage Criteria

Diabetes Mellitus

Authorization may be granted for the requested continuous glucose monitor and associated accessories for a diagnosis of diabetes mellitus when the following criteria are met:

1. The patient has a diagnosis of type 1 diabetes mellitus or type 2 diabetes mellitus **AND** requires insulin therapy.
 - And the patient meets **ONE** of the following:
 - A) The patient currently is not meeting glycemic targets,
 - B) The patient is experiencing hypoglycemia (including hypoglycemia unawareness),
 - C) The patient's blood glucose monitoring compliance would improve with use of a continuous glucose monitor (CGM)
2. The patient has a diagnosis of gestational diabetes

Glycogen Storage Disease

Authorization may be granted for the requested continuous glucose monitor and associated accessories for a diagnosis of glycogen storage disease.

Continuation of Therapy

Authorization may be granted to continue therapy with a CGM when

- The patient has experienced improved glycemic control OR decreased hypoglycemia episodes while using a continuous glucose monitor (CGM).
- The patient is being assessed every six months by the prescriber for adherence to their continuous glucose monitor regimen and diabetes treatment plan

Replacement Continuous Glucose Monitor

Authorization may be granted for a replacement continuous glucose monitor when:

- A replacement continuous glucose monitor (CGM) receiver, transmitter, or sensor is needed due to incompatibilities:
 - The patient uses an insulin pump that requires use of a specific continuous glucose monitor (CGM) OR
 - The insulin regimen changed such that the new regimen is not compatible with the patient's current continuous glucose monitor (CGM)?
- A replacement of the continuous glucose monitor (CGM) receiver, transmitter, or sensors is needed due to loss or dysfunction of current device or components

Duration of Approval (DOA)

Approval may be granted for 12 months for type 1 or type 2 diabetes mellitus.

Approval may be granted for 24 months for gestational diabetes.

Quantity Limits

Drug	1 Month Limit
Dexcom G6	3 sensors / 30 days
Dexcom G7	3 sensors / 30 days

Enlite	5 sensors / 30 days
Drug	4 Week Limit
Freestyle Libre 2	2 sensors / 28 days
Freestyle Libre 3	2 sensors / 28 days
Freestyle Libre 14-Day	2 sensors / 28 days
Guardian 3	5 sensors / 28 days
Guardian 4	5 sensors / 28 days
Instinct Sensor (Abbott)	2 sensors/ 30 days
Simplera Sync sensor	4 sensors/ 28 days
Drug	Limit
Eversense	1 sensor / 90 days
Eversense E3 (XL)	1 sensor / 180 days
Drug	Limit
Dexcom G6 and G7 Receivers	1 receiver / 365 days
Freestyle Libre Receivers	1 receiver / 365 days
Guardian Receivers	1 receiver / 365 days
Drug	Limit
Dexcom transmitters	1 transmitter / 90 days
Eversense	1 transmitter / 90 days
Guardian	1 transmitter / 90 days
Minilink	1 transmitter / 90 days
Minimed	1 transmitter / 90 days
Paradigm	1 transmitter / 90 days

Initial Prior Authorization with Quantity Limit

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists Injectable, Intravenous

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aimovig	erenumab-aooe
Ajovy	fremanezumab-vfrm
Emgality	galcanezumab-gnlm
Vyepti	eptinezumab-jjmr

Indications

FDA-approved Indications

Aimovig

Aimovig is indicated for the preventive treatment of migraine in adults.

Ajovy

Ajovy is indicated for:

Reference number(s)
2581-C, 3160-C

- the preventive treatment of migraine in adults.
- the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age who weigh 45 kg or more.

Emgality

Migraine

Emgality is indicated for the preventive treatment of migraine in adults.

Cluster Headache

Emgality is indicated for the treatment of episodic cluster headache in adults.

Vyepti

Vyepti is indicated for the preventive treatment of migraine in adults.

Coverage Criteria

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti.
- The patient has NOT received at least 3 months of treatment with the requested drug.

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headache in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg.
- The patient has NOT received at least 3 weeks treatment with the requested drug.
- The patient meets ONE of the following:
 - The patient experienced an inadequate treatment response to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral).
 - The patient experienced an intolerance to, or the patient has a contraindication to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral).

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine when ALL of the following criteria are met:

- The request is for Ajovy.

Reference number(s)
2581-C, 3160-C

- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- The patient has NOT received at least 3 months of treatment with the requested drug.

Continuation of Therapy

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti.
- The patient has received at least 3 months of treatment with the requested drug.
- The patient had a reduction in migraine days per month from baseline.

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headache in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg.
- The patient has received at least 3 weeks of treatment with the requested drug.
- The patient had a reduction in weekly cluster headache attack frequency from baseline.

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine when ALL of the following criteria are met:

- The request is for Ajovy.
- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- The patient has received at least 3 months of treatment with the requested drug.
- The patient had a reduction in migraine days per month from baseline.

Quantity Limits Apply

Migraine:

Drug	1 Month Limit	3 Month Limit
Aimovig (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy (fremanezumab-vfrm injection)	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection): Loading Dose Loading dose quantity applies to new starts of therapy (i.e. patient has not filled a prescription for Emgality in the past 180 days).	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection): Maintenance Dose Maintenance dose applies to those not new to therapy (i.e., patient has filled a prescription for Emgality in the past 180 days).	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days
Vyepti (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days

Cluster Headache:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Emgality 100 mg (galcanezumab-gnlm injection)	3 mL (3 syringes x 1 mL each) / 25 days	9 mL (9 syringes x 1 mL each) / 75 days

Episodic Migraine:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Ajovy (fremanezumab-vfrm injection)	1.5 mL (1 autoinjector or syringe x 1.5 mL each) / 25 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days

Duration of Approval (DOA)

- 2581-C:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
 - Ajovy (Episodic Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
- REG 3160-C:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention) DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
 - Ajovy (Episodic Migraine Prevention) DOA: 12 months

References

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; March 2025.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; August 2025.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2025.
4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc; March 2025.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed April 23, 2025.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/23/2025).
7. Silberstein S, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345.

Reference number(s)
2581-C, 3160-C

8. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2013;80(9):871.
9. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: <https://www.aan.com/Guidelines/Home/GetGuidelineContent/545>. Accessed April 2025.
10. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61(7):1021-1039.
11. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
12. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. *Headache* 2016;56(7):1093-1106.
13. Francis GJ, Becker WJ, Pringsheim TM. Acute and preventive pharmacologic treatment of cluster headache. *Neurology*. 2010;75(5):463-473.

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists Injectable, Intravenous

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aimovig	erenumab-aooe
Ajovy	fremanezumab-vfrm
Emgality	galcanezumab-gnlm
Vyepti	eptinezumab-jjmr

Indications

FDA-approved Indications

Aimovig

Aimovig is indicated for the preventive treatment of migraine in adults.

Reference number(s)
2761-E, 3155-E

Ajovy

Ajovy is indicated for:

- the preventive treatment of migraine in adults.
- the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age who weigh 45 kg or more.

Emgality

Migraine

Emgality is indicated for the preventive treatment of migraine in adults.

Cluster Headache

Emgality is indicated for the treatment of episodic cluster headache in adults.

Vyepti

Vyepti is indicated for the preventive treatment of migraine in adults.

Initial Step Therapy with Quantity Limit

Initial Step Therapy for Aimovig, Ajovy, Emgality (except 100 mg), Vyepti

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 56 day supply of divalproex sodium, topiramate, valproate sodium, valproic acid, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

Initial Step Therapy for Emgality 100 mg

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 1 day supply of sumatriptan (nasal or subcutaneous) or zolmitriptan (nasal or oral) within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not

meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

Initial Limit Quantity

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

Migraine:

Drug	1 Month Limit	3 Month Limit
Aimovig (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy (fremanezumab-vfrm injection)	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection): Loading Dose Loading dose quantity applies to new starts of therapy (i.e. patient has not filled a prescription for Emgality in the past 180 days).	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL each) / 75 days
Emgality 120 mg (galcanezumab-gnlm injection): Maintenance Dose Maintenance dose applies to those not new to therapy (i.e., patient has filled a prescription for Emgality in the past 180 days).	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days
Vyepti (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days

Cluster Headache:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Reference number(s)
2761-E, 3155-E

Drug	1 Month Limit	3 Month Limit
Emgality 100 mg (galcanezumab-gnlm injection)	3 mL (3 syringes x 1 mL each) / 25 days	9 mL (9 syringes x 1 mL each) / 75 days

Episodic Migraine:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Ajovy (fremanezumab-vfrm injection)	1.5 mL (1 autoinjector or syringe x 1.5 mL each) / 25 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days

Coverage Criteria

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti.
- The patient has NOT received at least 3 months of treatment with the requested drug.

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headache in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg.
- The patient has NOT received at least 3 weeks treatment with the requested drug.
- The patient meets ONE of the following:
 - The patient experienced an inadequate treatment response to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral).
 - The patient experienced an intolerance to, or the patient has a contraindication to sumatriptan (nasal or subcutaneous) OR zolmitriptan (nasal or oral).

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine when ALL of the following criteria are met:

Reference number(s)
2761-E, 3155-E

- The request is for Ajovy.
- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- The patient has NOT received at least 3 months of treatment with the requested drug.

Continuation of Therapy

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti.
- The patient has received at least 3 months of treatment with the requested drug.
- The patient had a reduction in migraine days per month from baseline.

Episodic Cluster Headache

Authorization may be granted when the requested drug is being prescribed for the treatment of episodic cluster headaches in an adult patient when ALL of the following criteria are met:

- The request is for Emgality 100 mg.
- The patient has received at least 3 weeks of treatment with the requested drug.
- The patient had a reduction in weekly cluster headache attack frequency from baseline.

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine when ALL of the following criteria are met:

- The request is for Ajovy.
- The patient is 6 to 17 years of age.
- The patient weighs 45 kilograms or more.
- The patient has received at least 3 months of treatment with the requested drug.
- The patient had a reduction in migraine days per month from baseline.

Quantity Limits Apply

Post Limit Quantity

Migraine:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Aimovig (erenumab-aooe injection)	1 mL (1 autoinjector) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy (fremanezumab-vfrm injection)	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120mg (galcanezumab-gnlm injection): Loading Dose Loading dose quantity applies to new starts of therapy (i.e. patient has not filled a prescription for Emgality in the past 180 days).	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL each) / 75 days
Emgality 120mg (galcanezumab-gnlm injection): Maintenance Dose Maintenance dose applies to those not new to therapy (i.e., patient has filled a prescription for Emgality in the past 180 days).	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days
Vyepti (eptinezumab-jjmr injection, for intravenous use)	3 mL (3 single dose vials x 1 mL each) / 75 days	3 mL (3 single dose vials x 1 mL each) / 75 days

Cluster Headache:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Emgality 100 mg (galcanezumab-gnlm injection)	3 mL (3 syringes x 1 mL each) / 25 days	9 mL (9 syringes x 1 mL each) / 75 days

Episodic Migraine:

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Ajovy (fremanezumab-vfrm injection)	1.5 mL (1 autoinjector or syringe x 1.5 mL each) / 25 days	4.5 mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days

Duration of Approval (DOA)

- 2761-E:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
 - Ajovy (Episodic Migraine Prevention): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
- REG 3155-E:
 - Aimovig, Ajovy, Emgality 120 mg, Vyepti (Migraine Prevention) DOA: 12 months
 - Emgality 100 mg (Cluster Headache): Initial therapy DOA: 1 month; Continuation of therapy DOA: 12 months
 - Ajovy (Episodic Migraine Prevention) DOA: 12 months

References

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; March 2025.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; August 2025.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2025.
4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; March 2025.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed April 23, 2025.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/23/2025).
7. Silberstein S, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345.

Reference number(s)
2761-E, 3155-E

8. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2013;80(9):871.
9. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: <https://www.aan.com/Guidelines/Home/GetGuidelineContent/545>. Accessed April 2025.
10. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021; 61(7):1021-1039.
11. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
12. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. *Headache* 2016;56(7):1093-1106.
13. Francis GJ, Becker WJ, Pringsheim TM. Acute and preventive pharmacologic treatment of cluster headache. *Neurology*. 2010;75(5):463-473.

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Oral, Nasal Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Nurtec Odt	rimegepant	orally disintegrating tablets
Qulipta	atogepant	tablets
Ubrelvy	ubrogepant	tablets
Zavzpret	zavegepant	nasal spray

Indications

FDA-approved Indications

Nurtec ODT

Acute Treatment of Migraine

Nurtec ODT is indicated for the acute treatment of migraine with or without aura in adults.

Reference number(s)
3481-E

Preventive Treatment of Episodic Migraine

Nurtec ODT is indicated for the preventive treatment of episodic migraine in adults.

Qulipta

Qulipta is indicated for the preventive treatment of migraine in adults.

Ubrelvy

Ubrelvy is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

Ubrelvy is not indicated for the preventive treatment of migraine.

Zavzpret

Zavzpret is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

Zavzpret is not indicated for the preventive treatment of migraine.

Initial Step Therapy with Quantity Limit for Ubrelvy and Zavzpret

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of two triptan 5-HT₁ receptor agonists (include combinations) within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a PA is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Step Therapy with Quantity Limit for Nurtec ODT

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of two triptan 5-HT₁ receptor agonists (include combinations) within the past 180 days OR at least a 56 day supply of divalproex sodium,

Reference number(s)
3481-E

topiramate, valproate sodium, valproic acid, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a PA is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Step Therapy with Quantity Limit for Qulipta

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 56 day supply of divalproex sodium, topiramate, valproate sodium, valproic acid, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, or venlafaxine within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a PA is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Initial Limit Quantity

Limits do not accumulate together; patient is allowed the maximum limit for each drug and strength.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases, the filling limit and day supply may be less than what is indicated.

The duration of 18 days is used for a 21-day fill period, 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Nurtec ODT (rimegepant)	16 orally disintegrating tablets / 25 days	48 orally disintegrating tablets / 75 days

Drug	1 Month Limit	3 Month Limit
Qulipta 10 mg, 30 mg, 60 mg (atogepant)	30 tablets / 25 days	90 tablets / 75 days
Ubrovelvy 50 mg, 100 mg (ubrogepant)	16 tablets / 25 days	48 tablets / 75 days
Zavzpret (zavegepant)	6 nasal spray units / 18 days	24 nasal spray units / 75 days

Coverage Criteria

Acute Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the acute treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Nurtec ODT, Ubrovelvy, or Zavzpret
- The patient meets ONE of the following criteria:
 - The patient experienced an inadequate treatment response or an intolerance to Two triptan 5-HT₁ receptor agonists
 - The patient has a contraindication that would prohibit a trial of triptan 5-HT₁ receptor agonists

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine in an adult patient when ALL of the following criteria are met:

- The request is for Nurtec ODT
- The patient has NOT received at least 3 months of treatment with the requested drug

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Qulipta
- The patient has NOT received at least 3 months of treatment with the requested drug

Continuation of Therapy

Acute Treatment of Migraine

All patients (including new patients) requesting authorization for continuation of therapy must meet All requirements in the coverage criteria section.

Preventive Treatment of Episodic Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of episodic migraine in an adult patient when ALL of the following criteria are met:

- The request is for Nurtec ODT
- The patient has received at least 3 months of treatment with the requested drug
- The patient had a reduction in migraine days per month from baseline

Preventive Treatment of Migraine

Authorization may be granted when the requested drug is being prescribed for the preventive treatment of migraine in an adult patient when ALL of the following criteria are met:

- The request is for Qulipta
- The patient has received at least 3 months of treatment with the requested drug
- The patient had a reduction in migraine days per month from baseline

Quantity Limits Apply

The duration of 18 days is used for a 21-day fill period, 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Ubrelvy	16 tablets per month	48 tablets per 3 months
Nurtec ODT	16 tablets per month	48 tablets per 3 months
Qulipta	30 tablets per month	90 tablets per 3 months
Zavzpret	6 nasal spray units per 3 weeks	24 nasal spray units per 3 months

Duration of Approval (DOA)

- 3481-E:
 - Nurtec ODT, Ubrelvy, Zavzpret (Acute Treatment): DOA: 12 months
 - Nurtec ODT, Qulipta (Preventive Treatment): Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Nurtec ODT [package insert]. New Haven, CT: Biohaven Pharmaceuticals, Inc; April 2023.
2. Qulipta [package insert]. Madison, NJ: Allergan USA, Inc.; June 2023.
3. Ubrelvy [package insert]. Madison, NJ: Allergan USA, Inc.; June 2023.
4. Zavzpret [package insert]. New York, NY: Pfizer Las Division of Pfizer Inc.; March 2023.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed April 11, 2024.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/11/2024).
7. American Headache Society. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache 2019; 59:1-18.
8. Marmura M, Silberstein S, Schwedt T. The Acute Treatment of Migraine in Adults: The American Headache Society Evidence Assessment of Migraine Pharmacotherapies. Headache 2015;55:3-20.
9. Ailani J, Burch RC, Robbins MS et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021; 61:1021-1039.
10. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. Neurology 2012;78:1337-1345.
11. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. Neurology 2013;80:871
12. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024; 00:1-9.
13. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: <https://www.aan.com/Guidelines/Home/GetGuidelineContent/545>. Accessed April 2024.

Specialty Guideline Management

Cibinqo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cibinqo	abrocitinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

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 is inadvisable.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and affected body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Atopic Dermatitis^{1-4,7}

Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when the member has had an inadequate response or intolerance to at least one biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Rinvoq) in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

- Member has had an inadequate response or intolerance to treatment with a biologic (e.g., Adbry, Dupixent, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Rinvoq) indicated for the treatment of atopic dermatitis.

Continuation of Therapy^{1,3}

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other^{1,5}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁶

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%

Potency	Drug	Dosage form	Strength
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.
2. Simpson EL, Sinclair R, Forman S, et al. Efficacy and safety of abrocitinib in adults and adolescents with moderate-to-severe atopic dermatitis (JADE MONO-1): a multicentre, double-blind, randomised, placebo-controlled, phase 3 clinical trial. *Lancet*. 2020;396:255-266.
3. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol*. 2014;70:338-51.
4. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
5. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 15, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
6. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
7. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024 Feb;90(2):e43-e56.

Specialty Guideline Management

Cimzia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cimzia	certolizumab pegol

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with active ankylosing spondylitis
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Reference number(s)
2005-A

Compendial Use²⁵

Immune checkpoint inhibitor-related toxicity - inflammatory arthritis

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid Arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Psoriatic Arthritis (PsA), and Immune Checkpoint Inhibitor-Related Toxicity

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Reference number(s)
2005-A

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Crohn's Disease (CD)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Plaque Psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Crohn's disease: gastroenterologist
- Plaque psoriasis: dermatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid Arthritis (RA)^{1,3-5,20,21,24}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis within the past 120 days.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).

- Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)^{1,26,27}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active polyarticular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of moderately to severely active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

Psoriatic Arthritis (PsA)^{1,6-9,17}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.

- Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
- Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,2,10-12}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Crohn's Disease (CD)^{1,13,14,22}

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Plaque Psoriasis (PsO)^{1,6,9,15,18,19,23}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

Immune Checkpoint Inhibitor-Related Toxicity²⁵

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid Arthritis (RA)^{1,3-5,20,21,24}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Polyarticular Juvenile Idiopathic Arthritis (pJIA)^{1,26}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for moderately to severely active polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Psoriatic Arthritis (PsA)^{1,6-9,17}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease

- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,2,10-12}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Crohn's Disease (CD)^{1,13,14,22}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Plaque Psoriasis (PsO)^{1,6,15,18,19,23}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,16}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, Cyclosporine, Acitretin, or Leflunomide¹⁹

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity

- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Polyarticular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

References

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;0:1-14.
3. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
5. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
7. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
8. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(Suppl II):ii14–ii17.
9. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
10. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896–904.
11. Landewe R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis*. 2014;73(1):39-47.

12. 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.
13. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
14. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113:481-517.
15. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
16. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 26, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.
17. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32. doi:10.1002/art.40726.
18. Menter A, Cordero KM, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82(1):161-201.
19. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-86.
20. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
21. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
22. Feuerstein J, Ho E, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021; 160:2496-2508.
23. Elmets C, Korman N, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol*. 2021; 84(2):432-470.
24. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2021;0:1-16.
25. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed August 13, 2024.
26. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Entesitis. *Arthritis Care Res*. 2019;71(6):717-734. doi:10.1002/acr.23870.
27. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.

Specialty Guideline Management

cinacalcet-Sensipar

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sensipar	cinacalcet

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1-4,9}

- Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
- Hypercalcemia in adult patients with parathyroid carcinoma
- Hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy

Compendial Uses^{2,5-6,10}

Hypercalcemia in post-kidney transplant patients with persistent hyperparathyroidism

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Secondary Hyperparathyroidism with CKD on Dialysis¹

Authorization of 12 months may be granted for treatment of secondary hyperparathyroidism in a member with chronic kidney disease on dialysis who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Primary Hyperparathyroidism¹

Authorization of 12 months may be granted for treatment of primary hyperparathyroidism in a member who is not able to undergo parathyroidectomy and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Persistent Hyperparathyroidism in Post-Kidney Transplant Patients^{2,5-7,10}

Authorization of 12 months may be granted for treatment of persistent hyperparathyroidism in a member who has had a kidney transplant and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Parathyroid Carcinoma¹

Authorization of 12 months may be granted for the treatment of parathyroid carcinoma in a member who has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the following criteria are met:

Secondary Hyperparathyroidism with CKD on Dialysis¹

Member is experiencing benefit from therapy as evidenced by a decrease in intact parathyroid hormone (iPTH) levels from pretreatment baseline.

All Other Indications^{1,5}

Member is experiencing benefit from therapy (e.g., decreased or normalized corrected serum calcium levels since starting therapy).

Appendix⁹

Corrected calcium = measured total calcium + 0.8(4.0 – serum albumin)

References

1. Cinacalcet [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; January 2024.
2. Sensipar [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2019.
3. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 7, 2024.
4. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 7, 2024.
5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available at: <http://www.clinicalpharmacology.com>. Accessed October 7, 2024.
6. Evenepoel P, Cooper K, Holdaas H, et al. A randomized study evaluating cinacalcet to treat hypercalcemia in renal transplant recipients with persistent hyperparathyroidism. *Am J Transplant* 2014;14:2545-2555.2023.
7. Kruse AE, Ensenberger U, Frey FJ, et al. The calcimimetic cinacalcet normalizes serum calcium in renal transplant patients with persistent hyperparathyroidism. *Nephrol Dial Transplant*. 2005;20:1311-1314.
8. Srinivas TR, Schold JD, Womer KL, et al. Improvement in hypercalcemia with cinacalcet after kidney transplantation. *Clin J Am Soc Nephrol*. 2006;1:323-326.
9. Shoback D. Hypoparathyroidism. *NEJM*. 2008;359: 391-403.
10. Palumbo VD, Damiano G, Messina M, et al. Tertiary hyperparathyroidism: a review. *Clin Ter*. 2021;172(3):241-246.

Specialty Guideline Management

Cinqair

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cinqair	reslizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Cinqair is indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype.

Limitations of Use

- Not for treatment of other eosinophilic conditions
- Not for the relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing pre-treatment blood eosinophil count, or dependence on systemic corticosteroids, if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

Prescriber Specialties

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Coverage Criteria¹⁻⁵

Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 18 years of age or older.
- Member meets either of the following:
 - Member has a baseline blood eosinophil count of at least 400 cells per microliter.
 - Member is dependent on systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - High-dose inhaled corticosteroid
 - Additional controller (i.e., long-acting beta₂-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Continuation of Therapy

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 18 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations
 - A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

References

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet Respir Med*. 2015;3(5):355-366.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: <https://annualmeeting.aaaai.org/>. Accessed March 8, 2025.
5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22):2301-2317.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

ACANYA
(clindamycin phosphate/benzoyl peroxide)

BENZACLIN
(clindamycin phosphate/benzoyl peroxide)

CLEOCIN T
(clindamycin phosphate)

CLINDACIN ETZ
(clindamycin phosphate)

CLINDACIN P
(clindamycin phosphate)

CLINDACIN KIT PAC
(clindamycin phosphate with cleanser)

CLINDAGEL
(clindamycin phosphate)

DUAC
(clindamycin phosphate/benzoyl peroxide)

EVOCLIN
(clindamycin phosphate)

NEUAC
(clindamycin phosphate/benzoyl peroxide)

NEUAC KIT
(clindamycin phosphate/benzoyl peroxide with moisturizer)

ONEXTON
(clindamycin phosphate/benzoyl peroxide)

VELTIN
(clindamycin phosphate/tretinoin)

Clindamycin Topical Age Restriction Exception C25470-B_06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428C 021423



ZIANA
(clindamycin phosphate/tretinoin)

Status: Client Requested Criteria
Type: Initial Prior Authorization

Ref # C25470-B

CRITERIA FOR APPROVAL

1	Is this request for an age restriction override? [If no, then no further questions.] [Tech note: If no, this guideline does not apply.]	Yes	No
2	Does the patient have ONE of the following diagnoses: A) Hidradenitis suppurativa, B) Follicular disorder, C) Rosacea? [If yes, then no further questions.]	Yes	No
3	Does the patient have the diagnosis of acne? [If no, then skip to question 7.]	Yes	No
4	Is the requested medication prescribed by a dermatologist? [If no, then no further questions.]	Yes	No
5	Is this request for a combination product that contains benzoyl peroxide? [If yes, then no further questions.]	Yes	No
6	Will this medication be used with benzoyl peroxide? [No further questions.]	Yes	No
7	Is this request for an FDA approved indication? [If yes, then no further questions.]	Yes	No
8	Is the requested drug being prescribed for a medically accepted indication and is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

Clindamycin Topical Age Restriction Exception C25470-B_06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428C 021423



Initial Prior Authorization Compounded Drug Products

Coverage Criteria

Authorization may be granted for compounded drug products when ONE of the following criteria is met:

- The request is for ANY of the following: Intravenous (IV) injections or infusion; Anti-infective for injectable use [NOTE: Examples of anti-infectives may include antibacterials, antivirals, antifungals]; Total parenteral nutrition (TPN); Leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1 mg per 0.2 mL kit); Pyrimethamine; Sirolimus for tuberous sclerosis, where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate
- The request is for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant
- Each of the active ingredients in the compound are FDA-approved drugs and ALL of the following are met: [NOTE: Examples of products that typically do not get FDA-approval include bulk ingredients, dietary supplements, vitamin and mineral products, botanical or herbal products, amino acid products, enzyme supplements]
 - Each of the active ingredients in the compound are FDA-approved for the indication for which the compound is being prescribed
 - The compound route of administration (ROA) is the same as the FDA-approved route of administration for each active ingredient [NOTE: Examples of ROAs include mucosal, oral, parenteral (by injection), inhalation, topical/dermal.]
 - The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration
 - The request is NOT for a topical compound or a topical compound kit for use on skin (e.g., cream, gel, lotion, ointment)
 - The compound is NOT intended for anti-aging or cosmetic use, or is NOT a compound kit, or does NOT contain a bulk powder or dietary supplement
 - The request is NOT for a hormone therapy compound for menopause or for androgen decline due to aging, (e.g., testosterone, estrogen, progestin, bioidentical hormone)
 - Coverage is provided for additional fills of the compounded drug if the patient needs more than 1 fill per month (necessity may include continuation of antibiotic therapy, stability is less than a month, dose adjustment)

- The patient meets ONE of the following:
 - There is a current supply shortage of the commercially manufactured product
 - The patient has a medical need for a dosage form or dosage strength that is not available commercially or manufactured
 - The patient had an intolerance or contraindication to the commercially manufactured product (examples may include allergen or adverse effects due to inactive ingredients)
 - The commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness

Duration of Approval (DOA)

- 1114-A:
 - tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant: 12 years of age or older DOA: 36 months; less than 12 years of age DOA: up to 12 years of age
 - Other drugs and indications: DOA 6 months

References

1. 21 USC 353a: Pharmacy compounding From Title 21-FOOD AND DRUGS CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER V-DRUGS AND DEVICES Part A-Drugs and Devices. Available at: <https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section353a&num=0&saved=%7CKGNvbXBvdW5klGRydWdzKQ%3D%3D%7CdHJlZXNvcnQ%3D%7CdHJlZQ%3D%3D%7C15%7Ctrue%7Cprelim>. Accessed July 2024.
2. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: <https://www.govinfo.gov/app/details/BILLS-113hr3204enr>. Accessed July 2024.
3. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pharmacy-compounding-human-drug-products-under-section-503a-federal-food-drug-and-cosmetic-act>. Accessed July 2024.
4. Human Drug Compounding. Available at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. Accessed July 2024.
5. Compounding and the FDA: Questions and Answers. Available at: <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>. Accessed July 2024.
6. USP Compounding Standards. Available at: <https://www.usp.org/compounding>. Accessed July 2024.
7. USP Compounding Standards and Beyond-Use Dates (BUDs). Available at: https://www.mbp.ms.gov/sites/default/files/2023-03/USP_Compounding_BUD_Fact_Sheet.pdf. Accessed July 2024.

Reference number(s)
1114-A

8. USP-NF Chapters on Pharmacy Compounding, 795.
https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc795.pdf. Accessed July 2024.
9. Is it Really FDA Approved? Available at:
<https://www.fda.gov/forconsumers/consumerupdates/ucm047470.htm>. Accessed July 2024.
10. FDA Drug Safety Communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-cautions-about-using-testosterone-products-low-testosterone-due>. Accessed July 2024.
11. Menopause. Available at: <https://www.fda.gov/consumers/womens-health-topics/menopause>. Accessed July 2024.
12. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy, Jackson L.M., Parker R.M., & Mattison D.R. (Eds.). (2020) *The clinical utility of compounded bioidentical hormone therapy: A review of safety, effectiveness, and use*. National Academies Press (US).
13. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed July 2024.
14. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2024.
<https://online.lexi.com> Accessed July 2024.
15. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at:
<https://www.micromedexsolutions.com/> (cited: 07/2024).
16. Tuberous Sclerosis. Available at: <https://rarediseases.info.nih.gov/diseases/7830/tuberous-sclerosis>. Accessed July 2024.
17. Drug Nomenclature Monographs. Route of Administration. Available at:
<https://www.fda.gov/drugs/data-standards-manual-monographs/route-administration>. Accessed July 2024.

Specialty Guideline Management

Cosentyx

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Cosentyx	secukinumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Moderate to severe plaque psoriasis (PsO) in patients 6 years of age and older who are candidates for systemic therapy or phototherapy
- Active psoriatic arthritis (PsA) in patients 2 years of age and older
- Adults with active ankylosing spondylitis (AS)
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- Adults with moderate to severe hidradenitis suppurativa (HS)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), enthesitis-related arthritis (ERA), and hidradenitis suppurativa

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Plaque psoriasis: dermatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- Ankylosing spondylitis, non-radiographic axial spondyloarthritis, and enthesitis-related arthritis: rheumatologist

Coverage Criteria

Plaque psoriasis (PsO)^{1-2,8,13,14}

Authorization of 12 months may be granted for members 6 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for members 6 years of age or older for the treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of 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 pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Psoriatic arthritis (PsA)^{1,3,4,10,13}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
 - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,5-7,15}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when any of the following criteria is met:

- Member has had an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Enthesitis-related arthritis (ERA)^{1,11,12}

Authorization of 12 months may be granted for members 4 years of age or older who have previously received a biologic for treatment of active enthesitis-related arthritis.

Authorization of 12 months may be granted for members 4 years of age or older for treatment of active enthesitis-related arthritis when both of the following criteria are met:

- Member has active disease demonstrated by at least three active joints involved and at least one site of active enthesitis at baseline or documented by history.
- Member meets either of the following:
 - Member has had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine, or methotrexate.
 - Member has an intolerance or contraindication to NSAIDs, sulfasalazine (e.g., porphyria, intestinal or urinary obstruction), and methotrexate (see Appendix).

Hidradenitis suppurativa^{1,16,17}

Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Continuation of Therapy

Plaque psoriasis (PsO)¹

Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who

achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Psoriatic arthritis (PsA)^{1,10,13}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,5-7,15}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Enthesitis-related arthritis (ERA)^{1,11,12}

Authorization of 12 months may be granted for all members 4 years of age or older (including new members) who are using the requested medication for active enthesitis-related arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of flares
- Number of joints with active arthritis (e.g., swelling, pain)
- Number of joints with limited movement
- Dactylitis
- Enthesitis

Hidradenitis suppurativa^{1,16,17}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Other^{1,9}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide¹⁴

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
3. 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.
4. McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2015;386(9999):1137-46.
5. Braun J, van den Berg R, Baraliakos X et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. Ann Rheum Dis. 2011;70:896-904.
6. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1285-1299.
7. Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. N Engl J Med. 2015;373(26):2534-48.
8. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
9. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 22, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.

Reference number(s)
2017-A

10. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum.* 2018;71:5-32.
11. Weiss PF. Diagnosis and treatment of enthesitis-related arthritis. *Adolesc Health Med Ther.* 2012;2012(3):67-74.
12. Brunner HI, Foeldvari I, Alexeeva E, et al. Secukinumab in enthesitis-related arthritis and juvenile psoriatic arthritis: a randomised, double-blind, placebo-controlled, treatment withdrawal, phase 3 trial. *Ann Rheum Dis.* 2023 Jan;82(1):154-160.
13. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
14. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486.
15. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82:19-34.
16. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. *J Am Acad Dermatol.* 2019; 81(1): 76-90.
17. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol.* 2019; 81(1): 91-101.

Specialty Guideline Management

Crysvita

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Crysvita	burosumab-twza

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Crysvita is indicated for the treatment of:

- X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

X-linked hypophosphatemia (XLH)

Initial requests:

- Radiographic evidence of rickets or other bone disease attributed to XLH
- At least one of the following:
 - Genetic testing results confirming the member has a PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) mutation
 - Genetic testing results confirming a PHEX mutation in a directly related family member with appropriate X-linked inheritance
 - Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is above the upper limit of normal or abnormal for the assay

Continuation requests:

- Chart notes or medical record documentation showing beneficial response to therapy

Tumor induced osteomalacia (TIO)

Initial requests:

- Lab test results confirming the member's serum fibroblast growth factor 23 (FGF23) level is above the upper limit of normal or abnormal for the assay
- Fasting serum phosphorus level
- Ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR)

Continuation requests:

- Chart notes or medical record documentation showing beneficial response to therapy

Coverage Criteria

X-linked hypophosphatemia (XLH)^{1-4,7}

Authorization of 12 months may be granted for treatment of X-linked hypophosphatemia (XLH) when both of the following criteria are met:

- Member meets one of the following criteria:
 - Genetic testing was conducted to confirm a PHEX mutation in the member.
 - Genetic testing was conducted to confirm a PHEX mutation in a directly related family member with appropriate X-linked inheritance.

- Member's FGF23 level is above the upper limit of normal or abnormal for the assay.
- Member has radiographic evidence of rickets or other bone disease attributed to XLH.

Tumor-induced osteomalacia (TIO)^{1,5-7}

Authorization of 12 months may be granted for treatment of tumor-induced osteomalacia (TIO) when both of the following criteria are met:

- Member's diagnosis is confirmed by ALL of the following:
 - Member's FGF23 level is above the upper limit of normal or abnormal for the assay.
 - Member's fasting serum phosphorus levels are less than 2.5 mg/dL.
 - Member's ratio of renal tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) is less than 2.5 mg/dL.
- Member's disease is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit and who are experiencing benefit from therapy as evidenced by disease improvement or disease stability (e.g., increase or normalization in serum phosphate, improvement in bone and joint pain, reduction in fractures, improvement in skeletal deformities).

References

1. Crysvida [package insert]. Princeton, NJ: Kyowa Kirin, Inc.; March 2023.
2. Linglart A, Imel EA, Whyte MP, et al. Sustained Efficacy and Safety of Burosumab, a Monoclonal Antibody to FGF23, in Children With X-Linked Hypophosphatemia. *J Clin Endocrinol Metab*. 2022;107(3):813-824.
3. Insogna KL, Briot K, Imel EA, et al. A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial Evaluating the Efficacy of Burosumab, an Anti-FGF23 Antibody, in Adults With X-Linked Hypophosphatemia: Week 24 Primary Analysis. *J Bone Miner Res*. 2018;33(8):1383-1393.
4. Dieter H, Emma F, Eastwood DM, et al. Clinical Practice Recommendations for the Diagnosis and Management of X-linked Hypophosphatemia. *Nat Rev Nephrol*. 2019;15(7):435-455.
5. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02304367. Study of Burosumab (KRN23) in Adults with Tumor-Induced Osteomalacia (TIO) or Epidermal Nevus Syndrome (ENS). 2020 June 30. Available from: <http://clinicaltrials.gov/ct2/show/NCT02304367>.

Reference number(s)
2562-A

6. Chong WH, Molinolo AA, Chen CC, et.al Tumor-induced Osteomalacia. Endocrine Related Cancer 2011;18(3):R53-R77.
7. Fauconnier C, Roy T, Gillerot G, et al. FGF23: Clinical usefulness and analytical evolution. Clin Biochem. 2019;66:1-12.

Specialty Guideline Management

dalfampridine-Ampyra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ampyra	dalfampridine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Indicated as a treatment to improve walking in adult patients with multiple sclerosis. This was demonstrated by an increase in walking speed.

All other indications are considered experimental/investigational and are not medically necessary.

Coverage Criteria^{1,2}

Authorization of 30 days may be granted to members with a diagnosis of multiple sclerosis if the member has sustained walking impairment (prior to initiating therapy with the requested medication).

Reference number(s)
1836-A

Continuation of Therapy¹⁻³

Authorization of 12 months may be granted to members with multiple sclerosis if the member has experienced an improvement in walking speed or other objective measure of walking ability since starting the requested medication.

References

1. Ampyra [package insert]. Pearl River, NY: Acorda Therapeutics, Inc.; June 2022.
2. Dalfampridine [package insert]. Raleigh, NC: Accord Healthcare, Inc.; October 2023.
3. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. *Lancet*. 2009; 373:732-8.

Specialty Guideline Management

deferasirox–Exjade–Jadenu

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Exjade	deferasirox
Jadenu	deferasirox

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻⁵

- Chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.
- Chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L.

Compendial Uses⁹⁻¹¹

Hereditary hemochromatosis

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Chronic iron overload due to blood transfusions (transfusional iron overload):
 - Initial requests: pretreatment serum ferritin level
 - Continuation requests: current serum ferritin level
- Chronic iron overload in patients with non-transfusion dependent thalassemia syndromes:
 - Initial requests: pretreatment serum ferritin level or liver iron concentration (where applicable)
 - Continuation requests: current serum ferritin level

Coverage Criteria

Chronic Iron Overload due to Blood Transfusions (Transfusional Iron Overload)¹⁻⁷

Authorization of 12 months may be granted for treatment of chronic iron overload due to blood transfusions when both of the following criteria are met:

- Pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
- Dose of deferasirox tablet for suspension/Exjade will not exceed 40 mg/kg per day, dose of deferasirox/Jadenu will not exceed 28 mg/kg per day.

Chronic Iron Overload in Patients with Non-Transfusion Dependent Thalassemia Syndromes^{1-5,8}

Authorization of 12 months may be granted for treatment of chronic iron overload in members with non-transfusion dependent thalassemia syndromes when both of the following criteria are met:

- Member meets any of the following:
 - Pretreatment serum ferritin level is greater than or equal to 800 mcg/L.
 - Pretreatment liver iron concentration (LIC) is at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
 - Pretreatment serum ferritin level is greater than 300 mcg/L to less than 800 mcg/L and member has clinical or laboratory measures indicative of iron overload (e.g., liver disease, renal disease).
- Dose of deferasirox tablet for suspension/Exjade will not exceed 20 mg/kg per day, dose of deferasirox/Jadenu will not exceed 14 mg/kg per day.

Hereditary Hemochromatosis⁹⁻¹¹

Authorization of 12 months may be granted for treatment of hereditary hemochromatosis when phlebotomy is not an option (e.g., poor venous access, poor candidate due to underlying medical disorders) or the member had an unsatisfactory response to phlebotomy.

Continuation of Therapy

Chronic Iron Overload due to Blood Transfusions (Transfusional iron overload)¹⁻⁵

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic iron overload due to blood transfusions (transfusional iron overload) when both of the following criteria are met:

- Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.
- Serum ferritin level is not consistently below 500 mcg/L.

Chronic Iron Overload in Patients with Non-Transfusion Dependent Thalassemia Syndromes^{1-5,8}

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic iron overload with non-transfusion dependent thalassemia syndrome when both of the following criteria are met:

- Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.
- Serum ferritin level is not consistently below 300 mcg/L.

Hereditary Hemochromatosis

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for hereditary hemochromatosis when the member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.

References

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Reference number(s)
1622-A

3. Deferasirox tablet for suspension [package insert]. Parsippany, NJ: Actavis Pharma, Inc; August 2021.
4. Deferasirox tablet [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; January 2021.
5. Deferasirox granule [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2024.
6. Taher AT, Farmakis D, Porter JB, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 5th Edition [Internet]. Thalassaemia International Federation. 2025. Available at: <https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-transfusion-dependent-%ce%b2-thalassaemia-5th-edition-2025>. Accessed January 30, 2025.
7. Shah FT, Porter JB, Sadasivam N, et al. Guidelines for the monitoring and management of iron overload in patients with haemoglobinopathies and rare anemias. *Br J Haematol*. 2022;196(2):336-350.
8. Taher A, Musallam K, Cappellini M, et al. Guidelines for the management of non-transfusion dependent β -thalassaemia 3rd Edition. Thalassaemia International Federation. 2023;1-132.
9. European Association for the Study of the Liver. EASL Clinical practice guidelines on haemochromatosis. *J Hepatol*. 2022;77(2):479-502.
10. Adams P, Barton J, et al. How I Treat Hemochromatosis. *Blood*. 2010;116(3): 317-325.
11. Kowdley KV, Brown KE, et al. ACG Clinical Guideline: Hereditary Hemochromatosis. *Am J Gastroenterol*. 2019;114(8):1202-1218.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

DIABETIC TEST STRIPS

ACCU-CHEK
ASSURE
CONTOUR
EASY TOUCH
FREESTYLE
GLUCOCARD
INFINITY
ONE TOUCH
PRODIGY
TRUE METRIX
OTHER, PLEASE SPECIFY

Status: Client Requested Criteria

Type: Initial Prior Authorization

Ref # C29666-A

CRITERIA FOR APPROVAL

1	Is there a documented contraindication to a preferred glucose monitor or test strips pursuant to the pharmaceutical manufacturers' prescribing information? [If yes, then no further questions.]	Yes	No
2	Is there a documented medical rationale that the requested glucose monitor or test strips would be safer and/or more efficacious than using a formulary product? [If yes, then no further questions.]	Yes	No
3	Does the patient use an insulin pump that requires use of a specific meter and test strips?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy: Test Strip Custom Criteria. September 2025.

DOCUMENT HISTORY

Created: ANB 07/2025
Revised: VLS 09/2025

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	DIABETIC TEST STRIPS/MONITORS/KITS
	ACCU-CHEK ASSURE CONTOUR EASY TOUCH FREESTYLE GLUCOCARD INFINITY ONE TOUCH PRODIGY TRUE METRIX OTHER, PLEASE SPECIFY
Status: Client Requested Criteria Type: Initial Prior Authorization	
Ref # C29666-A	

CRITERIA FOR APPROVAL			
1	Is there a documented contraindication to a preferred glucose monitor or test strips pursuant to the pharmaceutical manufacturers' prescribing information? [If yes, then no further questions.]	Yes	No
2	Is there a documented medical rationale that the requested glucose monitor or test strips would be safer and/or more efficacious than using a formulary product? [If yes, then no further questions.]	Yes	No
3	Does the patient use an insulin pump that requires use of a specific meter and test strips?	Yes	No

Mapping Instructions		
	Yes	No
1.	Approve, 12 months	Go to 2
2.	Approve, 12 months	Go to 3
3.	Approve, 12 months	Deny

REFERENCES

1. CountyCare Prior Authorization Approval Policy: Test Strip Custom Criteria. September 2025.

DOCUMENT HISTORY

Created: ANB 07/2025
Revised: VLS 09/2025, 11/2025

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

Signature

Date

Client Name

Initial Prior Authorization with Quantity Limit Diclofenac Sodium Gel 3 Percent

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
diclofenac sodium gel 3% (brand unavailable)	diclofenac sodium gel 3%

Indications

FDA-approved Indications

Diclofenac sodium topical gel is indicated for the topical treatment of actinic keratosis (AK).

Coverage Criteria

Actinic Keratosis (AK)

Authorization may be granted when the requested drug [diclofenac sodium gel 3 percent (generic Solaraze)] is being prescribed for the treatment of actinic keratosis (AK) when the following criteria is met:

- The patient experienced an inadequate treatment response, intolerance, OR has a contraindication to ONE of the following: imiquimod 5 percent cream, fluorouracil cream or solution.

Reference number(s)
621-C

Continuation of Therapy

Actinic Keratosis (AK)

Authorization may be granted when the requested drug is being prescribed for the treatment of actinic keratosis (AK) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., percentage of actinic keratosis lesions cleared, patient/prescriber satisfaction, etc.).

Quantity Limits Apply

100 grams per 25 days

The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

Duration of Approval (DOA)

- 621-C: DOA: 3 months

References

1. Diclofenac Gel 3% [package insert]. Parsippany, NJ: Teva Pharmaceuticals; January 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 28, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/27/2025).
4. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 2.2025. February 7, 2025. NCCN.org. Accessed May 27, 2025.
5. Eisen DB, Asgari MM, Bennett DD, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85:e209-e233.

Specialty Guideline Management

dimethyl fumarate-Tecfidera

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tecfidera	dimethyl fumarate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication^{1,2}

Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Reference number(s)
1845-A

Relapsing Forms of Multiple Sclerosis¹⁻³

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹⁻³

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving the requested medication.

Other

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

References

1. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
2. Dimethyl fumarate [package insert]. Parsippany, NJ: Ascend Laboratories, LLC.; March 2024.
3. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology*. 2018;90(17):777-788.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

ELIQUIS
(apixaban)

PRADAXA
(dabigatran)

SAVAYSA
(edoxaban)

XARELTO ORAL SUSPENSION
(rivaroxaban oral suspension)

Status: Client Requested Criteria
Type: Initial Prior Authorization

Ref # C25427-A

CRITERIA FOR APPROVAL

1	Is this request for continuation of therapy? [If no, then skip to question 8.]	Yes	No
2	Does the patient demonstrate the need for continued anticoagulation for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
3	Does the patient demonstrate the need for continued anticoagulation for ONE of the following FDA-approved labeled indications: A) Treatment of deep vein thrombosis (DVT), B) Treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
4	Is this request for Eliquis (apixaban), Xarelto (rivaroxaban), or Pradaxa (dabigatran) in a patient who demonstrates a need for continued anticoagulation for reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
5	Is this request for Xarelto (rivaroxaban) in a patient who demonstrates a need for continued anticoagulation for ONE of the following FDA approved indications: A) Reduction of the risk of major cardiovascular (CV) events in coronary artery disease (CAD), B) Reduction of the risk of major thrombotic events in peripheral arterial disease (PAD), C) Thromboprophylaxis in pediatric patients 2 years of age and older with congenital heart disease after the Fontan procedure? [If yes, then no further questions.]	Yes	No
6	Is this request for Xarelto (rivaroxaban) in a pediatric patients less than 18 years of age who demonstrates a need for continued anticoagulation for treatment of venous thromboembolism (VTE) and reduction in risk of recurrent VTE?	Yes	No

Direct Oral Anticoagulants PA CountyCare C25427-A_06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed, or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428B 021423



[If yes, then no further questions.]

7	Does the patient demonstrate the need for continued anticoagulation for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, or D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [No further questions.]	Yes	No
8	Is this request for Xarelto (rivaroxaban) Oral Suspension? [If no, then go to question 13.]	Yes	No
9	Is this request for the treatment of venous thromboembolism (VTE) and reduction in risk of recurrent VTE in patients less than 18 years of age? [If no, then skip to question 12.]	Yes	No
10	Is the patient less than 6 months of age? [If no, then no further questions.]	Yes	No
11	Does the patient meet ALL of the following criteria: A) Greater than or equal to 37 weeks of gestation, B) Greater than or equal to 10 days of oral feeding, C) Greater than or equal to 2.6kg at time of dosing? [No further questions.]	Yes	No
12	Is this request for thromboprophylaxis in pediatric patients greater than or equal to 2 years of age with congenital heart disease after the Fontan procedure? [If yes, then no further questions.] [If no, then skip to questions 26.]	Yes	No
13	Is this request for Eliquis (apixaban)? [If no, then skip to question 20.]	Yes	No
14	Does the patient have documented clinically significant treatment failure, intolerance, or contraindication to Xarelto (rivaroxaban)? [If no, then no further questions.]	Yes	No
15	Is this request for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
16	Is this request for treatment of deep vein thrombosis (DVT) or treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
17	Is this request for deep vein thromboembolism (DVT) prophylaxis after hip replacement surgery? [If yes, then no further questions.]	Yes	No

Direct Oral Anticoagulants PA CountyCare C25427-A_06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed, or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428B 021423



18	Is this request for deep vein thromboembolism (DVT) prophylaxis after knee replacement surgery? [If yes, then no further questions.]	Yes	No
19	Is this request for the reduction in risk of recurrence of deep vein thromboembolism (DVT) or pulmonary embolism (PE)? [If yes, then no further questions.] [If no, then skip to questions 26.]	Yes	No
20	Is this request for Pradaxa (dabigatran) or Savaysa (edoxaban)? [If no, then no further questions.]	Yes	No
21	Does the patient have documented clinically significant treatment failure, intolerance, or contraindication to PREFERRED direct oral anticoagulants? [If no, then no further questions.]	Yes	No
22	Is this request for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
23	Is the requested drug being used for treatment of deep vein thrombosis (DVT) or treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
24	Is this request for Pradaxa (dabigatran) for deep vein thromboembolism (DVT) prophylaxis after hip surgery? [If yes, then no further questions.]	Yes	No
25	Is this request for Pradaxa (dabigatran) for the reduction in risk of recurrence of deep vein thromboembolism (DVT) or pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
26	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, or D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [No further questions.]	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

Written by: UM Development (VLS)
Date Written: 06/2023
Revised:
Reviewed: Medical Affairs: (APN) 08/2023

Direct Oral Anticoagulants PA CountyCare C25427-A_06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed, or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428B 021423



Initial Prior Authorization with Quantity Limit

Disposable Insulin Pumps

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Omnipod (all prescription products)
V-Go (all products)

Coverage Criteria

Authorization may be granted for the requested medical device when the following criteria are met:

- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5) or V-Go and ONE of the following criteria are met:
 - The patient is NOT currently established on therapy with an insulin pump and ALL of the following criteria are met:
 - The patient is managing their diabetes with multiple daily insulin injections
 - The patient has completed a comprehensive diabetes education program
 - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
 - If the patient does NOT have a diagnosis of type 1 diabetes, then the patient has experienced an elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent) while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 6 months OR the patient has experienced ANY of the following while on multiple daily injections of insulin (i.e., at least 3 injections per day) for at least 3 months: history of recurrent hypoglycemia (e.g., blood glucose levels less

than 70 mg/dL), wide fluctuations in blood glucose before mealtime, “dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, history of severe glycemic excursions

- If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period
- The patient is currently established on therapy with an insulin pump and ALL of the following criteria are met:
 - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
 - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

Type 2 Diabetes Mellitus

Authorization may be granted for the requested medical device when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The request is for Omnipod GO and ALL of the following criteria are met:
 - The patient does NOT require bolus or mealtime insulin
 - The patient has completed a comprehensive diabetes education program
 - The patient meets ONE of the following:
 - The patient has documented frequency of glucose self-testing at least once daily
 - The patient has been using a continuous glucose monitor (CGM)
 - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)

Quantity Limits Apply

Omnipod GO: 10 pods (2 kits) per 25 days or 30 pods (6 kits) per 75 days

Other Omnipod products (e.g., Omnipod 5, Omnipod Dash):

Omnipod starter kit: 1 kit per 999 days

Omnipod pod refills: 10 pods per 25 days or 30 pods per 75 days for patients using less than 200 units of insulin per 72-hour period

Omnipod pod refills: 15 pods per 25 days or 45 pods per 75 days for patients using greater than 200 units of insulin per 72-hour period

V-Go: 30 pumps per 25 days or 90 pumps per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3762-C: DOA: 12 months

References

1. Omnipod GO. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/K223372.pdf. Accessed March 11, 2024.
2. Omnipod, Omnipod DASH Insulin Management System. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed March 13, 2024.
3. Omnipod 5 ACE Pump (Pod). 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203768.pdf. Accessed March 13, 2024.
4. V-Go. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/K100504.pdf. Accessed March 13, 2024.
5. Omnipod DASH User Guide. Acton, MA: Insulet Corporation; October 2023. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf. Accessed March 6, 2024.
6. Omnipod 5 User Guide. Acton, MA: Insulet Corporation: October 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf. Accessed March 5, 2024.
7. Omnipod GO User Guide. Acton, MA: Insulet Corporation: October 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-GO_User_Guide_US_English.pdf. Accessed March 5, 2024.
8. Omnipod System User Guide. Acton, MA. Insulet Corporation: October 2021. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-System_User-Guide_English.pdf. Accessed March 6, 2024.
9. V-Go Wearable Insulin Delivery Device Instructions for Patient Use. Mannkind Corporation; June 2022. Available at: https://www.go-vgo.com/wp-content/uploads/2023/07/ART-1361-Rev-D-V-Go-IFU-2023_20230628.pdf. Accessed March 13, 2024.
10. American Diabetes Association, Standards of Care in Diabetes – 2024. Diabetes Care 2024;47(Suppl. 1):S1-S321.
11. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. *Endocr Pract.* 2022; 28(10):923-1049.

12. McAdams BH, Rizvi AA. An Overview of Insulin Pumps and Glucose Sensors for the Generalist. *J Clin Med* 2016;5;1-17.
13. Samson SL, Vellanki P, Blonde L et. al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. *Endocrine Pract.* 2023; 29:305-340.
14. Grunberger G, Sherr J, Allende M et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus. *Endocrine Pract.* 2021. 27: 505-537.
15. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 Position Statement on Integration of Insulin Pumps and Continuous Glucose Monitoring in Patients with Diabetes Mellitus. *Endocr Pract.* 2018;24(3):302-308.
16. National Coverage Determination (NCD) for Infusion Pumps (280.14); Revision Effective Date 12/17/2004. Available at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&NCAId=41&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=47&KeyWord=INSULIN+PUMP&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=EAAAABAAIAAA&>. Accessed March 7, 2024.

Specialty Guideline Management

Dupixent

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Dupixent	dupilumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids
- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
- Add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
- Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE)
- Treatment of adult patients with prurigo nodularis (PN)

Reference number(s)
1690-A

- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
- Treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
- Treatment of adult patients with bullous pemphigoid (BP)

Limitations of Use

- Not indicated for the relief of acute bronchospasm or status asthmaticus.
- Not indicated for treatment of other forms of urticaria.

Compendial Uses²⁵

Immune checkpoint inhibitor-related toxicities

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Atopic Dermatitis

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Asthma

Initial requests

- Chart notes or medical record documentation showing pre-treatment blood eosinophil count (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), Meltzer Clinical Score, or endoscopic nasal polyp score (NPS) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Eosinophilic Esophagitis (EoE)

Initial requests

- Chart notes or medical record documentation showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.
- Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prurigo Nodularis (PN)

Initial requests

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Chronic Obstructive Pulmonary Disease (COPD)

Initial requests

- Chart notes or medical record documentation demonstrating classic signs and/or symptoms of COPD.

Reference number(s)
1690-A

- Chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication.
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Chronic Spontaneous Urticaria (CSU)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

Immune Checkpoint Inhibitor-Related Toxicities

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Bullous Pemphigoid (BP)

Initial requests

- Chart notes or medical record documentation demonstrating clinical features of bullous pemphigoid.
- Chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Atopic dermatitis: dermatologist or allergist/immunologist

- Asthma: allergist/immunologist or pulmonologist
- Chronic rhinosinusitis with nasal polyps: allergist/immunologist or otolaryngologist
- Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
- Prurigo nodularis: dermatologist or allergist/immunologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist
- Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- Immune checkpoint inhibitor-related toxicity and bullous pemphigoid: dermatologist, hematologist, or oncologist

Coverage Criteria

Atopic Dermatitis^{1-3,7,10,16}

Authorization of 4 months may be granted for members 6 months of age or older who have previously received a biologic (e.g., Adbry, Ebglyss, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 6 months of age or older when both of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix A)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Asthma^{1,4-6,11}

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of moderate-to-severe asthma in members 6 years of age or older when all of the following criteria are met:

- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member meets either of the following criteria:
 - Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - Medium-to-high-dose inhaled corticosteroid
 - Additional controller (i.e., long-acting beta₂-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
 - Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses (Members should be receiving treatment with an inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months [e.g., 50% of days, 3 steroid bursts in the previous 6 months]):
 - High-dose inhaled corticosteroid
 - Additional controller (i.e., long-acting beta₂-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
 - Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)^{1,8,9,12,17,18,33}

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Nucala, Xolair) indicated for CRSwNP in the past year.

Authorization of 6 months may be granted for treatment of CRSwNP in members 12 years of age or older when all of the following criteria are met:

- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- Member has CRSwNP despite one of the following:
 - Prior sino-nasal surgery
 - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
- Member has one of the following:

- A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
- Meltzer Clinical Score of 2 or higher in both nostrils.
- A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - Rhinorrhea (anterior/posterior)
 - Reduction or loss of smell
 - Facial pain or pressure
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Eosinophilic Esophagitis (EoE)^{1,13-15,27,28,32}

Authorization of 6 months may be granted for treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when all of the following criteria are met:

- Member is experiencing symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, vomiting, abdominal pain, food refusal, failure to thrive).
- Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field.
- Member has had an inadequate treatment response to either of the following:
 - Proton pump inhibitor
 - Swallowed topical corticosteroid therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation]), unless contraindicated or not tolerated

Prurigo Nodularis¹⁹⁻²²

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nemludio) indicated for prurigo nodularis in the past year.

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

- Member has pruritus lasting at least 6 weeks.
- Member has a history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
 - Member has had an inadequate response to one of the following:
 - A medium to super-high potency topical corticosteroid (see Appendix A)

- A topical calcineurin inhibitor
- Phototherapy (e.g., UVB, PUVA)
- Pharmacologic treatment with methotrexate or cyclosporine
- Member has had an intolerance or a clinical reason to avoid either of the following:
 - Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
 - Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

Chronic Obstructive Pulmonary Disease (COPD)^{1,29-31}

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nucala) indicated for COPD in the past year.

Authorization of 12 months may be granted for treatment of COPD in members 18 years of age or older when all of the following criteria are met:

- Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV₁)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.
- Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
- Member has an absolute blood eosinophil count of at least 300 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing either of the following in the last year:
 - At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.
 - One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets either of the following:
 - Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and long-acting beta₂-agonist [LABA]).
 - Member is currently receiving a LAMA and LABA, and has a contraindication to ICS.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Chronic Spontaneous Urticaria (CSU)^{1,34,35}

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Xolair) indicated for CSU in the past year.

Authorization of 6 months may be granted for treatment of CSU in members 12 years of age or older when all of the following criteria are met:

- Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
- Member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
- Member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks.

Immune Checkpoint Inhibitor-Related Toxicities^{25,26}

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used for severe (G3) pruritus if no response to gabapentinoids in one month.

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used as additional therapy for severe (G3) or life-threatening (G4) bullous dermatitis.

Bullous Pemphigoid³⁶⁻³⁸

Authorization of 12 months may be granted for treatment of bullous pemphigoid in members 18 years of age or older when all of the following criteria are met:

- Diagnosis has been confirmed by either of the following:
 - Direct immunofluorescence (DIF) study
 - Immune serological test(s) (e.g., Indirect immunofluorescence microscopy [IIF], ELISA)
- Member demonstrates characteristic clinical features of bullous pemphigoid (e.g., urticarial or eczematous or erythematous plaques, bullae, pruritus).
- Member has moderate to severe disease.
- Member meets either of the following:
 - Member has had an inadequate treatment response with either of the following:
 - A super-high potency topical corticosteroid (see Appendix A)
 - An oral corticosteroid
 - The use of super-high potency topical corticosteroid or oral corticosteroid is not advisable for the member (e.g., contraindications, prior intolerances).

Continuation of Therapy

Atopic Dermatitis^{1-3,10}

Authorization of 12 months may be granted for members 6 months of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the

member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Asthma^{1,4-6,11}

Authorization of 12 months may be granted for continuation of treatment of moderate-to-severe asthma in members 6 years of age or older when both of the following criteria are met:

- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency or severity of symptoms and exacerbations
 - A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)^{1,8,9,12}

Authorization of 12 months may be granted for continuation of treatment of CRSwNP in members 12 years of age or older when both of the following are met:

- Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia or facial pressure or pain, reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Eosinophilic Esophagitis (EoE)^{1,13-15}

Authorization of 12 months may be granted for continuation of treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of EoE (e.g., dysphagia, heartburn, chest pain, emesis).

Prurigo Nodularis¹⁹⁻²²

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by either of the following:

- Low disease activity (i.e., clear or almost clear skin)
- Reduction in pruritus intensity and improvement in extent and severity of nodular lesions

Chronic Obstructive Pulmonary Disease (COPD)^{1,29-31}

Authorization of 12 months may be granted for continuation of treatment of COPD in members 18 years of age or older when both of the following criteria are met:

- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV₁) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Chronic Spontaneous Urticaria^{1,34-35}

Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria in members 12 years of age or older, when the member has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy).

Immune Checkpoint Inhibitor-Related Toxicities²⁵

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immune checkpoint inhibitor-related severe (G3) pruritus, severe (G3) or life-threatening (G4) bullous dermatitis, and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Bullous Pemphigoid³⁶⁻³⁸

Authorization of 12 months may be granted for continuation of treatment of bullous pemphigoid in members 18 years of age or older, when the member has achieved or maintained a positive clinical response as evidenced by either of the following:

- Low disease activity (e.g., absence of new or established lesions)
- Reduction in pruritus intensity and improvement in extent and severity of lesions

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Appendix

Appendix A: Relative Potency of Select Topical Corticosteroid Products⁷

Potency	Drug	Dosage form	Strength
I. Super-high potency (Group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (Group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (Group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (Group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (Group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (Group 2)	Amcinonide	Ointment	0.1%
II. High potency (Group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (Group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (Group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (Group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (Group 2)	Desoximetasone	Gel	0.05%
II. High potency (Group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (Group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (Group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (Group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (Group 3)	Amcinonide	Cream, Lotion	0.1%
III. High potency (Group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (Group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (Group 3)	Betamethasone valerate	Foam	0.12%

Potency	Drug	Dosage form	Strength
III. High potency (Group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (Group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (Group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (Group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (Group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (Group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (Group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (Group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (Group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (Group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (Group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (Group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (Group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (Group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (Group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (Group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (Group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (Group 5)	Flurandrenolide	Cream, Lotion	0.05%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (Group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (Group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (Group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (Group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (Group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (Group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (Group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (Group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (Group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (Group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (Group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (Group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (Group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (Group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (Group 7)	Hydrocortisone acetate	Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine^{23,24}

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2025.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
3. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med*. 2016;375:2335-2348.
4. Castro M, Corren J, Pavord ID, et al. Dupilumab Efficacy and Safety in Moderate-to-Severe Uncontrolled Asthma. *N Engl J Med*. 2018;378(26):2486-2496.
5. Rabe KF, Nair P, Brusselle G, et al. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. *N Engl J Med*. 2018;378(26):2475-2485.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
7. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
8. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02912468. A Controlled Clinical Study of Dupilumab in Patients with Nasal Polyps (SINUS-24) 2016 Sep 23. Available from: <https://clinicaltrials.gov/ct2/show/NCT02912468>.
9. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02898454. A Controlled Clinical Study of Dupilumab in Patients with Nasal Polyps (SINUS-52) 2016 Sep 13. Available from: <https://clinicaltrials.gov/ct2/show/NCT02898454>.
10. Fishbein AB, Silverberg JI, Wilson EJ, et al. Update on atopic dermatitis: Diagnosis, severity assessment, and treatment selection. *J Allergy Clin Immunol Pract*. 2020;8(1): 91-101.
11. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22): 2301-2317.

12. Bachert C, Han JK, Wagenmann M, et al. EUFOREA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRSwNP) and biologics: Definitions and management. *J Allergy Clin Immunol*. 2021;147(1):29-36.
13. Lucendo AJ, Molina-Infante J, Arias A, et al. Guidelines on eosinophilic esophagitis: evidence-based statements and recommendations for diagnosis and management in children and adults. *United European Gastroenterol J*. 2017;5(3):355-358.
14. Gonsalves NP, Aceves S. Diagnosis and treatment of eosinophilic esophagitis. *J Allergy Clin Immunol*. 2020;145(1):1-7.
15. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03633617. Study to determine the efficacy and safety of Dupilumab in Adult and Adolescent Patients with Eosinophilic Esophagitis (EoE) 2022 May 27. Available from: <https://clinicaltrials.gov/ct2/show/NCT03633617>.
16. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03346434. Safety, Pharmacokinetics and Efficacy of Dupilumab in Patients ≥6 months to <6 years with Moderate-to-Severe Atopic Dermatitis (Liberty AD PRESCHOOL) 2022 Jun 10. Available from: <https://clinicaltrials.gov/ct2/show/NCT03346434>.
17. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. *Rhinology*. 2020;58(Suppl S29):1-464.
18. Hopkins C. Chronic Rhinosinusitis with Nasal Polyps. *N Engl J Med*. 2019;381(1):55-63.
19. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04183335. Study of Dupilumab for the Treatment of Patients With Prurigo Nodularis, Inadequately Controlled on Topical Prescription Therapies or When Those Therapies Are Not Advisable (LIBERTY-PN PRIME). 2022 February 17. Available from: <https://clinicaltrials.gov/ct2/show/NCT04183335>.
20. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04202679. Study of Dupilumab for the Treatment of Patients With Prurigo Nodularis, Inadequately Controlled on Topical Prescription Therapies or When Those Therapies Are Not Advisable (PRIME2). 2022 September 28. Available from: <https://clinicaltrials.gov/ct2/show/NCT04202679>.
21. Ständer HF, Elmariah S, Zeidler C, et al. Diagnostic and treatment algorithm for chronic nodular prurigo. *J Am Acad Dermatol*. 2020;82(2):460-468.
22. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. *J Am Acad Dermatol*. 2021;84(3):747-760.
23. Cyclosporine. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; November 6, 2024. Accessed November 10, 2024.
24. Methotrexate. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; November 7, 2024. Accessed November 10, 2024.
25. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 3, 2025.
26. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immune Checkpoint-Related Toxicities. Version 1.2025. Available at: www.nccn.org. Accessed March 3, 2025.
27. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04394351. Study to Investigate the Efficacy and Safety of Dupilumab in Pediatric Patients With Active Eosinophilic Esophagitis (EoE) (EoE KIDS). 2023 June 05. Available from: <https://clinicaltrials.gov/ct2/show/NCT04394351>.

28. Lucendo AJ, Sánchez-Cazalilla M. Adult versus pediatric eosinophilic esophagitis: important differences and similarities for the clinician to understand. *Expert Rev Clin Immunol*. 2012;8(8):733-45.
29. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2024 Report). Available at: <https://goldcopd.org/2024-gold-report/>. Accessed March 2025.
30. Bhatt SP, Rabe KF, Hanania NA, et al. Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts. *N Engl J Med*. 2023;389(3):205-214.
31. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04456673. Pivotal Study to Assess the Efficacy, Safety and Tolerability of Dupilumab in Patients with Moderate to Severe COPD with Type 2 Inflammation (NOTUS). Last updated October 15, 2024. Accessed 2025 March 12. Available from: <https://clinicaltrials.gov/ct2/show/NCT04456673>.
32. Dellon E, Muir AB, Katzka DA, et al. ACG Clinical Guideline: Diagnosis and Management of Eosinophilic Esophagitis. *AJC*. 2025;120(1):p31-59.
33. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023 Feb;151(2):386-398.
34. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022 Mar;77(3):734-766.
35. Bernstein DI, Blessing-Moore J, Cox L, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. American Academy of Allergy, Asthma & Immunology Practice Parameter. <http://www.aaaai.org/practice-resources/statements-and-practice-parameters/practice-parameter-guidelines.aspx>. Accessed April 23, 2025.
36. Borradori L, Van Beek N, Feliciani C, et al. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). *J Eur Acad Dermatol Venereol*. 2022 Oct;36(10):1689-1704.
37. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04206553. A Study to Evaluate the Efficacy and Safety of Dupilumab in Adult Patients With Bullous Pemphigoid (LIBERTY-BP). Last updated February 6, 2025. Accessed 2025 July 1. Available from: <https://clinicaltrials.gov/study/NCT04206553>.
38. Murrell DF, Joly P, Werth VP, et al. Study Design of a Phase 2/3 Randomized Controlled Trial of Dupilumab in Adults with Bullous Pemphigoid: LIBERTY-BP ADEPT. *Adv Ther*. 2024 Jul;41(7):2991-3002.

Specialty Guideline Management

Ebglyss

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ebglyss	lebrikizumab-lbkz

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication¹

Treatment of adults and pediatric patients aged 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss can be used with or without topical corticosteroids.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Atopic dermatitis^{1-6,8}

Authorization of 4 months may be granted for members 12 years of age or older weighing at least 40 kg who have previously received a biologic (e.g., Adbry, Dupixent, Nemluvio) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year.

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older weighing at least 40 kg when both of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Continuation of Therapy

Authorization of 12 months may be granted for members 12 years of age or older (including new members) weighing at least 40 kg who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products⁷

Potency	Drug	Dosage form	Strength
I.Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I.Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I.Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I.Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I.Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II.High potency (group 2)	Amcinonide	Ointment	0.1%
II.High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II.High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II.High potency (group 2)	Clobetasol propionate	Cream	0.025%

Potency	Drug	Dosage form	Strength
II.High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II.High potency (group 2)	Desoximetasone	Gel	0.05%
II.High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II.High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II.High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II.High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III.High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
III.High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III.High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III.High potency (group 3)	Betamethasone valerate	Foam	0.12%
III.High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III.High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III.High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III.High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III.High potency (group 3)	Mometasone furoate	Ointment	0.1%
III.High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV.Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV.Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV.Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV.Medium potency (group 4)	Flurandrenolide	Ointment	0.05%

Potency	Drug	Dosage form	Strength
IV.Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV.Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV.Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V.Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V.Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V.Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V.Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V.Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V.Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V.Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V.Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V.Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V.Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI.Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI.Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI.Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%

Potency	Drug	Dosage form	Strength
VI.Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI.Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

References

1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024.
2. Silverberg JI, Guttman-Yassky E, Thaçi D, et al. Two Phase 3 Trials of Lebrikizumab for Moderate-to-Severe Atopic Dermatitis. N Engl J Med. 2023;388(12):1080-1091.
3. Simpson EL, Gooderham M, Wollenberg A, et al. Efficacy and Safety of Lebrikizumab in Combination With Topical Corticosteroids in Adolescents and Adults With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial (ADhere). JAMA Dermatol. 2023;159(2):182-191.
4. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
5. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
6. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024;90(2):e43-e56.
7. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
8. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Specialty Guideline Management

Enbrel

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Enbrel	etanercept

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Moderately to severely active rheumatoid arthritis (RA)
- Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- Active psoriatic arthritis (PsA)
- Active ankylosing spondylitis (AS)
- Chronic moderate to severe plaque psoriasis (PsO) in patients 4 years or older who are candidates for systemic therapy or phototherapy
- Active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older

Compendial Uses

- Non-radiographic axial spondyloarthritis^{2,23}
- Oligoarticular juvenile idiopathic arthritis²⁶
- Reactive arthritis⁴

- Hidradenitis suppurativa, severe, refractory⁴
- Behcet's disease^{4,17}
- Graft versus host disease^{4,16,22,23}
- Immune checkpoint inhibitor-related toxicity²²

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Articular juvenile idiopathic arthritis (JIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), reactive arthritis, hidradenitis suppurativa, immune checkpoint inhibitor-related inflammatory arthritis, and chronic graft versus host disease

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Acute graft versus host disease and immune checkpoint inhibitor-related toxicity (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Behcet's disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, reactive arthritis, and Behcet's disease: rheumatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist

- Plaque psoriasis: dermatologist
- Graft versus host disease: oncologist or hematologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or dermatologist

Coverage Criteria

Rheumatoid arthritis (RA)^{1,5-7,30,31}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).

- Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
- Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine, (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.

Articular juvenile idiopathic arthritis (JIA)^{1,8,26}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of moderately to severely active articular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease

- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

Psoriatic arthritis (PsA)^{1,10-13,20}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
 - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,2,14,15}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when any of the following criteria is met:

- Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Plaque psoriasis (PsO)^{1,9,10,13,18,24,25,27}

Authorization of 12 months may be granted for members 4 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for members 4 years of age or older for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

Reactive arthritis^{3,4,21,31,32}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:

- Member has had an inadequate response to methotrexate or sulfasalazine.
- Member has an intolerance or contraindication to methotrexate (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

Hidradenitis suppurativa^{4,28,29}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of severe, refractory hidradenitis suppurativa.

Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Graft versus host disease^{4,16,22,23}

Authorization of 12 months may be granted for treatment of graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Behcet's disease^{4,17}

Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of Behcet's disease.

Authorization of 12 months may be granted for the treatment of Behcet's disease when the member has had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids).

Immune checkpoint inhibitor-related toxicity²²

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has Stevens-Johnson syndrome or toxic epidermal necrolysis.

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following is met:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid arthritis (RA)^{1,5-7,30,31}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Articular juvenile idiopathic arthritis (JIA)^{1,8}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Psoriatic arthritis (PsA)^{1,10-13,20}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)^{1,2,14,15}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Plaque psoriasis (PsO)^{1,9,10,18,24,25,27}

Authorization of 12 months may be granted for all members 4 years of age or older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Reactive arthritis^{3,21}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for reactive arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, or pain).

Hidradenitis suppurativa^{4,28,29}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for severe, refractory hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Acute graft versus host disease and immune checkpoint inhibitor-related toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Chronic graft versus host disease

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for chronic graft versus host disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Behcet's disease

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for Behcet's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Immune checkpoint inhibitor-related inflammatory arthritis

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,19}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA] within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage And Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. Dose optimization with 50 mg product formulations should be used when possible. Exceptions for higher quantities of 25 mg vials will be allowed when the member has a latex allergy or is following FDA-approved weight-based dosing.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, Leflunomide, Cyclosporine, or Acitretin²⁵

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy

Reference number(s)
2003-A

- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

References

1. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; July 2024.
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;0:1-14.
3. Flagg SD, Meador R, Hsia E, et al. Decreased pain and synovial inflammation after etanercept therapy in patients with reactive and undifferentiated arthritis: an open-label trial. *Arthritis Rheum*. 2005;53(4):613-617.
4. IBM Micromedex® DRUGDEX® System (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/12/2024).
5. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
7. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
8. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care Res*. 2019;71(6):717-734. doi:10.1002/acr.23870.
9. Menter A, Gottlieb A, Feldman SR, et al. Guidelines for the management of psoriasis and psoriatic arthritis. Section 1: Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008;58(5):826-850.
10. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.

11. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
12. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(Suppl II):ii14-ii17.
13. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
14. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896-904.
15. 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.
16. Martin PJ, Rizzo JD, Wingard JR, et al. First and second line systemic treatment of acute graft versus host disease: Recommendations of the American Society of Blood and Marrow Transplantation. *Biol Blood Marrow Transplant*. 2012;18(8):1150-1163.
17. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis*. 2018;77:808-818.
18. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
19. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on August 12, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
20. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32. doi:10.1002/art.40726.
21. Flores D, Marquez J, Garza M, Espinoza LR. Reactive arthritis: newer developments. *Rheum Dis Clin North Am*. 2003;29(1):37-vi.
22. The NCCN Drugs & Biologics Compendium 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed August 12, 2024.
23. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; <https://online.lexi.com/lco/action/home> [available with subscription]. Accessed August 12, 2024.
24. Menter, A, Cordero, KM, Davis, DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82(1):161-201.
25. Menter, A, Gelfand, JM, Connor, C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-86.
26. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
27. Elmets C, Korman N, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol*. 2021; 84(2):432-470.

28. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019;81(1):76-90.
29. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101.
30. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
31. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthrit Care Res. 2021;0:1-16.
32. Azulfidine [package insert]. New York, NY: Pfizer; October 2022.

Initial Prior Authorization

Entresto

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Entresto	sacubitril and valsartan

Indications

FDA-approved Indications

Adult Heart Failure

Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.

LVEF is a variable measure, so use clinical judgment in deciding whom to treat.

Pediatric Heart Failure

Entresto is indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes.

Coverage Criteria

Adult Heart Failure

Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure when ALL of the following criteria are met:

- The patient is 18 years of age or older.
- The patient has a diagnosis of symptomatic chronic heart failure and ONE of the following criteria are met:
 - The patient has ANY of the following: left ventricular ejection fraction less than or equal to 40 percent (i.e., Heart Failure with reduced Ejection Fraction [HFrEF]), previous left ventricular ejection fraction less than or equal to 40 percent and a follow-up left ventricular ejection fraction measurement of greater than 40 percent (i.e., Heart Failure with improved Ejection Fraction [HFimpEF]). [ACTION REQUIRED: Documentation is required for approval]. In addition, the patient meets ONE of the following criteria:
 - The patient will receive concomitant treatment with a maximally tolerated dose of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).
 - The patient has experienced an intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).
 - The patient has a contraindication that would prohibit a trial of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol).
 - The patient has ANY of the following: left ventricular ejection fraction of 41 to 49 percent (i.e., Heart Failure with mildly reduced Ejection Fraction [HFmrEF]), left ventricular ejection fraction greater than or equal to 50 percent (i.e., Heart Failure with preserved Ejection Fraction [HFpEF]). In addition, the patient meets the following criteria:
 - The patient has evidence or history of spontaneous or provokable increased left ventricular filling pressures (e.g., elevated natriuretic peptide, noninvasive and invasive hemodynamic measurement). [ACTION REQUIRED: Documentation is required for approval].
- If the patient has a diagnosis of diabetes, the requested drug will NOT be used in combination with Tekturna (aliskiren).
- If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m²]), the requested drug will NOT be used in combination with Tekturna (aliskiren).

Pediatric Heart Failure

Authorization may be granted when the requested drug is being prescribed for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction when ALL of the following criteria are met:

- This request is for a pediatric patient one year of age or older.
- If the patient has a diagnosis of diabetes, the requested drug will NOT be used in combination with Tekturna (aliskiren).
- If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m²]), the requested drug will NOT be used in combination with Tekturna (aliskiren).

Duration of Approval (DOA)

- 1277-A: DOA: 36 months
- 1276-A: DOA: 12 months

References

1. Entresto [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed April 18, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/18/2025).
4. Heidenreich PA, Bozkurt B, Aguilar D et. al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022; 79:e263-e421.
5. Kittleson MM, Panjra GS, Amancherla K et. al. 2023 ACC expert consensus decision pathway on management of heart failure with preserved ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2023;81(18):1835-1878.
6. Maddox TM, Januzzi JL Jr, Allen LA, et. al. 2024 ACC expert consensus decision pathway for treatment of heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2024;83(15):1444-1448.

Reference number(s)
C29080-A

CountyCare IL Custom Criteria ENTYVIO (vedolizumab)

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

Ashley M Robinson PharmD _____ 10/21/25 _____
Signature Date

CountyCare
Client Name

CRITERIA FOR APPROVAL

1	What is the diagnosis?		
	☐ Crohn's Disease (If checked, go to 2)		
	☐ Ulcerative colitis (If checked, go to 4)		
	☐ Other, please specify. (If checked, go to 9)		
2	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following products: A) Cimzia OR B) An adalimumab product? [If Yes, then go to 9. If No, then go to 3.]	Yes	No
3	Does the patient have ONE of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
4	Has the patient tried and failed BOTH of the following products: A) An adalimumab product AND B) Xeljanz/Xeljanz XR? [If Yes, then go to 9. If No, then go to 5.]	Yes	No
5	Does the patient have ONE of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 6. If No, then go to 7.]	Yes	No
6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR?	Yes	No

[If Yes, then go to 9. If No, then no further questions.]

7	Does the patient have ONE of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 8. If No, then no further questions.]	Yes	No

8	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with an adalimumab product? [If Yes, then go to 9. If No, then no further questions.]	Yes	No

9	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz)? [If Yes, then no further questions. If No, then go to 10.]	Yes	No

10	What is the diagnosis? ☐ Ulcerative colitis (If checked, go to 11) ☐ Crohn's disease (If checked, go to 16) ☐ Immune checkpoint inhibitor-related diarrhea or colitis (If checked, go to 21) ☐ Acute graft versus host disease (If checked, go to 27) ☐ Other, please specify. _____ (If checked, no further questions)		

11	Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? [If Yes, then go to 12. If No, then no further questions.]	Yes	No

12	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 13. If No, then no further questions.]	Yes	No

13	Which of the following applies to this request for the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 33) ☐ Initiation of the intravenous (IV) maintenance dose (If checked, go to 33) ☐ Continuation of the intravenous (IV) maintenance dose (If checked, go to 14) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 33) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 14)		

14	Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response to treatment as evidenced by		

low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission or positive clinical response to therapy.

☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 15)

☐ None of the above (If checked, no further questions)

15 Which of the following has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response to therapy.

☐ Stool frequency **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Rectal bleeding **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Urgency of defecation **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ C-reactive protein (CRP) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Fecal calprotectin (FC) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ None of the above (If checked, no further questions)

16	Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No

17	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 18. If No, then no further questions.]	Yes	No

18 Which of the following applies to this request for the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 33)

☐ Initiation of the intravenous (IV) maintenance dose (If checked, go to 33)

☐ Continuation of the intravenous (IV) maintenance dose (If checked, go to 19)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 33)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 19)

19 Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission or positive clinical response to therapy.

☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 20)

☐ None of the above (If checked, no further questions)

20 Which of the following has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response to therapy.

☐ Abdominal pain or tenderness **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Diarrhea **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Body weight **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Abdominal mass **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Hematocrit **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 33)

☐ None of the above (If checked, no further questions)

21	Is the requested drug being prescribed by or in consultation with a gastroenterologist, hematologist, or oncologist? [If Yes, then go to 22. If No, then no further questions.]	Yes	No

22	Has the patient experienced an inadequate response to systemic corticosteroids or infliximab? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 25. If No, then go to 23.]	Yes	No
23	Has the patient experienced an intolerance to systemic corticosteroids or infliximab? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 25. If No, then go to 24.]	Yes	No
24	Does the patient have a contraindication to systemic corticosteroids or infliximab? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 25. If No, then no further questions.]	Yes	No
25	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? [If Yes, then go to 26. If No, then no further questions.]	Yes	No
26	What is the prescribed route of administration? ☐ Intravenous (vial) (If checked, no further questions) ☐ Subcutaneous (syringe or pen) (If checked, no further questions)		
27	Is the requested drug being prescribed by or in consultation with a hematologist or oncologist? [If Yes, then go to 28. If No, then no further questions.]	Yes	No
28	Has the patient had an inadequate response to systemic corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 31. If No, then go to 29.]	Yes	No
29	Does the patient have an intolerance to corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 31. If No, then go to 30.]	Yes	No
30	Does the patient have a contraindication to corticosteroids? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 31. If No, then no further questions.]	Yes	No
31	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?	Yes	No

[If Yes, then go to 32. If No, then no further questions.]

32 What is the prescribed route of administration?

☐ Intravenous (vial) (If checked, no further questions)

☐ Subcutaneous (syringe or pen) (If checked, no further questions)

33 Which of the following applies to this request for the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 34)

☐ Initiation of the intravenous (IV) maintenance dose (If checked, go to 42)

☐ Continuation of the intravenous (IV) maintenance dose (If checked, go to 42)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 40)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 40)

34 Which route of administration applies to the prescribed therapy?

☐ Intravenous (vial) loading dose followed by intravenous (vial) maintenance dose (If checked, go to 37)

☐ Intravenous (vial) loading dose followed by subcutaneous (syringe or pen) maintenance dose (If checked, go to 35)

☐ Intravenous (vial) loading dose only (If checked, go to 39)

35 Does the prescribed dose exceed an intravenous loading dose of 300 mg at weeks 0 and 2, and a subcutaneous maintenance dose of 108 mg thereafter starting at week 6?
[If Yes, then no further questions. If No, then go to 36.]

Yes

No

36 Is the prescribed frequency for the subcutaneous maintenance dose more frequent than one dose every 2 weeks?
[No further questions]

Yes

No

37 Does the prescribed dose exceed an intravenous loading dose of 300 mg at weeks 0, 2, and 6, and an intravenous maintenance dose of 300 mg thereafter?
[If Yes, then no further questions. If No, then go to 38.]

Yes

No

38 Is the prescribed frequency for the intravenous maintenance dose more frequent than one dose every 8 weeks?
[No further questions]

Yes

No

39 Does the prescribed dose exceed an intravenous loading dose of 300 mg at weeks 0, 2, and 6?
[No further questions]

Yes

No

40 Does the prescribed subcutaneous maintenance dose exceed 108 mg?

Yes

No

[If Yes, then no further questions. If No, then go to 41.]

41	Is the prescribed frequency for the subcutaneous maintenance dose more frequent than one dose every 2 weeks? [No further questions]	Yes	No
42	Does the prescribed intravenous dose exceed 300 mg? [If Yes, then no further questions. If No, then go to 43.]	Yes	No
43	Is the prescribed frequency for the intravenous maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No

Mapping Instructions

	Yes	No
1.	1=2 ;2=4 ;3=9	
2.	Go to 9	Go to 3
3.	Go to 9	Deny OR Pend and Continue to 9
4.	Go to 9	Go to 5
5.	Go to 6	Go to 7
6.	Go to 9	Deny OR Pend and Continue to 9
7.	Go to 8	Deny OR Pend and Continue to 8
8.	Go to 9	Deny OR Pend and Continue to 9
9.	Deny OR Pend and Continue to 10	Go to 10
10.	1=11 ;2=16 ;3=21 ;4=27 ;5=Deny	
11.	Go to 12	Deny OR Pend and Continue to 12
12.	Go to 13	Deny OR Pend and Continue to 13
13.	1=33 ;2=33 ;3=14 ;4=33 ;5=14	
14.	1=33 ;2=15 ;3=Deny OR Pend and Continue to 15	
15.	1=33 ;2=33 ;3=33 ;4=33 ;5=33 ;6=33 ;7=33 ;8=Deny OR Pend and Continue to 33	
16.	Go to 17	Deny OR Pend and Continue to 17
17.	Go to 18	Deny OR Pend and Continue to 18
18.	1=33 ;2=33 ;3=19 ;4=33 ;5=19	
19.	1=33 ;2=20 ;3=Deny OR Pend and Continue to 20	

Reference number(s)
C29080-A

20.	1=33 ;2=33 ;3=33 ;4=33 ;5=33 ;6=33 ;7=33 ;8=Deny OR Pend and Continue to 33	
21.	Go to 22	Deny OR Pend and Continue to 22
22.	Go to 25	Go to 23
23.	Go to 25	Go to 24
24.	Go to 25	Deny OR Pend and Continue to 25
25.	Go to 26	Deny OR Pend and Continue to 26
26.	1=Approve, 6 Months ;2=Deny	
27.	Go to 28	Deny OR Pend and Continue to 28
28.	Go to 31	Go to 29
29.	Go to 31	Go to 30
30.	Go to 31	Deny OR Pend and Continue to 31
31.	Go to 32	Deny OR Pend and Continue to 32
32.	1=[Allow loading dose of 3 vials of 300mg per 42 days and maintenance dose of 1 vial per 56 days]. Approve, 12 Months ;2=Deny	
33.	1=34 ;2=42 ;3=42 ;4=40 ;5=40	
34.	1=37 ;2=35 ;3=39	
35.	Deny OR Pend and Continue to 36	Go to 36
36.	Deny	[Allow loading dose of 3 vials of 300mg per 42 days and maintenance dose of 2 pens per 28 days of 108 MG/0.68ML]. Approve, 12 Months
37.	Deny OR Pend and Continue to 38	Go to 38
38.	Deny	[Allow loading dose of 3 vials of 300mg per 42 days and maintenance dose of 1 vial per 56 days]. Approve, 12 Months
39.	Deny	[Allow loading dose of 3 vials of 300mg per 42 days.]. Approve, 12 Months
40.	Deny OR Pend and Continue to 41	Go to 41
41.	Deny	[Allow 2 pens per 28 days of 108 MG/0.68ML.]. Approve, 12 Months
42.	Deny OR Pend and Continue to 43	Go to 43

Reference number(s)
C29080-A

43.	Deny	[Allow 1 vial of 300mg per 56 days.]. Approve, 12 Months

Specialty Guideline Management

Epidiolex

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Epidiolex	cannabidiol

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Seizures Associated with Lennox-Gastaut Syndrome, Dravet Syndrome, and Tuberous Sclerosis Complex¹

Authorization of 12 months may be granted for treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in members 1 year of age and older.

Reference number(s)
2609-A

Continuation of Therapy

Authorization of 12 months may be granted for continuation of treatment in members (including new members) 1 year of age or older requesting reauthorization for an indication listed in the coverage criteria when the member has achieved or maintained a positive clinical response (e.g., decrease in seizure frequency).

References

1. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2025.

Specialty Guideline Management

Epogen-Procrit-Retacrit

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Epogen	epoetin alfa
Procrit	epoetin alfa
Retacrit	epoetin alfa-epbx

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻³

- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.
- Treatment of anemia due to zidovudine administered at less than or equal to 4200 milligrams (mg) per week in patients with human immunodeficiency virus (HIV)-infection with endogenous serum erythropoietin levels of less than or equal to 500 milliunits per milliliter (mUnits/mL).
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy.
- To reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 grams per deciliter (g/dL) who are at high

Reference number(s)
1619-A

risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively.

Compendial Uses

- Symptomatic anemia in patients with myelodysplastic syndromes (MDS)^{4,5,13,14,15}
- Anemia in patients who will not/cannot receive blood transfusions^{5,6}
- Myelofibrosis-associated anemia^{4,5,9}
- Cancer patients who are undergoing palliative treatment⁴

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before starting Epogen/Procrit/Retacrit. Members may not use Epogen/Procrit/Retacrit concomitantly with other erythropoiesis-stimulating agents.

Anemia Due to Chronic Kidney Disease (CKD)^{1-3,7}

Authorization of 12 weeks may be granted for treatment of anemia due to chronic kidney disease in members with pretreatment hemoglobin less than 10 g/dL.

Anemia Due to Myelosuppressive Chemotherapy^{1-3,8}

Authorization of 12 weeks may be granted for treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and pretreatment hemoglobin less than 10 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)^{4,5,8,12-13}

Authorization of 12 weeks may be granted for treatment of anemia in myelodysplastic syndrome in members with pretreatment hemoglobin less than 10 g/dL.

Reduction of Allogeneic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery¹⁻³

Authorization of 8 weeks may be granted for reduction of allogeneic red blood cell transfusion in members scheduled to have an elective, noncardiac, nonvascular surgery with pretreatment hemoglobin less than or equal to 13 g/dL.

Anemia Due to Zidovudine in HIV-infected Patients¹⁻³

Authorization of 12 months may be granted for treatment of anemia due to zidovudine in HIV-infected members currently receiving zidovudine with pretreatment hemoglobin less than 10 g/dL whose pretreatment serum EPO level is less than or equal to 500 mU/mL.

Anemia in Members Who Will Not/Cannot Receive Blood Transfusions⁵

Authorization of 12 weeks may be granted for treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with pretreatment hemoglobin less than 10 g/dL.

Myelofibrosis-associated Anemia^{4,5,9,10}

Authorization of 12 weeks may be granted for treatment of myelofibrosis-associated anemia in members who meet both of the following criteria:

- Pretreatment hemoglobin less than 10 g/dL.
- Pretreatment serum EPO level less than 500 mU/mL.

Anemia Due to Cancer^{4,8}

Authorization of 12 weeks may be granted for treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

Continuation of Therapy

Note: Requirements regarding current hemoglobin level exclude values due to a recent transfusion. All members must be assessed for iron deficiency anemia and have adequate iron stores (defined as a serum transferrin saturation [TSAT] level greater than or equal to 20% within the prior 3 months) or are receiving iron therapy before continuation of treatment with Epogen/Procrit/Retacrit. Members may not use Epogen/Procrit/Retacrit concomitantly with other erythropoiesis stimulating agents.

For all indications below (excluding Anemia due to Zidovudine in HIV infected patients): All members (including new members) requesting authorization for continuation of therapy after at least 12 weeks of erythropoiesis-stimulating agent (ESA) treatment must show a response with a rise in hemoglobin of greater than or equal to 1 g/dL. Members who completed less than 12 weeks of ESA treatment and have not yet responded with a rise in hemoglobin of greater than or equal to 1 g/dL may be granted authorization of up to 12 weeks to allow for sufficient time to demonstrate a response.

Anemia Due to CKD^{1-3,7}

Authorization of 12 weeks may be granted for continued treatment of anemia due to chronic kidney disease in members with current hemoglobin less than 12 g/dL.

Anemia Due to Myelosuppressive Chemotherapy^{1-3,8}

Authorization of 12 weeks may be granted for the continued treatment of anemia due to myelosuppressive chemotherapy in members with non-myeloid malignancy and current hemoglobin less than 12 g/dL.

Anemia in Myelodysplastic Syndrome (MDS)^{4,5,8,12,14}

Authorization of 12 weeks may be granted for continued treatment of anemia in myelodysplastic syndrome in members with current hemoglobin is less than 12 g/dL.

Reduction of Allogenic Red Blood Cell Transfusion in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery¹⁻³

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Anemia Due to Zidovudine in HIV-infected Patients¹⁻³

Authorization of 12 months may be granted for continued treatment of anemia due to zidovudine in HIV-infected members receiving zidovudine with current hemoglobin less than 12 g/dL.

Anemia in Members Who Will Not/Cannot Receive Blood Transfusions⁵

Authorization of 12 weeks may be granted for continued treatment of anemia in members who will not/cannot receive blood transfusions (e.g., religious beliefs) with current hemoglobin less than 12 g/dL.

Myelofibrosis-associated Anemia^{4,5,9,10}

Authorization of 12 weeks may be granted for continued treatment of anemia in myelofibrosis-associated anemia with current hemoglobin less than 12 g/dL.

Anemia Due to Cancer⁴

Authorization of 12 weeks may be granted for continued treatment of anemia due to cancer in members who have cancer and are undergoing palliative treatment.

References

1. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
3. Retacrit [package insert]. New York, NY: Pfizer Labs; June 2024.
4. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed September 5, 2024.
5. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed September 5, 2024.
6. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed September 5, 2024.
7. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int.* 2012;Suppl 2:279-335.
8. Bohlius J, Bohlke K, Castelli R, et al. Management of cancer-associated anemia with erythropoiesis-stimulating agents: ASCO/ASH clinical practice guideline update *J Clin Oncol.* 2019 May 20;37(15):1336-1351.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 2.2024. http://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed September 07, 2023.
10. Cervantes F, Alvarez-Larran A, Hernandez-Boluda JC, et al. Erythropoietin treatment of the anemia of myelofibrosis with myeloid metaplasia: results in 20 patients and review of the literature. *Br J Haematol.* 2004;127(4):399-403.
11. Henry DH, Beall GN, Benson CA, Carey J, Cone LA, Eron LJ, et al. Recombinant Human Erythropoietin in the Treatment of Anemia Associated with Human Immunodeficiency Virus (HIV) Infection and Zidovudine Therapy: Overview of Four Clinical Trials. *Ann Intern Med.*; 117:739-748. doi: 10.7326/0003-4819-117-9-739.
12. Gabrilove j, Paquette R, Lyons R, Mushtaq C, Sekeres M, Tomita D, Dreiling L. Phase 2, single-arm trial to evaluate the effectiveness of darbepoetin alfa for correcting anemia in patients with myelodysplastic syndromes. *Br J Haematol.* 2008 Aug; 142(3): 379-393.
13. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed September 5, 2024

Initial Prior Authorization with Quantity Limit Eucrisa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Eucrisa	crisaborole

Indications

FDA-approved Indications

Eucrisa is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

Coverage Criteria

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The patient is 3 months of age or older.
- The patient meets ONE of the following criteria:
 - The patient is less than 2 years of age.

- The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds) and the following criteria is met :
 - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor.
- The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid.
- If additional quantities are being requested, then 5 percent or greater body surface area is affected.

Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The patient is 3 months of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)].
- If additional quantities are being requested, then 5 percent or greater body surface area is affected.

Quantity Limits Apply

60 grams per 25 days or 180 grams per 75 days.

5% or greater Body Surface Area (BSA): 120 grams per 25 days or 360 grams per 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 1565-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Eucrisa [package insert]. New York, NY: Pfizer Inc.; April 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 5, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/05/2025).
4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71:116-32.
5. Paller AS, Tom WL, et. al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. J Am Acad Dermatol. 2016 Jul 1175(3)494-503.e4.
6. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. December 26, 2024. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed February 6, 2025.
7. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014; 70:338-51.
8. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1): e1-e20.

Specialty Guideline Management

Evenity

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Evenity	romosozumab-aqqg

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Limitations of Use

Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Chart notes or medical record documentation indicating a history of fragility fractures, T-score, and Fracture Risk

Assessment Tool (FRAX) fracture probability as applicable to the coverage criteria section.

Coverage Criteria

Postmenopausal Osteoporosis^{1-5,7}

Authorization of a total of 12 months may be granted to postmenopausal members with osteoporosis when either of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B) and meets any of the following criteria:
 - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], a denosumab product [Prolia, Jubbonti, Ospomyv, Stoboclo], abaloparatide [Tymlos])
 - Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section and have received less than 12 monthly doses of Evenity.

Appendix

Appendix A: Clinical Reasons to Avoid Oral Bisphosphonate Therapy³

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)
- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders)

Reference number(s)
2921-A

- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take oral bisphosphonate at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance <35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B: FRAX Fracture Risk Assessment Tool⁶

- High FRAX fracture 10-year probability: Major osteoporosis-related fracture risk $\geq 20\%$ or hip fracture risk $\geq 3\%$.
- 10-year probability; calculation tool available at: <https://frax.shef.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

References

1. Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2024.
2. LeBoff MS, Greenspan SL, Insogna KL, et al. The Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022;33(10): 2049-2102.
3. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 update. *Endocr Pract*. 2020;26 (Suppl 1):1-46.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2019;104:1595-1622.
5. Carey, John. What is failure of bisphosphonate therapy for osteoporosis. *Cleve Clinic J Med*. 2005; 72:1033-1039.
6. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: <https://frax.shef.ac.uk/FRAX/>. Accessed October 2, 2024.
7. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med* 2017;167(03):ITC17-ITC32.

Specialty Guideline Management

Eylea-Eylea HD

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Eylea	aflibercept
Eylea HD	aflibercept
Ahzantive	aflibercept-mrbb
Enzeevu	aflibercept-abzv
Opuviz	aflibercept-yszy
Pavblu	aflibercept-ayyh
Yesafili	aflibercept-jbvf

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2,6,7,8,9,10}

Eylea is indicated for the treatment of:

- Diabetic macular edema
- Diabetic retinopathy
- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion
- Retinopathy of Prematurity

Eylea HD is indicated for the treatment of:

- Diabetic macular edema
- Diabetic retinopathy
- Neovascular (wet) age-related macular degeneration

Ahzantive, Opuviz, Pavblu and Yesafili are indicated for the treatment of:

- Diabetic macular edema
- Diabetic retinopathy
- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion

Enzeevu is indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Diabetic Macular Edema^{1,2,4,6-8,10}

Authorization of 6 months may be granted for treatment of diabetic macular edema.

Diabetic Retinopathy^{1,2,4,6-8,10}

Authorization of 6 months may be granted for treatment of diabetic retinopathy.

Neovascular (Wet) Age-Related Macular Degeneration^{1-3,6-10}

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Macular Edema Following Retinal Vein Occlusion (Eylea and Biosimilars Only)^{1,5-8,10}

Authorization of 6 months may be granted for treatment of macular edema following retinal vein occlusion.

Retinopathy of Prematurity (Eylea and Biosimilars Only)¹

Authorization of 6 months may be granted for treatment of retinopathy of prematurity.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

References

1. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2024.
2. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2024.
3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
5. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.
6. Opuviz [package insert]. Cambridge, MA: Biogen MA Inc.; May 2024.
7. Yesafili [package insert]. Cambridge, MA: Biocon Biologics Inc.; May 2024.
8. Ahzantive [package insert]. Martinsried/Planegg, Germany: Formycon AG; June 2024.
9. Enzeevu [package insert]. Princeton, NJ: Sandoz Inc.; August 2024.
10. Pavblu [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2024.

Specialty Guideline Management

Factor VIII Concentrates

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Advate	antihemophilic factor [recombinant]
Adynovate	antihemophilic factor [recombinant], PEGylated
Alphanate	antihemophilic factor/von Willebrand factor complex [human]
Altuviiio	antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl
Afstyla	antihemophilic factor [recombinant], single chain
Eloctate	antihemophilic factor [recombinant], Fc fusion protein
Esperoct	antihemophilic factor [recombinant], Glycopegylated-exei
Hemofil M	antihemophilic factor [human] monoclonal antibody purified
Humate-P	antihemophilic factor/von Willebrand factor complex [human]
Jivi	antihemophilic factor [recombinant], PEGylated-aucl
Koate	antihemophilic factor [human]
Kogenate FS	antihemophilic factor [recombinant]
Kovaltry	antihemophilic factor [recombinant]

Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

Brand Name	Generic Name
Novoeight	antihemophilic factor [recombinant]
Nuwiq	antihemophilic factor [recombinant]
Recombinate	antihemophilic factor [recombinant]
Xyntha	antihemophilic factor [recombinant]

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

All other indications are considered experimental/investigational and not medically necessary.

Table: Factor VIII Concentrates and Covered Uses^{1-19,20-24,34,35}

Recombinant Factor VIII Concentrates

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Advate	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Afstyla	antihemophilic factor [recombinant], single chain	Hemophilia A	-
Kogenate FS	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Kovaltry	antihemophilic factor [recombinant]	Hemophilia A	-
Novoeight	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Nuwiq	antihemophilic factor [recombinant]	Hemophilia A	-
Recombinate	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A
Xyntha	antihemophilic factor [recombinant]	Hemophilia A	Acquired Hemophilia A

Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

Extended Half-life Recombinant Factor VIII Concentrates

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Adynovate	antihemophilic factor [recombinant], PEGylated	Hemophilia A	-
Altuviiio	antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl	Hemophilia A	-
Eloctate	antihemophilic factor [recombinant], Fc fusion protein	Hemophilia A	-
Jivi	antihemophilic factor [recombinant], PEGylated-aucl	Hemophilia A	-
Esperoct	antihemophilic factor [recombinant], Glycopegylated-exei	Hemophilia A	-

Human Plasma-Derived Factor VIII Concentrate

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Hemofil M	antihemophilic factor [human] monoclonal antibody purified	Hemophilia A	Acquired Hemophilia A

Human Plasma-Derived Factor VIII Concentrates That Contain Von Willebrand Factor

Brand	Generic	FDA-Approved Indication(s)	Compendial Indication(s)
Alphanate	antihemophilic factor/von Willebrand factor complex [human]	Hemophilia A, von Willebrand Disease	Acquired Hemophilia A, Acquired von Willebrand Syndrome
Humate-P	antihemophilic factor/von Willebrand factor complex [human]	Hemophilia A, von Willebrand Disease	Acquired Hemophilia A, Acquired von Willebrand Syndrome
Koate	antihemophilic factor [human]	Hemophilia A	Acquired Hemophilia A, von Willebrand Disease

Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A^{1,19,24,25,32,34,35}

Authorization of 12 months of Advate, Adynovate, Afstyla, Alphanate, Altuviiio, Eloctate, Esperoct, Hemofil M, Humate-P, Koate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Recombinate, or Xyntha may be granted for treatment of hemophilia A when either of the following criteria is met:

- Member has mild disease (see Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
- Member has moderate or severe disease (see Appendix A).

Authorization of 12 months of Jivi may be granted for treatment of hemophilia A when BOTH of the following criteria are met:

- Member has previously received treatment for hemophilia A with a factor VIII product.
- Member is ≥ 7 years of age.

Von Willebrand Disease (VWD)^{20,21,23,24}

Authorization of 12 months of Alphanate, Humate-P, or Koate may be granted for treatment of VWD when any of the following criteria is met:

- Member has type 1, 2A, 2M, or 2N VWD and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (see Appendix B).
- Member has type 2B or type 3 VWD.

Acquired Hemophilia A^{20,27,29}

Authorization of 12 months of Advate, Alphanate, Hemofil M, Humate-P, Koate, Kogenate FS, Novoeight, Recombinate, or Xyntha may be granted for treatment of acquired hemophilia A.

Acquired von Willebrand Syndrome^{21,23}

Authorization of 12 months of Alphanate or Humate-P may be granted for treatment of acquired von Willebrand syndrome.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).

Appendix

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes^{24,30}

Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.²³

Severity	Clotting Factor Level % activity	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A and Type 1, 2A, 2M and 2N VWD^{20,25,31,32}

- Age < 2 years
- Pregnancy
- Fluid/electrolyte imbalance
- High risk for cardiovascular or cerebrovascular disease (especially the elderly)
- Predisposition to thrombus formation
- Trauma requiring surgery
- Life-threatening bleed
- Contraindication or intolerance to desmopressin
- Severe type 1 von Willebrand disease
- Stimute Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

References

1. Advate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
2. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2025.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; May 2016.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
8. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
9. Recombinate with 5 mL Sterile Water for Injection using BAXAJECT II [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
10. Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
11. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.
12. Adynovate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; August 2023.
13. Afstylia [package insert]. Kankakee, IL: CSL Behring LLC.; June 2023.
14. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2023.
15. Hemofil M [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
16. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
17. Humate-P [package insert]. Kankakee, IL: CSL Behring LLC; June 2020.
18. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; June 2018.
19. Koate-DVI [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2012.
20. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed December 9, 2024.
21. National Institutes of Health. The diagnosis, evaluation, and management of von Willebrand disease. Bethesda, MD: US Dept of Health and Human Services, National Institutes of Health; 2007. NIH publication No. 08-5832.
22. Tiede A, Rand J, Budde U, et al. How I treat the acquired von Willebrand syndrome. *Blood*. 2011;117(25):6777-85.
23. Federici A, Budde U, Castaman G, Rand J, Tiede A. Current diagnostic and therapeutic approaches to patients with acquired von Willebrand syndrome: a 2013 update. *Semin Thromb Hemost*. 2013;39(2):191-201.
24. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020;26 Suppl 6:1-158. doi:10.1111/hae.14046.
25. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised August 2023. MASAC Document #290. <https://www.hemophilia.org/sites/default/files/document/files/MASAC-Products-Licensed.pdf>. Accessed December 9, 2024.

Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

26. National Hemophilia Foundation. MASAC recommendations regarding the treatment of von Willebrand disease. Revised February 2021. MASAC Document #266.
<https://www.hemophilia.org/sites/default/files/document/files/266.pdf>. Accessed December 9, 2024.
27. Acquired hemophilia. World Federation of Hemophilia. <http://www1.wfh.org/publications/files/pdf-1186.pdf>. Accessed December 9, 2024.
28. Tiede A, Collins P, Knoebl P, et al. International recommendations on the diagnosis and treatment of acquired hemophilia A. *Haematologica*. 2020;105(7):1791-1801. doi:10.3324/haematol.2019.230771.
29. Franchini M, Mannucci PM. Acquired haemophilia A: a 2013 update. *Thromb Haemost*. 2013;110(6):1114-20.
30. National Hemophilia Foundation. Hemophilia A (Factor VIII Deficiency). Available at: <http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=180&contentid=45&rpname=bleeding>. Accessed December 9, 2024.
31. Stimate [package insert]. King of Prussia, PA: CSL Behring LLC; June 2021.
32. Leissinger C, Carcao M, Gill JC, et al. Desmopressin (DDAVP) in the management of patients with congenital bleeding disorders. *Haemophilia*. 2014;20:158-167.
33. Reding MT, NG HJ, Poulsen LH, et al. Safety and efficacy of BAY 94-9027, a prolonged-half-life factor VIII. *Journal of thrombosis and Haemostasis*. 2017; 15: 411-9.
34. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2024.
35. Altuviiio [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; September 2024.

Specialty Guideline Management

Fasenra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Fasenra	benralizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Limitations of Use

Not indicated for the relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Asthma

Initial requests

- Chart notes or medical record documentation showing pretreatment blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

EGPA

Initial requests

- Chart notes or medical record documentation showing pretreatment blood eosinophil count or percentage of blood eosinophil level (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting beneficial response to treatment.

Prescriber Specialties

For the indication of asthma: This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Coverage Criteria

Asthma¹⁻⁵

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Member meets either of the following criteria:
 - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
 - Member is dependent on systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)

- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - High-dose inhaled corticosteroid
 - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic granulomatosis with polyangiitis (EGPA)^{1,6-8}

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nucala) indicated for EGPA in the past year.

Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has a history or the presence of a blood eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
- Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
- Member has at least two of the following disease characteristics of EGPA:
 - Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - Pulmonary infiltrates, non-fixed
 - Sino-nasal abnormality
 - Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - Alveolar hemorrhage (by bronchoalveolar lavage)
 - Palpable purpura
 - Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
- Member has had at least one relapse (i.e., requiring increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication or has a refractory disease.

Continuation of Therapy

Asthma

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations

- A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorization of 12 months may be granted for continuation of treatment of EGPA when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has a beneficial response to treatment with the requested medication as demonstrated by any of the following:
 - A reduction in the frequency of relapses
 - A reduction or discontinuation of daily oral corticosteroid dose
 - No active vasculitis

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

References

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med*. 2017;376:2448-2458.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: <https://annualmeeting.aaaai.org/>. Accessed March 8, 2025.
5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22):2301-2317.
6. AstraZeneca. Efficacy and Safety of Benralizumab in EGPA Compared to Mepolizumab. (MANDARA) Available from <https://clinicaltrials.gov/ct2/show/record/NCT04157348>. NLM identifier: NCT04157348. Accessed March 16, 2025.
7. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force Recommendations for evaluation and management. *Eur J Intern Med*. 2015;26(7):545-553.
8. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. *Arthritis Rheumatol*. 2021;73(8):1366-1383.

CountyCare IL: Fingolimod Products
GILENYA (fingolimod hydrochloride)
TASCENSO ODT (fingolimod lauryl sulfate)
fingolimod hydrochloride

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CountyCare.

CRITERIA FOR APPROVAL

1. What is the diagnosis?
 - a. Relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) → **Go to #2**
 - b. Clinically isolated syndrome of multiple sclerosis → **Go to #2**
 - c. Other, please specify. _____ → **Deny**
2. Will the patient be taking the requested drug concomitantly with other disease modifying multiple sclerosis (MS) agents? Note: Ampyra and Nuedexta are not disease modifying.
 - a. Yes → **Deny**
 - b. No → **Go to #3**
3. Is the requested drug being prescribed by or in consultation with a neurologist?
 - a. Yes → **Go to #4**
 - b. No → **Deny**
4. Is the patient 10 years of age or older?
 - a. Yes → **Go to #5**
 - b. No → **Deny**
5. Is the request for continuation of therapy with the requested drug?
 - a. Yes → **Go to #10**
 - b. No → **Go to #50**

Continuation

Relapsing form of multiple sclerosis and Clinically isolated syndrome of multiple sclerosis

10. Is the patient experiencing disease stability or improvement while receiving the requested drug?
 - a. Yes → **Approve for 12 months**
 - b. No → **Deny**

Initial

Relapsing form of multiple sclerosis and Clinically isolated syndrome of multiple sclerosis

50. What is the requested drug?
 - a. fingolimod hydrochloride → **Approve for 12 months**
 - b. Gilenya → **Approve for 12 months**
 - c. Tascenso ODT → **Go to #51**
 - d. Other → **Deny**
51. Is the patient unable to swallow fingolimod or Gilenya capsules?
 - a. Yes → **Approve for 12 months**

Reference number(s)
C29902-A

b. No → **Deny**

REFERENCE

1. CountyCare Prior Authorization Guidelines. Fingolimod Products.

Document History

Created: SD 10/2025

Revised:

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

_____*Ashley M Robinson PharmD*_____
Signature Date 10/23/25

CountyCare
Client Name

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

GENERAL AGE LIMIT

Status: Client Requested Criteria

Type: Initial Prior Authorization

Ref # C25421-B

CRITERIA FOR APPROVAL

1	Is the request for an age restriction override? [If no, then no further questions.]	Yes	No
2	Does the patient have an age-related contraindication to the requested drug? [If yes, then no further questions.]	Yes	No
3	Is the requested drug being used for an FDA-approved indication for the patient's age? [If yes, then no further questions.]	Yes	No
4	Is the requested drug being used for a medically accepted indication and is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice for the patient's age?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

General Age Limit Exception C25421-B 06-2023.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428C 021423



PRIOR AUTHORIZATION CRITERIA

DRUG CLASS GENERAL FORMULARY EXCEPTION

Status: Client Requested Criteria

Type: Initial Prior Authorization

Ref # C25463-A

CRITERIA FOR APPROVAL

1	Is the requested drug used to treat an urgent condition (e.g., situations requiring anticoagulation, acute psychotic episodes, acute bleeding, neutropenia)? [If yes, then no further questions.]	Yes	No
2	Is the request for a drug that is within any of the following CMS protected drug classes: A) anticonvulsants, B) antidepressants, C) antineoplastics, D) antipsychotics, E) antiretrovirals, F) immunosuppressants? [If yes, then no further questions.]		
3	Is this request for continuation of a previously approved non-formulary agent? [Note: Definition of previously approved non-formulary agent is a prior authorization (PA) on file with CountyCare for the requested drug.] [If no, then skip to question 5.]	Yes	No
4	Does the patient have a documented positive clinical response to the requested therapy? [No further questions.]	Yes	No
5	Is the drug/product being used for an FDA-approved (labeled) indication? [If yes, then skip to question 7.]	Yes	No
6	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [If no, then no further questions.]	Yes	No
7	Is the request for a combination agent? [If no, then skip to question 9.]	Yes	No
8	Has the patient tried the preferred single agents within the requested drug classes and indicated for the specified indication? [If yes, then no further questions.]	Yes	No
9	Does the patient have a documented contraindication to preferred products pursuant to the pharmaceutical manufacturer's prescribing information? [If yes, then no further questions.]	Yes	No
10	Is there documented medical rationale that the requested product would be safer and/or more efficacious than using the formulary products? [If yes, then no further questions.]	Yes	No

11	Are there two or more clinically appropriate formulary alternatives within the requested drug class for the requested indication? [If no, then go to question 13.]	Yes	No
12	Has the patient tried and failed TWO clinically appropriate formulary alternatives within the requested drug class for the requested indication? [Note: If there are two clinically appropriate formulary alternatives AND the patient has tried and failed one preferred and one non-preferred agent within the same drug class and with the same indication, the non-preferred agent should be considered as meeting the requirement.] [No further questions.]	Yes	No
13	Is there a preferred clinically appropriate formulary alternative within the requested drug class for the requested indication? [If no, then no further questions.]	Yes	No
14	Has the patient tried and failed ONE preferred clinically appropriate formulary alternative within the requested drug class for the requested indication?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS

GENERAL QUANTITY LIMIT

Status: Client Requested Criteria

Type: Initial Prior Authorization

Ref # C25423-J

CRITERIA FOR APPROVAL

1	Is the request for a quantity limit (QL) override? [If no, then no further questions.]	Yes	No
2	Is the request a QL override for a CMS protected class medication including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, or immunosuppressants? [If yes, then no further questions.]	Yes	No
3	Is the quantity requested within the dosing for an FDA approved indication? [If yes, then no further questions.]	Yes	No
4	Is the quantity requested supported by peer-reviewed medical literature OR standard of care guidelines (GOLD, IDSA, AASLD, etc.)? [If yes, then no further questions.]	Yes	No
5	Does the patient require incremental dosage increase (e.g., dose titration)?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

General Quantity Limit PA C25423-J 06-2024.docx

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed, or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2024 CVS Health and/or its affiliates. All rights reserved. 106-58428C 021423



Specialty Guideline Management

Glatiramer Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Copaxone	glatiramer acetate
Glatopa	glatiramer acetate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁴

Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis¹⁻⁶

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹⁻⁶

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving the requested medication.

Other

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

References

1. Copaxone [package insert]. Parsippany, NY: Teva Pharmaceuticals USA, Inc.; January 2025.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; February 2025.
3. Glatiramer acetate 20 mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2025.
4. Glatiramer acetate 40 mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2025.
5. The Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed April 14, 2025.
6. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology*. 2018;90(17):777-788.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

ADLYXIN
(lixisenatide)

BYDUREON BCISE
(exenatide extended release)

BYETTA
(exenatide)

MOUNJARO
(tirzepatide)

OZEMPIC
(semaglutide injection)

RYBELSUS
(semaglutide oral)

TRULICITY
(dulaglutide)

VICTOZA
(liraglutide)

Status: Client Requested Criteria

Type: Initial Prior Authorization with Quantity Limit

Ref # C29735-C

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of type 2 diabetes mellitus? [If no, then no further questions.]	Yes	No
2	Does the patient have a history of an A1C greater than or equal to 6.5 percent? ACTION REQUIRED: If yes, the prescriber MUST submit chart notes or other documentation supporting a history of an A1C greater than or equal to 6.5 percent. [If no, then skip to question 4.] Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in the next question	Yes	No
3	Have chart notes or other documentation supporting a history of an A1C greater than or equal to 6.5 percent been submitted? ACTION REQUIRED: Submit supporting documentation [If yes, then skip to question 11.] [If no, then no further questions.] Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.	Yes	No

4	Does the patient have a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT)? ACTION REQUIRED: If yes, the prescriber MUST submit chart notes or other documentation supporting a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [If no, then skip to question 6.]	Yes	No
	Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in the next question.		
5	Have chart notes or other documentation supporting a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT) been submitted? ACTION REQUIRED: <i>Submit supporting documentation</i> [If yes, then skip to question 11.] [If no, then no further questions.]	Yes	No
	Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.		
6	Does the patient have a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL? ACTION REQUIRED: If yes, the prescriber MUST submit chart notes or other documentation supporting a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [If no, then skip to question 8.]	Yes	No
	Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in the next question.		
7	Have chart notes or other documentation supporting a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL been submitted? ACTION REQUIRED: <i>Submit supporting documentation</i> [If yes, then skip to question 11.] [If no, then no further questions.]	Yes	No
	Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.		
8	Does the patient have a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL? ACTION REQUIRED: If yes, the prescriber MUST submit chart notes or other documentation supporting a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL. [If no, then no further questions.]	Yes	No
	Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in question 10.		
9	Did the patient fast for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL? [If no, then no further questions.]	Yes	No
10	Have chart notes or other documentation supporting a history of fasting plasma glucose (FPG) greater than or equal to 126 mg/dL been submitted? ACTION REQUIRED: <i>Submit supporting documentation</i> [If no, then no further questions.]	Yes	No

Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.

11	Is this request for Adlyxin, Bydureon BCise, exenatide (Byetta), Ozempic, or Mounjaro? [If no, then no further questions.]	Yes	No
12	Has the patient had an adequate trial of 3 consecutive months of a stable maintenance dose with TWO of the preferred glucagon-like peptide 1 (GLP-1) Agonist products: A) liraglutide (generic Victoza), B) Rybelsus, C) Trulicity, or D) Victoza? ACTION REQUIRED: Provide required documentation including name of medication(s) tried, length of therapy with stable maintenance dose. [If no, then no further questions.]	Yes	No
	Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in the next question.		
13	Have chart notes or other documentation supporting an adequate trial of 3 consecutive months of a stable maintenance dose with TWO of the preferred glucagon-like peptide 1 (GLP-1) Agonist products: A) liraglutide (generic Victoza), B) Rybelsus, C) Trulicity, or D) Victoza, been submitted? ACTION REQUIRED: Submit supporting documentation [If no, then no further questions.]		
	Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation.		
14	Has the patient been able to achieve a HbA1c reduction of greater than 0.5 percent after 6 months of therapy with the preferred products: A) liraglutide (generic Victoza), B) Rybelsus, C) Trulicity, or D) Brand Only Victoza? ACTION REQUIRED: Provide required documentation including name of medication(s) tried and documentation of HbA1C reduction. [If yes, then no further questions.]	Yes	No
	Tech Note: Leave response as answered by prescriber. Verification of chart note will be addressed in the next question.		
15	Have chart notes or other documentation supporting the patient has been unable to achieve a HbA1c reduction of greater than 0.5 percent after 6 months of therapy with the preferred products: A) liraglutide (generic Victoza), B) Rybelsus, C) Trulicity, or D) Brand Only Victoza, been submitted? ACTION REQUIRED: Submit supporting documentation [If no, then no further questions.]	Yes	No
16	Will the patient be using the requested agent in combination with a Dipeptidyl Peptidase-4 (DPP-4) Inhibitor containing agent (e.g., alogliptin, alogliptin/metformin, alogliptin/pioglitazone, Januvia, Janumet/Janumet XR, Jentadueto/Jentadueto XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, saxagliptin, sitagliptin, Tradjenta, Zituvio, Zituvimet)?	Yes	No

Quantity Limits Apply

Drug	Maximum Dosing	Package Size(s)	1 Month Limit 3 Months Limit
Adlyxin	20mcg daily	Starter pack - 2 pens (1 pen of 10mcg, 1 pen of 20mcg), 14 doses per pen, 3mL each Maintenance pack - 2 pens of 20mcg, 14 doses per pen, 3mL each	2 prefilled pens (6mL) / 21 days 6 prefilled pens (18mL) / 63 days
Bydureon BCise	2mg once weekly	Carton of 4 single-dose autoinjectors (2mg/0.85mL each)	4 auto-injectors (3.4mL) / 21 days 12 auto-injectors (10.2mL) / 63 days
Byetta	10mcg twice daily	5mcg dose, 60 doses, 1.2mL prefilled pen	1 prefilled pen (1.2mL) / 25 days 3 prefilled pens (3.6mL) / 75 days
Byetta	10mcg twice daily	10mcg dose, 60 doses, 2.4mL prefilled pen	1 prefilled pen (2.4mL) / 25 days 3 prefilled pens (7.2mL) / 75 days
Mounjaro	15mg once weekly	Carton of 4 pre-filled single-dose pens or 1 single-dose vial (0.5 mL each) of 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, 15 mg/0.5 mL	4 pre-filled single-dose pens or 4 single-dose vials (2 mL) / 21 days 12 pre-filled single-dose pens or 12 single-dose vials (6 mL) / 63 days
Ozempic	2mg once weekly	Carton of 1 pen (2mg/1.5mL)	1 prefilled pen (1.5mL) / 21 days 3 prefilled pens (4.5mL) / 63 days
Ozempic	2mg once weekly	Carton of 1 pen (2mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
Ozempic	2mg once weekly	Carton of 1 pen (4mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
Ozempic	2mg once weekly	Carton of 1 pen (8mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
Rybelsus (R2 formulation)	9mg once daily	1.5mg, 4mg, 9mg in bottles of 30 tablets	30 tablets / 25 days 90 tablets / 75 days
Rybelsus (R1 formulation)	14mg once daily	3mg, 7mg, 14mg in bottles of 30 tablets	30 tablets / 25 days 90 tablets / 75 days
Trulicity	4.5mg once weekly	0.75mg/0.5mL, 1.5mg/0.5mL, 3mg/0.5mL, 4.5mg/0.5mL in cartons of 4 single-dose pens (0.5mL each)	4 pens (2mL) / 21 days 12 pens (6mL) / 63 days
Victoza	1.8mg once daily	Package of 2 or 3 pens (18mg/3mL each)	3 prefilled pens (9mL) / 25 days 9 prefilled pens (27mL) / 75 days

REFERENCES

1. CountyCare IL Prior Authorization Approval Policy: Antidiabetic GLP-1 Receptor Agonist and GIP/GLP-1 Receptor Agonists Prior Authorization with Quantity Limit. August 2025.

CountyCare IL Humira and Biosimilars Custom Criteria

Abrilada (adalimumab-afzb)
adalimumab-aacf
adalimumab-aaty
adalimumab-adaz
adalimumab-adbm
adalimumab-fkjp
adalimumab-ryvk
Amjevita (adalimumab-atto)
Cyltezo (adalimumab-adbm)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Simlandi (adalimumab-ryvk)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)

CRITERIA FOR APPROVAL

- 1 What is the requested product?
 - ☐ Humira (If checked, go to 2)
 - ☐ Abrilada (If checked, go to 2)
 - ☐ adalimumab (If checked, go to 2)
 - ☐ adalimumab-aacf (If checked, go to 2)
 - ☐ adalimumab-aaty (If checked, go to 2)
 - ☐ adalimumab-adaz (If checked, go to 2)
 - ☐ adalimumab-adbm (If checked, go to 30)
 - ☐ adalimumab-fkjp (If checked, go to 2)
 - ☐ adalimumab-ryvk (If checked, go to 2)
 - ☐ Amjevita (If checked, go to 2)
 - ☐ Cyltezo (If checked, go to 2)
 - ☐ Hadlima (If checked, go to 2)
 - ☐ Hulio (If checked, go to 2)
 - ☐ Hyrimoz (If checked, go to 2)

☐ Idacio (If checked, go to 2)

☐ Simlandi (If checked, go to 30)

☐ Yuflyma (If checked, go to 2)

☐ Yusimry (If checked, go to 2)

2 What is the diagnosis?

☐ Ankylosing spondylitis (If checked, go to 3)

☐ Crohn's disease (If checked, go to 6)

☐ Hidradenitis suppurativa (If checked, go to 7)

☐ Plaque psoriasis (If checked, go to 11)

☐ Polyarticular juvenile idiopathic arthritis (If checked, go to 13)

☐ Psoriatic arthritis (If checked, go to 16)

☐ Rheumatoid arthritis (If checked, go to 19)

☐ Ulcerative colitis (If checked, go to 22)

☐ Uveitis (If checked, go to 27)

☐ Other, please specify: _____ (If checked, go to 30)

3	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication to ONE of the following: A) TWO different adalimumab products or B) ONE adalimumab product AND either Cosentyx or Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 30. If No, then go to 4.]	Yes	No
4	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 30. If No, then go to 5.]	Yes	No
5	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 30. If No, then no further questions.]	Yes	No

6	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following : A) TWO different adalimumab products or B) ONE adalimumab product AND Cimzia? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
7	What is the patient's age? ☐ Less than 12 years of age (If checked, no further questions) ☐ 12 years of age to less than 18 years of age (If checked, go to 8) ☐ 18 years of age or older (If checked, go to 9)		
8	Is the requested drug Humira? [If Yes, then go to 30. If No, then no further questions.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following: A) TWO different adalimumab products or B) ONE adalimumab product AND Cosentyx? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 10.]	Yes	No
10	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
11	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following: A) TWO different adalimumab products or B) ONE adalimumab product and ONE either Cosentyx or Enbrel? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 12.]	Yes	No
12	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx or Enbrel? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
13	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following: A) TWO adalimumab products or B) ONE adalimumab product and either Enbrel or Xeljanz/XeljanzXR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation	Yes	No

[If Yes, then go to 30. If No, then go to 14.]

14	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 15.]	Yes	No
15	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
16	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following: A) TWO different adalimumab products or B) ONE adalimumab product AND any one of Cosentyx, Cimzia, Enbrel, or Xeljanz/Xeljanz XR)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 17.]	Yes	No
17	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 18.]	Yes	No
18	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
19	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the Following : A) TWO different adalimumab products or B) ONE adalimumab product and any one of Cimzia, Enbrel, or Xeljanz/Xeljanz XR)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 20.]	Yes	No

20	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 21.]	Yes	No
21	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation. [If Yes, then go to 30. If No, then no further questions.]	Yes	No
22	What is the patient's age? ☐ Less than 5 years of age (If checked, no further questions) ☐ 5 years of age to less than 18 years of age (If checked, go to 23) ☐ 18 years of age or older (If checked, go to 24)		
23	Is the requested drug Humira? [If Yes, then go to 30. If No, then no further questions.]	Yes	No
24	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following: A) TWO different adalimumab products or B) ONE adalimumab product and Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 25.]	Yes	No
25	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then go to 26.]	Yes	No
26	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No
27	What is the patient's age? ☐ Less than 2 years of age (If checked, no further questions)		

☐ 2 years of age to less than 18 years of age (If checked, go to 28)

☐ 18 years of age or older (If checked, go to 29)

28	Is the requested drug Humira? [If Yes, then go to 30. If No, then no further questions.]	Yes	No

29	Has the patient had a documented inadequate response, intolerable adverse event, with TWO different adalimumab products OR has a contraindication to adalimumab? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 30. If No, then no further questions.]	Yes	No

30	Will the requested drug be used in combination with any other biologic (e.g., Cimzia) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 31.]	Yes	No

31	Has the patient ever received (including current utilizers) a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 35. If No, then go to 32.]	Yes	No

32	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy? [If Yes, then go to 33. If No, then no further questions.]	Yes	No

33 What were the results of the tuberculosis (TB) test?

☐ Positive for TB (If checked, go to 34)

☐ Negative for TB (If checked, go to 35)

☐ Unknown (If checked, no further questions)

34 Which of the following applies to the patient?

☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 35)

☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 35)

☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions)

☐ Patient has active TB (If checked, no further questions)

35 What is the diagnosis?

☐ Rheumatoid arthritis (If checked, go to 38)

☐ Crohn's disease (If checked, go to 89)

☐ Plaque psoriasis (If checked, go to 101)

- ☐ Ulcerative colitis (If checked, go to 95)
- ☐ Psoriatic arthritis (If checked, go to 65)
- ☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 36)
- ☐ Ankylosing spondylitis (If checked, go to 80)
 - ☐ Non-radiographic axial spondyloarthritis (If checked, go to 80)
- ☐ Polyarticular juvenile idiopathic arthritis (If checked, go to 52)
 - ☐ Oligoarticular juvenile idiopathic arthritis (If checked, go to 52)
- ☐ Systemic juvenile idiopathic arthritis (If checked, no further questions)
- ☐ Hidradenitis suppurativa (If checked, go to 116)
- ☐ Behcet's disease (If checked, go to 127)
- ☐ Pyoderma gangrenosum (If checked, go to 144)
- ☐ Uveitis (If checked, go to 133)
- ☐ Immune checkpoint inhibitor-related toxicity - inflammatory arthritis (If checked, go to 152)
- ☐ Other, please specify. _____ (If checked, no further questions)

36	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 37. If No, then no further questions.]	Yes	No
37	What is the primary diagnosis being treated? ☐ Psoriatic arthritis (If checked, go to 66) ☐ Plaque psoriasis (If checked, go to 102)		
38	Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)? [If Yes, then go to 39. If No, then no further questions.]	Yes	No
39	Is the patient an adult (18 years of age or older)? [If Yes, then go to 40. If No, then no further questions.]	Yes	No
40	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 41. If No, then no further questions.]	Yes	No
41	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 42. If No, then go to 45.]	Yes	No
42	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient		

assistance program?

☐ Yes (If checked, go to 45)

☐ No (If checked, go to 43)

☐ Unknown (If checked, go to 45)

43	Has the patient achieved or maintained a positive clinical response since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 44. If No, then no further questions.]	Yes	No

44	Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting positive clinical response and substantial disease activity improvement. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then no further questions.]	Yes	No

Tech/RPh note: Percentage of disease activity improvement is per prescriber attestation and does not have to be explicitly stated in the chart notes or medical record documentation.

45	Has the patient ever received or is currently receiving a biologic (e.g., Enbrel) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then go to 46.]	Yes	No

46	Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive? ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 48. If No, then go to 47.]	Yes	No

47	Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 48. If No, then no further questions.]	Yes	No

48	Has the patient had an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION	Yes	No

REQUIRED: Submit supporting documentation
[If Yes, then go to 160. If No, then go to 49.]

49	Has the patient had an intolerance to methotrexate? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then go to 50.]	Yes	No
50	Does the patient have a contraindication to methotrexate? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 51. If No, then no further questions.]	Yes	No
51	Please indicate the contraindication to methotrexate.		
	☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 160)		
	☐ Drug interaction (If checked, go to 160)		
	☐ Risk of treatment-related toxicity (If checked, go to 160)		
	☐ Pregnancy or currently planning pregnancy (If checked, go to 160)		
	☐ Breastfeeding (If checked, go to 160)		
	☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 160)		
	☐ Hypersensitivity (If checked, go to 160)		
	☐ History of intolerance or adverse event (If checked, go to 160)		
	☐ Other, please specify. _____ (If checked, no further questions)		
52	Has the patient been diagnosed with moderately to severely active articular juvenile idiopathic arthritis? [If Yes, then go to 53. If No, then no further questions.]	Yes	No
53	Is the patient 2 years of age or older? [If Yes, then go to 54. If No, then no further questions.]	Yes	No
54	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 55. If No, then no further questions.]	Yes	No
55	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 56. If No, then go to 59.]	Yes	No
56	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 59)

☐ No (If checked, go to 57)

☐ Unknown (If checked, go to 59)

57	Has the patient achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 58. If No, then no further questions.]	Yes	No

58	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 160)

☐ Number of joints with limitation of movement **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 160)

☐ Functional ability **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 160)

☐ None of the above (If checked, no further questions)

59	Has the patient ever received or is currently receiving a biologic (e.g., Enbrel) or targeted synthetic drug (e.g., Xeljanz) indicated for moderately to severely active articular juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 60.]	Yes	No

60	Has the patient had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 61.]	Yes	No

61	Has the patient had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 62. If No, then go to 63.]	Yes	No

62	Does the patient have any of the following risk factors for poor outcome: a) involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ), b) presence of erosive disease or	Yes	No

enthesitis, c) delay in diagnosis, d) elevated levels of inflammation markers, or e) symmetric disease?
[If Yes, then go to 160. If No, then go to 63.]

63	Does the patient have any of the following risk factors for disease severity and potentially a more refractory disease course: a) positive rheumatoid factor, b) positive anti-cyclic citrullinated peptide antibodies, or c) pre-existing joint damage? [If Yes, then go to 64. If No, then no further questions.]	Yes	No
64	Does the patient meet any of the following: a) high-risk joints are involved (e.g., cervical spine, wrist, or hip), b) high disease activity, or c) high risk for disabling joint disease? [If Yes, then go to 160. If No, then no further questions.]	Yes	No
65	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 66. If No, then no further questions.]	Yes	No
66	Is the patient an adult (18 years of age or older)? [If Yes, then go to 67. If No, then no further questions.]	Yes	No
67	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 68. If No, then go to 71.]	Yes	No
68	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?		
	☐ Yes (If checked, go to 71)		
	☐ No (If checked, go to 69)		
	☐ Unknown (If checked, go to 71)		
69	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 70. If No, then no further questions.]	Yes	No
70	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		
	☐ Number of swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)		
	☐ Number of tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)		
	☐ Dactylitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)		
	☐ Enthesitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)		

☐ Axial disease *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Skin and/or nail involvement *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Functional status *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ None of the above (If checked, no further questions)

71	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 72. If No, then no further questions.]	Yes	No
72	Has the patient ever received or is currently receiving a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 73.]	Yes	No
73	What is the patient's disease severity? ☐ Mild to moderate (If checked, go to 74) ☐ Severe (If checked, go to 160)		
74	Does the patient have enthesitis or predominantly axial disease? [If Yes, then go to 160. If No, then go to 75.]	Yes	No
75	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 76.]	Yes	No
76	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 77.]	Yes	No
77	Does the patient have a contraindication to methotrexate or leflunomide? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 78. If No, then go to 79.]	Yes	No

78 Please indicate the contraindication to methotrexate or leflunomide.

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 160)

☐ Drug interaction (If checked, go to 160)

☐ Risk of treatment-related toxicity (If checked, go to 160)

☐ Pregnancy or currently planning pregnancy (If checked, go to 160)

☐ Breastfeeding (If checked, go to 160)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 160)

☐ Hypersensitivity (If checked, go to 160)

☐ History of intolerance or adverse event (If checked, go to 160)

☐ Other, please specify. _____ (If checked, no further questions)

79	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then no further questions.]	Yes	No

80	Is the patient an adult (18 years of age or older)? [If Yes, then go to 81. If No, then no further questions.]	Yes	No

81	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 82. If No, then no further questions.]	Yes	No

82	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 83. If No, then go to 86.]	Yes	No

83	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 86)

☐ No (If checked, go to 84)

☐ Unknown (If checked, go to 86)

84	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 85. If No, then no further questions.]	Yes	No

85	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or		

medical records supporting positive clinical response.

☐ Functional status *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Total spinal pain *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Inflammation (e.g., morning stiffness) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Swollen joints *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Tender joints *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ None of the above (If checked, no further questions)

86 Has the patient been diagnosed with active ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA)?

☐ Yes - Active ankylosing spondylitis (If checked, go to 87)

☐ Yes - Active non-radiographic axial spondyloarthritis (If checked, go to 87)

☐ No (If checked, no further questions)

87 Has the patient ever received or is currently receiving a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? *ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 160. If No, then go to 88.]

Yes

No

88 Has the patient had an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least two NSAIDs? *ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 160. If No, then no further questions.]

Yes

No

89 Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? [If Yes, then go to 90. If No, then no further questions.]

Yes

No

90 Is the patient 6 years of age or older? [If Yes, then go to 91. If No, then no further questions.]

Yes

No

91	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 92. If No, then no further questions.]	Yes	No
92	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 93. If No, then go to 160.]	Yes	No
93	Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission. ☐ Yes, achieved or maintained remission ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Yes, achieved or maintained a positive clinical response (If checked, go to 94) ☐ No or none of the above (If checked, no further questions)		
94	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy. ☐ Abdominal pain or tenderness ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Diarrhea ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Body weight ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Abdominal mass ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Hematocrit ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI]) score ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ None of the above (If checked, no further questions)		
95	Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? [If Yes, then go to 96. If No, then no further questions.]	Yes	No

96	Is the patient 5 years of age or older? [If Yes, then go to 97. If No, then no further questions.]	Yes	No
97	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 98. If No, then no further questions.]	Yes	No
98	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 99. If No, then go to 160.]	Yes	No
99	Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission. ☐ Yes, achieved or maintained remission ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Yes, achieved or maintained a positive clinical response (If checked, go to 100) ☐ No or none of the above (If checked, no further questions)		
100	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy. ☐ Stool frequency ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Rectal bleeding ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Urgency of defecation ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ C-reactive protein (CRP) ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Fecal calprotectin (FC) ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) ACTION REQUIRED: <i>Submit supporting documentation</i> (If checked, go to 160) ☐ None of the above (If checked, no further questions)		

101	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 102. If No, then no further questions.]	Yes	No
102	Has the patient been diagnosed with moderate to severe plaque psoriasis? [If Yes, then go to 103. If No, then no further questions.]	Yes	No
103	Is the patient an adult (18 years of age or older)? [If Yes, then go to 104. If No, then no further questions.]	Yes	No
104	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 105. If No, then go to 109.]	Yes	No
105	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 109) ☐ No (If checked, go to 106) ☐ Unknown (If checked, go to 109)		
106	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 107. If No, then no further questions.]	Yes	No
107	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 108.]	Yes	No
108	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then no further questions.]	Yes	No
109	Has the patient ever received or is currently receiving a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medication tried. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 110.]	Yes	No
110	Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of	Yes	No

affected areas. *ACTION REQUIRED: Submit supporting documentation*

[If Yes, then go to 160. If No, then go to 111.]

111	Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%? [If Yes, then no further questions. If No, then go to 112.]	Yes	No

112	What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? Indicate percentage. <i>ACTION REQUIRED: Please attach chart notes or medical record documentation of body surface area affected.</i>		

☐ Greater than or equal to 3% to less than 10% of BSA
ACTION REQUIRED: Submit supporting documentation (If checked, go to 113)

☐ Greater than or equal to 10% of BSA
ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)

113	Has the patient had an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 114.]	Yes	No

114	Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 115. If No, then no further questions.]	Yes	No

115	Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin.		

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease, (If checked, go to 160)

☐ Drug interaction (If checked, go to 160)

☐ Risk of treatment-related toxicity (If checked, go to 160)

☐ Pregnancy or currently planning pregnancy (If checked, go to 160)

☐ Breastfeeding (If checked, go to 160)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 160)

☐ Hypersensitivity (If checked, go to 160)

☐ History of intolerance or adverse event (If checked, go to 160)

☐ Other, please specify. _____ (If checked, no further questions)

116	Has the patient been diagnosed with moderate to severe hidradenitis suppurativa? [If Yes, then go to 117. If No, then no further questions.]	Yes	No

117	Is the patient 12 years of age or older? [If Yes, then go to 118. If No, then no further questions.]	Yes	No

118	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 119. If No, then no further questions.]	Yes	No

119	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 120. If No, then go to 123.]	Yes	No

120	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 123) ☐ No (If checked, go to 121) ☐ Unknown (If checked, go to 123)		

121	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 122. If No, then no further questions.]	Yes	No

122	Which of the following has the patient experienced an improvement in since starting treatment with the requested drug or a biosimilar of the requested drug? ACTION REQUIRED: Please attach chart notes or medical records supporting positive clinical response. ☐ Reduction in abscess and inflammatory nodule count from baseline ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Reduced formation of new sinus tracts and scarring ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Decrease in frequency of inflammatory lesions from baseline ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Reduction in pain from baseline ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Reduction in suppuration from baseline ACTION REQUIRED: Submit supporting documentation (If checked, go to 160) ☐ Improvement in frequency of relapses from baseline ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)		

160)

☐ Improvement in quality of life from baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Improvement on a disease severity assessment tool from baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ None of the above (If checked, no further questions)

123	Has the patient ever received or is currently receiving a biologic indicated for the treatment of moderate to severe hidradenitis suppurativa (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medication tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 124.]	Yes	No
124	Has the patient had an inadequate response after at least 90 days of treatment with an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 125.]	Yes	No
125	Has the patient had an intolerance to oral antibiotics used for the treatment of hidradenitis suppurativa? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 126.]	Yes	No
126	Does the patient have a contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then no further questions.]	Yes	No
127	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 128. If No, then no further questions.]	Yes	No
128	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 129. If No, then go to 131.]	Yes	No
129	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 131) ☐ No (If checked, go to 130)		

☐ Unknown (If checked, go to 131)

130	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 160. If No, then no further questions.]	Yes	No

131	Has the patient ever received or is currently receiving Otezla or a biologic indicated for the treatment of Behcet's disease (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then go to 132.]	Yes	No

132	Has the patient had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then no further questions.]	Yes	No

133	Has the patient been diagnosed with non-infectious intermediate, posterior, or panuveitis? [If Yes, then go to 134. If No, then no further questions.]	Yes	No

134	Is the patient 2 years of age or older? [If Yes, then go to 135. If No, then no further questions.]	Yes	No

135	Is the requested drug being prescribed by or in consultation with an ophthalmologist or rheumatologist? [If Yes, then go to 136. If No, then no further questions.]	Yes	No

136	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 137. If No, then go to 140.]	Yes	No

137	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 140)

☐ No (If checked, go to 138)

☐ Unknown (If checked, go to 140)

138	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 139. If No, then no further questions.]	Yes	No

139	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or		

medical record documentation supporting positive clinical response.

☐ Reduced frequency of disease flares compared to baseline
ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)

☐ Stability or improvement in anterior chamber (AC) cell grade compared to baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Stability or improvement in vitreous haze (VH) grade compared to baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ Stability or improvement in visual acuity compared to baseline
ACTION REQUIRED: Submit supporting documentation (If checked, go to 160)

☐ Reduction in glucocorticoid requirements from baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 160)

☐ None of the above (If checked, no further questions)

140	Has the patient ever received or is currently receiving a biologic indicated for non-infectious intermediate, posterior, and panuveitis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 141.]	Yes	No
141	Has the patient had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 142.]	Yes	No
142	Has the patient had an intolerance to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 143.]	Yes	No
143	Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 160. If No, then no further questions.]

144	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 145. If No, then no further questions.]	Yes	No

145	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 146. If No, then go to 148.]	Yes	No

146	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 148)

☐ No (If checked, go to 147)

☐ Unknown (If checked, go to 148)

147	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 160. If No, then no further questions.]	Yes	No

148	Has the patient ever received or is currently receiving a biologic indicated for the treatment of pyoderma gangrenosum (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 149.]	Yes	No

149	Has the patient had an inadequate response with corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 150.]	Yes	No

150	Has the patient had an intolerance to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then go to 151.]	Yes	No

151	Does the patient have a contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil)? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 160. If No, then no further questions.]	Yes	No

152	Is the requested drug being prescribed by or in consultation with an oncologist, hematologist, or rheumatologist? [If Yes, then go to 153. If No, then no further questions.]	Yes	No
153	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 154. If No, then go to 156.]	Yes	No
154	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 156) ☐ No (If checked, go to 155) ☐ Unknown (If checked, go to 156)		
155	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then no further questions.]	Yes	No
156	Does the patient have moderate or severe immunotherapy-related inflammatory arthritis? [If Yes, then go to 157. If No, then no further questions.]	Yes	No
157	Has the patient had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then go to 158.]	Yes	No
158	Does the patient have an intolerance or contraindication to corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 159. If No, then no further questions.]	Yes	No
159	Does the patient have an intolerance or contraindication to a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 160. If No, then no further questions.]	Yes	No
160	What is the diagnosis?		

- ☐ Rheumatoid arthritis (If checked, go to 161)
- ☐ Crohn's disease (If checked, go to 190)
- ☐ Plaque psoriasis (If checked, go to 184)
- ☐ Ulcerative colitis (If checked, go to 196)
- ☐ Psoriatic arthritis (If checked, go to 166)
- ☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 184)
- ☐ Ankylosing spondylitis (If checked, go to 166)
 - ☐ Non-radiographic axial spondyloarthritis (If checked, go to 166)
- ☐ Polyarticular juvenile idiopathic arthritis (If checked, go to 169)
 - ☐ Oligoarticular juvenile idiopathic arthritis (If checked, go to 169)
- ☐ Hidradenitis suppurativa (If checked, go to 172)
- ☐ Behcet's disease (If checked, go to 220)
- ☐ Pyoderma gangrenosum (If checked, go to 220)
- ☐ Uveitis (If checked, go to 168)
- ☐ Immunotherapy-related inflammatory arthritis (If checked, go to 220)

161	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 162. If No, then go to 166.]	Yes	No
162	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then go to 164. If No, then go to 163.]	Yes	No
163	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No
164	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 165.]	Yes	No
165	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
166	Does the prescribed dose exceed 40 mg? [If Yes, then no further questions. If No, then go to 167.]	Yes	No
167	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
168	What is the patient's age?		

☐ 2 years of age to less than 18 years of age (If checked, go to 169)

☐ 18 years of age or older (If checked, go to 184)

169 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than 10 kilograms (kg) _____ (If checked, no further questions)

☐ 10 kg or greater _____ (If checked, go to 170)

170	Does the prescribed dose exceed 40 mg? [If Yes, then no further questions. If No, then go to 171.]	Yes	No

171	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No

172 What is the patient's age?

☐ 12 years of age to less than 18 years of age (If checked, go to 173)

☐ 18 years of age or older (If checked, go to 174)

173 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than 30 kilograms (kg) _____ (If checked, no further questions)

☐ 30 kg or greater _____ (If checked, go to 174)

174	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 176. If No, then go to 175.]	Yes	No

175	Is a loading dose prescribed? [If Yes, then go to 180. If No, then go to 176.]	Yes	No

176	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then go to 178. If No, then go to 177.]	Yes	No

177	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No

178	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 179.]	Yes	No

179	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No

180	Does the prescribed dose exceed a loading dose of 160 mg on day 1 and 80 mg on day 15, and a maintenance dose of 40 mg thereafter? [If Yes, then go to 182. If No, then go to 181.]	Yes	No

181	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No
182	Does the prescribed dose exceed a loading dose of 160 mg on day 1 and 80 mg on day 15, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 183.]	Yes	No
183	Does the prescribed frequency for the maintenance dose exceed one dose every 2 weeks? [No further questions]	Yes	No
184	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 186. If No, then go to 185.]	Yes	No
185	Is a loading dose prescribed? [If Yes, then go to 188. If No, then go to 186.]	Yes	No
186	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then no further questions. If No, then go to 187.]	Yes	No
187	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
188	Does the prescribed dose exceed a loading dose of 80 mg on day 1 and 40 mg on day 8, and a maintenance dose of 40 mg thereafter? [If Yes, then no further questions. If No, then go to 189.]	Yes	No
189	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
190	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 192. If No, then go to 191.]	Yes	No
191	Is a loading dose prescribed? [If Yes, then go to 194. If No, then go to 192.]	Yes	No
192	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then no further questions. If No, then go to 193.]	Yes	No
193	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
194	Does the prescribed dose exceed a loading dose of 160 mg on day 1 and 80 mg on day 15, and a maintenance dose of 40 mg thereafter? [If Yes, then no further questions. If No, then go to 195.]	Yes	No
195	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
196	Is the patient currently receiving the requested drug or a biosimilar of the requested drug?	Yes	No

[If Yes, then go to 197. If No, then go to 212.]

197 What is the patient's age?

☐ 5 years of age to less than 18 years of age (If checked, go to 198)

☐ 18 years of age or older (If checked, go to 203)

198 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than 20 kilograms (kg) _____ (If checked, no further questions)

☐ 20 kg or greater _____ (If checked, go to 199)

199	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then go to 201. If No, then go to 200.]	Yes	No

200	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No

201	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 202.]	Yes	No

202	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No

203	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then go to 208. If No, then go to 204.]	Yes	No

204	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [If Yes, then go to 205. If No, then no further questions.]	Yes	No

205	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 206.]	Yes	No

206	Is this a continuation of a regimen with the requested drug or a biosimilar of the requested drug that was started before the patient turned 18 years old? [If Yes, then go to 207. If No, then no further questions.]	Yes	No

207	Is the patient well-controlled on the requested regimen? [No further questions]	Yes	No

208	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 209.]	Yes	No

209	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [If Yes, then no further questions. If No, then go to 210.]	Yes	No

210	Is this a continuation of a regimen with the requested drug or a biosimilar of the requested drug that was started before the patient turned 18 years old?	Yes	No

[If Yes, then go to 211. If No, then no further questions.]

211	Is the patient well-controlled on the requested regimen? [No further questions]	Yes	No
212	What is the patient's age? ☐ 5 years of age to less than 18 years of age (If checked, go to 213) ☐ 18 years of age or older (If checked, go to 218)		
213	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 20 kilograms (kg) _____ (If checked, no further questions) ☐ 20 kg or greater _____ (If checked, go to 214)		
214	Does the prescribed dose exceed a loading dose of 160 mg on day 1, 80 mg on day 8, and 80 mg on day 15, and a maintenance dose of 40 mg thereafter? [If Yes, then go to 216. If No, then go to 215.]	Yes	No
215	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No
216	Does the prescribed dose exceed a loading dose of 160 mg on day 1, 80 mg on day 8, and 80 mg on day 15, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 217.]	Yes	No
217	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
218	Does the prescribed dose exceed a loading dose of 160 mg on day 1 and 80 mg on day 15, and a maintenance dose of 40 mg thereafter? [If Yes, then no further questions. If No, then go to 219.]	Yes	No
219	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [No further questions]	Yes	No
220	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? [If Yes, then go to 221. If No, then no further questions.]	Yes	No
221	Does the prescribed maintenance dose exceed 40 mg? [If Yes, then go to 224. If No, then go to 222.]	Yes	No
222	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 223.]	Yes	No

Reference number(s)
C29091-A

223	Is a loading dose prescribed? [No further questions]	Yes	No
224	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 225.]	Yes	No
225	Is the prescribed frequency for the maintenance dose more frequent than one dose every two weeks? [If Yes, then no further questions. If No, then go to 226.]	Yes	No
226	Is a loading dose prescribed? [No further questions]	Yes	No

Specialty Guideline Management

Ilaris

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ilaris	canakinumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Periodic Fever Syndromes

Cryopyrin-Associated Periodic Syndromes (CAPS)

Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and pediatric patients 4 years of age and older including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients.

Reference number(s)
1801-A

Familial Mediterranean Fever (FMF)

Ilaris is indicated for the treatment of FMF in adult and pediatric patients.

Still's Disease (Adult-Onset Still's Disease [AOSD] and systemic Juvenile Idiopathic Arthritis [sJIA])

Ilaris is indicated for the treatment of active Still's disease, including AOSD and sJIA in patients 2 years of age and older.

Gout Flares

Ilaris is indicated for the symptomatic treatment of adult patients with gout flares in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

Compendial Uses

Pseudogout^{5-7,9}

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) and Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Initial requests

Chart notes, medical record documentation, or laboratory result (if applicable) indicating number of active flares within the last 6 months and Physician's Global Assessment (PGA) score or C-reactive protein (CRP) level.

Familial Mediterranean Fever (FMF) (initial requests only)

- Chart notes or medical record documentation indicating number of active flares within the last 6 months.
- Laboratory results, chart notes, or medical record documentation of CRP level.
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Systemic Juvenile Idiopathic Arthritis (sJIA) and Adult-onset Still's disease (AOSD)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Gout and pseudogout flares (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Cryopyrin-associated periodic syndromes (CAPS), TRAPS, HIDS/MKD, and FMF: rheumatologist or immunologist
- Systemic juvenile idiopathic arthritis (sJIA), AOSD, gout, and pseudogout: rheumatologist

Coverage Criteria

Periodic Fever Syndromes^{1-2,4}

Authorization of 12 months may be granted for members 4 years of age or older for treatment of CAPS when both of the following criteria are met:

- Member has a diagnosis of familial cold autoinflammatory syndrome (FCAS) with classic signs and symptoms (i.e., recurrent, intermittent fever and rash that were often exacerbated by exposure to generalized cool ambient temperature) or Muckle-Wells syndrome (MWS) with classic signs and symptoms (i.e., chronic fever and rash of waxing and waning intensity, sometimes exacerbated by exposure to generalized cool ambient temperature).
- Member has functional impairment limiting the activities of daily living.

Authorization of 12 months may be granted for treatment of TRAPS when both of the following criteria are met:

- Member has chronic or recurrent disease activity with active flares within the last 6 months.
- Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

Authorization of 12 months may be granted for treatment of HIDS/MKD when both of the following criteria are met:

- Member has had active flares within the last 6 months.
- Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

Authorization of 12 months may be granted for treatment of FMF when all of the following criteria are met:

- Member has active disease with flares within the last 6 months.
- C-reactive protein (CRP) greater than 10 mg/L.
- Member has had an inadequate response or intolerance to or has a contraindication to colchicine.

Systemic Juvenile Idiopathic Arthritis (sJIA)^{1,4,10}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Adult-Onset Still's Disease (AOSD)^{1,11}

Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for active AOSD.

Authorization of 12 months may be granted for adult members for treatment of active AOSD when both of the following criteria are met:

- Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
- Member meets any of the following:
 - Member has had an inadequate response to a trial of non-steroidal anti-inflammatory drugs (NSAIDs).
 - Member has had an inadequate response to a trial of corticosteroids.
 - Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

Gout and Pseudogout Flares^{1,5-7,9}

Authorization of 12 months may be granted for adult members for the treatment of flares for gout and pseudogout (also known as calcium pyrophosphate deposition disease) when both of the following criteria are met:

- Member has experienced at least three flares in the last 12 months.
- Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

Continuation of Therapy

Systemic Juvenile Idiopathic Arthritis (sJIA)^{1,4,10}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for sJIA and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Adult-Onset Still's Disease (AOSD)^{1,11}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for AOSD and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)¹⁻²

Authorization of 12 months may be granted for all members 4 years of age or older (including new members) who are using the requested medication for CAPS, including FCAS and MWS, and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

All Other Diagnoses

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,8}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

References

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2024.
2. De Benedetti F, Gattorno M, Anton J, et al; Canakinumab for the treatment of autoinflammatory recurrent fever syndromes. *N Engl J Med*. 2018;378:1908-19.
3. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al; Canakinumab in CAPS Study Group. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med*. 2009;360(23):2416-2425.
4. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical

therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Care Res.* 2013;65(10):1551-63.

5. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com> [available with subscription]. Accessed November 14, 2024.
6. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis.* 2017;76:29–42.
7. Zhang W, Doherty M, Pascual E, et al. EULAR recommendations for calcium pyrophosphate deposition. Part II: Management. *Ann Rheum Dis.* 2011;70:571–575.
8. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 14, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
9. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in *Arthritis Care Res (Hoboken)*. 2020 Aug;72(8):1187]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
10. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
11. Efthimiou P, Kontzias A, Hur P, et al. Adult-onset Still's disease in focus: Clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. *Semin Arthritis Rheum.* 2021;51(4):858-874.

Specialty Guideline Management

Ilumya

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ilumya	tildrakizumab-asnm

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist.

Coverage Criteria

Plaque psoriasis (PsO)^{1-5,7}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Continuation of Therapy

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following criteria is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Other^{1,6}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin⁵

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding

- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009;61(3):451-485.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072.
5. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486.
6. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 15, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.
7. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol. 2022;18(8):465-479.

Specialty Guideline Management infliximab-Remicade and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Remicade	infliximab
Avsola	infliximab-axxq
Inflectra	infliximab-dyyb
Renflexis	infliximab-abda
Zymfentra	infliximab-dyyb
infliximab (unbranded Remicade)	infliximab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹⁻⁶

infliximab/Avsola/Inflectra/Remicade/Renflexis

- Adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy and adult patients with fistulizing CD
- Pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy
- Moderately to severely active ulcerative colitis (UC) in patients 6 years of age and older who have had an inadequate response to conventional therapy

Reference number(s)
2182-A

- Adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
- Adult patients with active ankylosing spondylitis (AS)
- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with chronic severe plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

Zymfentra

- Maintenance treatment of moderately to severely active ulcerative colitis in adults following treatment with an infliximab product administered intravenously
- Maintenance treatment of moderately to severely active Crohn's disease in adults following treatment with an infliximab product administered intravenously

Compendial Uses

- Non-radiographic axial spondyloarthritis⁷
- Behcet's disease^{8,32}
- Hidradenitis suppurativa⁸
- Pyoderma gangrenosum^{8,33}
- Sarcoidosis⁸
- Takayasu's arteritis⁸
- Uveitis⁸
- Reactive arthritis³¹
- Immune checkpoint inhibitor-related toxicity²⁷
- Acute graft versus host disease²⁷
- Moderate to severe plaque psoriasis²²

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Crohn's disease (CD) and ulcerative colitis (UC)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Rheumatoid arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), reactive arthritis, hidradenitis suppurativa, uveitis, and immune checkpoint inhibitor-related inflammatory arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Plaque psoriasis (PsO)

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Behcet's disease (initial requests only)

Reference number(s)
2182-A

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

Pyoderma gangrenosum, sarcoidosis, Takayasu’s arteritis, immune checkpoint inhibitor-related toxicity, and acute graft versus host disease (initial requests only)

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Crohn’s disease and ulcerative colitis: gastroenterologist
- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Behcet’s disease, Takayasu’s arteritis, and reactive arthritis: rheumatologist
- Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
- Plaque psoriasis and pyoderma gangrenosum: dermatologist
- Sarcoidosis: dermatologist, pulmonologist, rheumatologist, cardiologist, neurologist, or ophthalmologist
- Uveitis: ophthalmologist or rheumatologist
- Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
- Immune checkpoint inhibitor-related toxicity: gastroenterologist, oncologist, or hematologist
- Acute graft versus host disease: oncologist or hematologist

Coverage Criteria

Crohn’s disease (CD)^{1-6,9,10,42}

Authorization of 12 months may be granted for treatment of moderately to severely active CD.

Ulcerative colitis (UC)^{1-6,9,30}

Authorization of 12 months may be granted for treatment of moderately to severely active UC.

Rheumatoid arthritis (RA)

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,11-13,37,41,42}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days. The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.

- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,7,18,21}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,14-17,29}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:

- Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
- Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
- Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,14,17,22,43}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Behcet's disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{8,23,32}

Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for treatment of Behcet's disease.

Authorization of 12 months may be granted for the treatment of Behcet's disease when the member has had an inadequate response to at least one non-biologic medication for Behcet's disease (e.g., azathioprine, colchicine, cyclosporine, systemic corticosteroids).

Hidradenitis suppurativa (Avsola/Inflectra/infliximab/Remicade/Renflexis only)⁸

Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of severe, refractory hidradenitis suppurativa.

Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:

- Member has had an inadequate response to an oral antibiotic used for the treatment of hidradenitis suppurativa (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines) for at least 90 days.
- Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Pyoderma gangrenosum

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{8,24-26,33}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

Sarcoidosis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)⁸

Authorization of 12 months may be granted for treatment of sarcoidosis in members when either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy.
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy.

Takayasu's arteritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)⁸

Authorization of 12 months may be granted for treatment of refractory Takayasu's arteritis when either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil).
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil).

Uveitis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{8,45,46}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for uveitis.

Authorization of 12 months may be granted for treatment of uveitis when either of the following criteria is met:

- Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
- Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).

Reactive arthritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{31,41,47}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:

- Member has had an inadequate response to methotrexate or sulfasalazine.
- Member has an intolerance or contraindication to methotrexate (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

Immune checkpoint inhibitor-related toxicity (Avsola/Inflectra/infliximab/Remicade/Renflexis only)²⁷

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and either of the following is met:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Acute graft versus host disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)²⁷

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.

Continuation of Therapy

Crohn's disease (CD)^{1-6,9,42}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Ulcerative colitis (UC)^{1-6,9,29,36}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)

- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Rheumatoid arthritis (RA)

(Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,11-13,37,41,42}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,7,18,21}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,14-17,29}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease

- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{1-5,14,22,43}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Hidradenitis suppurativa (Avsola/Inflectra/infliximab/Remicade/Renflexis only)^{8,38,39}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for severe, refractory hidradenitis suppurativa and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

- Reduction in abscess and inflammatory nodule count from baseline
- Reduced formation of new sinus tracts and scarring
- Decrease in frequency of inflammatory lesions from baseline
- Reduction in pain from baseline
- Reduction in suppuration from baseline
- Improvement in frequency of relapses from baseline
- Improvement in quality of life from baseline
- Improvement on a disease severity assessment tool from baseline

Uveitis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)⁸

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for uveitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when the patient meets any of the following:

- Reduced frequency of flare recurrence compared to baseline
- Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
- Decreased reliance on topical corticosteroids

Reactive arthritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)³¹

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for reactive arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., tender joint count, swollen joint count, pain).

Immune checkpoint inhibitor-related inflammatory arthritis (Avsola/Inflectra/infliximab/Remicade/ Renflexis only)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Immune checkpoint inhibitor-related toxicity and acute graft versus host disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All other indications (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria section and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other¹⁻⁶

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, Hydroxychloroquine, or Leflunomide³⁵

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
2. Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
3. Inflectra [package insert]. New York, NY: Pfizer Inc; April 2023.
4. infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
5. Renflexis [package insert]. Jersey City, NJ: Organon LLC, Inc; December 2023.
6. Zymfentra [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2024.
7. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;0:1-14.
8. IBM Micromedex® DRUGDEX® System (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed August 13, 2024.

9. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
10. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113:481-517.
11. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
12. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
13. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
14. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
15. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
16. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(Suppl II):ii14-ii17.
17. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
18. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896-904.
19. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
20. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013;65:2499-2512.
21. 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.
22. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
23. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis*. 2018;77:808-818.
24. Agarwal A, Andrews JM. Systematic review: IBD-associated pyoderma gangrenosum in the biologic era, the response to therapy. *Aliment Pharmacol Ther*. 2013;38(6):563-572.

25. Arguelles-Arias F, Castro-Laria L, Lobaton T, et al. Characteristics and treatment of pyoderma gangrenosum in inflammatory bowel disease. *Dig Dis Sci*. 2013;58(10):2949-2954.
26. Marzano AV, Ishak RS, Saibeni S, et al. Autoinflammatory skin disorders in inflammatory bowel diseases, pyoderma gangrenosum and Sweet's syndrome: A comprehensive review and disease classification criteria. *Clin Rev Allergy Immunol*. 2013;45(2):202-10.
27. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed August 19, 2024.
28. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on August 12, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
29. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
30. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158:1450.
31. Flores D, Marquez J, Garza M, et al. Reactive arthritis: newer developments. *Rheum Dis Clin North Am*. 2003;29(1):37-vi.
32. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed August 13, 2024.
33. George, C, Deroide, F, Rustin, M. Pyoderma gangrenosum – a guide to diagnosis and management. *Clin Med*. 2019;19(3):224-8.
34. Menter A, Cordero KM, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020;82(1):161-201.
35. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6): 1445-86.
36. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114:384-413.
37. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
38. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part I: Diagnosis, evaluation, and the use of complementary and procedural management. *J Am Acad Dermatol*. 2019; 81(1):76-90.
39. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management. *J Am Acad Dermatol*. 2019; 81(1):91-101.
40. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
41. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2021;0:1-16.

42. Feuerstein J, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160:2496-2508.
43. Elmetts C, Korman N, Prater EF, et al. Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures. *J Am Acad Dermatol*. 2021;84:432-470.
44. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
45. Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the screening, monitoring, and treatment of juvenile idiopathic arthritis-associated uveitis. *Arthritis Care Res*. 2019; 71(6):703-716.
46. Mehta, NA, Emani-Naeini P. A review of systemic biologics and local immunosuppressive medications in uveitis. *J Ophthalmic Vis Res*. 2022;17(2):276-289.
47. Azulfidine [package insert]. New York, NY: Pfizer; October 2022.

Specialty Guideline Management

Ingrezza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ingrezza	valbenazine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Treatment of adults with:

- Tardive dyskinesia
- Chorea associated with Huntington's disease

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.

Reference number(s)
1750-A

- Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.

Coverage Criteria

Tardive dyskinesia¹⁻³

Authorization of 6 months may be granted for treatment of tardive dyskinesia when both of the following criteria are met:

- Member exhibits clinical manifestations of disease.
- Member's tardive dyskinesia has been assessed through clinical examination or with a structured evaluative tool (e.g., Abnormal Involuntary Movement Scale [AIMS], Dyskinesia Identification System: Condensed User Scale [DISCUS]).

Chorea associated with Huntington's disease^{1,4}

Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:

- Member demonstrates characteristic motor examination features.
- Member meets one of the following conditions:
 - Laboratory results indicate an expanded HTT CAG repeat sequence of at least 36
 - Member has a positive family history for Huntington's disease

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Ingrezza [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.; February 2025.
2. Hauser RA, Factor SA, Marder SR, et al. KINECT-3: a phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. *Am J Psychiatry*. 2017;174(5):476-484.
3. American Psychiatric Association. (2021). Practice Guideline for the Treatment of Patients With Schizophrenia, third edition. <https://doi.org/10.1176/appi.books.9780890424841>.

Reference number(s)
1750-A

4. Stimming EF, Claassen DO, Kayson E, et al. Safety and efficacy of valbenazine for the treatment of chorea associated with Huntington's disease (KINECT-HD): a phase 3, randomized, double-blind, placebo-controlled trial. *Lancet Neurol.* 2023;22:494-504.

Initial Prior Authorization with Quantity Limit

Insomnia (Belsomra, Dayvigo, Quviviq)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Belsomra	suvorexant
Dayvigo	lemborexant
Quviviq	daridorexant

Indications

FDA-approved Indications

Belsomra

Belsomra (suvorexant) is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

Dayvigo

Dayvigo is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Quviviq

Quviviq is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Coverage Criteria

Insomnia Characterized by Difficulties with Sleep Onset and/or Sleep Maintenance

Authorization may be granted when the requested drug is being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance when ALL of the following criteria are met:

- Potential factors contributing to sleep disturbances have been addressed or are currently being addressed (e.g., inappropriate sleep hygiene and sleep environment issues) as well as treatable medical/psychiatric disorders that are co-morbid with insomnia.
- The patient meets ONE of the following:
 - The patient is 65 years of age or older.
 - The patient is less than 65 years of age and ONE of the following criteria is met:
 - The patient experienced an inadequate treatment response to ANY of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).
 - The patient experienced an intolerance to ANY of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).
 - The patient has a contraindication that would prohibit a trial of ALL of the following: a generic non-benzodiazepine sedative-hypnotic (e.g., eszopiclone, zaleplon, zolpidem), a benzodiazepine (e.g., temazepam).

Continuation of Therapy

Insomnia Characterized by Difficulties with Sleep Onset and/or Sleep Maintenance

Authorization may be granted when the requested drug is being prescribed for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance when ALL of the following criteria are met:

- The patient has achieved or maintained a positive response to treatment from baseline.
- The patient's need for continued therapy has been assessed.
- Potential factors contributing to sleep disturbances continue to be addressed (e.g., inappropriate sleep hygiene, sleep environment issues, treatable medical/psychiatric comorbid disorders).

Reference number(s)
1177-C

Quantity Limits Apply

30 tablets per 25 days or 90 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 1177-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

References

1. Belsomra [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; February 2023.
2. Dayvigo [package insert]. Nutley, NJ: Eisai Inc.; December 2023.
3. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; September 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 27, 2024.
5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/26/2024).
6. Sateia MJ, Buysse DJ, Krystal AD, et al. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349.
7. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
8. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(2):255-262.
9. 2023 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2023 updated AGS Beers Criteria® for potentially inappropriate medication use in older adults. *J Am Geriatr Soc*. 2023;71(7):2052-2081.

Initial Prior Authorization

Isotretinoins (All Oral)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Absorica	isotretinoin
Absorica LD	isotretinoin
Accutane	isotretinoin
Amnesteem	isotretinoin
Claravis	isotretinoin
Zenatane	isotretinoin

Indications

FDA-approved Indications

Absorica, Absorica LD

Absorica and Absorica LD are indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Absorica and Absorica LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Limitations of Use

If a second course of Absorica/Absorica LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.

Accutane, Amnesteem, Claravis, Zenatane

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those patients who are not pregnant, because isotretinoin can cause life-threatening birth defects.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

Compendial Uses

Acne – severe⁸

Cutaneous T-Cell Lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome)⁶

Keratosis follicularis (Darier Disease) – severe⁸

Keratosis Palmaris et Plantaris - severe⁶

Lamellar ichthyosis – severe skin involvement⁶

Neuroblastoma⁸

Pityriasis rubra pilaris⁶

Rosacea – severe refractory⁸

Squamous Cell Cancers – to reduce the development of precancers and skin cancers in high risk patients⁸

Transient acantholytic dermatosis (Grover's Disease) – severe⁸

Coverage Criteria

Acne Vulgaris, Rosacea

Authorization may be granted when the patient has a diagnosis of severe recalcitrant nodular acne vulgaris, severe acne vulgaris, OR severe refractory rosacea when ALL of the following criteria are met:

- The patient has tried and had an inadequate treatment response to ANY topical acne product AND an oral antibiotic. [Note: Topical products include salicylic acid, benzoyl peroxide, azelaic acid, adapalene, tretinoin, tazarotene, clindamycin, erythromycin, or metronidazole for rosacea. Oral antibiotics include minocycline, doxycycline, tetracycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, azithromycin.]
- Treatment will be limited to 40 weeks (2 courses) or less AND with at least 8 weeks between each course.

Neuroblastoma, Cutaneous T-cell Lymphoma (CTCL), Squamous Cell Cancers, Grover's Disease, Darier Disease, Lamellar Ichthyosis, Pityriasis Rubra Pilaris, Keratosis Palmaris et Plantaris

Authorization may be granted when the patient has a diagnosis of neuroblastoma, cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome), is at high risk for developing skin cancer (squamous cell cancers), transient acantholytic dermatosis (Grover's Disease), keratosis follicularis (Darier Disease), lamellar ichthyosis, pityriasis rubra pilaris, OR keratosis palmaris et plantaris.

Duration of Approval (DOA)

- 118-A: DOA 12 months

References

1. Absorica, Absorica LD [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; June 2023.
2. Accutane [package insert]. Scottsdale, AZ: JG Pharma Inc.; September 2022.
3. Amnesteem [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2024.
4. Claravis [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2022.
5. Zenatane [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; September 2022.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed July 15, 2024.
7. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed July 15, 2025.
8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 07/15/2025).
9. Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024;90(5):1006.e1-1006.e30.

Reference number(s)
118-A

10. Rosacea. National Institute of Arthritis and Musculoskeletal and Skin Diseases.
http://www.niams.nih.gov/Health_Info/Rosacea/default.asp#6. Accessed July 15, 2025.
11. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus recommendations from the american acne & rosacea society on the management of rosacea, Part 3: A status report on systemic therapies. *CUTIS*. 2014;93:134-38.
12. Neuroblastoma Treatment. National Cancer Institute at the National Institute of Health.
https://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq#_707_toc. Accessed July 15, 2025.
13. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 2.2025. February 7, 2025. Available at: www.NCCN.org. Accessed July 15, 2025.
14. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Primary Cutaneous Lymphomas. Version 3.2025. June 10, 2025. Available at: www.NCCN.org. Accessed July 15, 2025.
15. American Osteopathic College of Dermatology. Grover's Disease.
<http://www.aocd.org/?page=GroversDisease>. Accessed July 15, 20245
16. NIH National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. Darier disease. <https://rarediseases.info.nih.gov/diseases/6243/darier-disease>. Accessed July 15, 2025.
17. Darier Disease. American Osteopathic College of Dermatology.
http://www.aocd.org/skin/dermatologic_diseases/darier_disease.html. Accessed July 15, 2025.
18. NIH National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. Lamellar ichthyosis. <https://rarediseases.info.nih.gov/diseases/10803/lamellar-ichthyosis>. Accessed July 15, 2025.
19. NIH National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. Pityriasis rubra pilaris. <https://rarediseases.info.nih.gov/diseases/7401/pityriasis-rubra-pilaris>. Accessed July 15, 2025.
20. Pityriasis Rubra Pilaris. American Osteopathic College of Dermatology.
<http://www.aocd.org/?page=PityriasisRubraPil>. Accessed July 15, 2025.
21. NIH National Center for Advancing Translational Sciences. Genetic and Rare Diseases Information Center. Keratosis Palmaris Et Plantaris-Clinodactyly Syndrome.
<https://rarediseases.info.nih.gov/diseases/16766/x>. Accessed July 17, 2025.

Specialty Guideline Management

Intravenous Immune Globulin (IVIg)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name
Alyglo
Asceniv
Bivigam
Flebogamma DIF
Gammagard Liquid
Gammagard S/D
Gammaked
Gammaplex
Gamunex-C
Octagam
Panzyga
Privigen
Yimmugo

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

- Primary immunodeficiency

Reference number(s)
2042-A

- Idiopathic thrombocytopenic purpura (ITP)
- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Multifocal motor neuropathy
- Kawasaki syndrome
- B-cell chronic lymphocytic leukemia (CLL)
- Dermatomyositis

Compendial Uses

- Prophylaxis of bacterial infections in pediatric human immunodeficiency virus (HIV) infection
- Bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT)
- Polymyositis
- Myasthenia gravis
- Guillain-Barré syndrome
- Lambert-Eaton myasthenic syndrome
- Fetal/neonatal alloimmune thrombocytopenia
- Parvovirus B19-induced pure red cell aplasia
- Stiff-person syndrome
- Management of immune checkpoint inhibitor-related toxicities
- Acquired red cell aplasia
- Acute disseminated encephalomyelitis
- Autoimmune mucocutaneous blistering diseases
- Autoimmune hemolytic anemia
- Autoimmune neutropenia
- Birdshot retinochoroidopathy
- BK virus associated nephropathy
- Churg-Strauss Syndrome
- Enteroviral meningoencephalitis
- Hematophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS)
- Hemolytic disease of newborn
- HIV-associated thrombocytopenia
- Hyperimmunoglobulinemia E Syndrome
- Hypogammaglobulinemia from chimeric antigen receptor T (CAR-T) therapy
- Multiple myeloma
- Neonatal hemochromatosis, prophylaxis
- Opsoclonus-myoclonus
- Paraneoplastic opsoclonus-myoclonus ataxia associated with neuroblastoma
- Post-transfusion purpura
- Rasmussen encephalitis
- Renal transplantation from a live donor with ABO incompatibility or positive cross match
- Secondary immunosuppression associated with major surgery, hematological malignancy, major burns, and collagen-vascular diseases

- Solid organ transplantation, for allosensitized members
- Toxic epidermal necrolysis and Stevens-Johnson syndrome
- Toxic shock syndrome
- Systemic lupus erythematosus (SLE)
- Toxic necrotizing fasciitis due to group A streptococcus
- Measles (Rubeola) prophylaxis
- Tetanus treatment and prophylaxis
- Varicella prophylaxis

All other indications are considered experimental/investigational and not medically necessary.

Documentation

The following information is necessary to initiate the prior authorization review:

Primary immunodeficiency

- Diagnostic test results
 - Copy of laboratory report with serum immunoglobulin levels: IgG, IgA, IgM, and IgG subclasses
 - Vaccine response to pneumococcal polysaccharide vaccine (post-vaccination Streptococcus pneumoniae antibody titers)
 - Pertinent genetic or molecular testing in members with a known genetic disorder
 - Copy of laboratory report with lymphocyte subset enumeration by flow cytometry
- IgG trough level for those continuing with IG therapy

Myasthenia gravis

- Clinical records describing standard treatments tried and failed

Secondary hypogammaglobulinemia (e.g., CLL, BMT/HSCT recipients)

- Copy of laboratory report with pre-treatment serum IgG level

Chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN)

- Pre-treatment electrodiagnostic studies (electromyography [EMG] or nerve conduction studies [NCS])

Dermatomyositis and polymyositis

- Clinical records describing standard treatments tried and failed

Lambert-Eaton Myasthenic Syndrome (LEMS)

- Neurophysiology studies (e.g., electromyography)
- A positive anti- P/Q type voltage-gated calcium channel antibody test

Idiopathic thrombocytopenic purpura

- Laboratory report with pre-treatment/current platelet count
- Chronic/persistent ITP: copy of medical records supporting trial and failure with corticosteroid or anti-D therapy (unless contraindicated)

Parvovirus B19-indicated Pure Red Cell Aplasia (PRCA)

- Copy of test result confirming presence of parvovirus B19

Stiff-person syndrome

- Anti-glutamic acid decarboxylase (GAD) antibody testing results
- Clinical records describing standard treatments tried and failed

Toxic shock syndrome or toxic necrotizing fasciitis due to group A streptococcus

- Documented presence of fasciitis (toxic necrotizing fasciitis due to group A streptococcus only)
- Microbiological data (culture or Gram stain)

Coverage Criteria

Primary Immunodeficiency

Initial authorization of 6 months may be granted for members with any of the following diagnoses:

- Severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (eg, X-linked or autosomal recessive agammaglobulinemia):
 - Diagnosis confirmed by genetic or molecular testing, or
 - Pretreatment IgG level < 200 mg/dL, or
 - Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only)

- Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency):
 - Diagnosis confirmed by genetic or molecular testing (if applicable), and
 - History of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
 - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
- Common variable immunodeficiency (CVID):
 - Age 2 years or older, and
 - Other causes of immune deficiency have been excluded (e.g., drug induced, genetic disorders, infectious diseases such as HIV, malignancy), and
 - Pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age, and
 - History of recurrent bacterial infections, and
 - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
- Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency:
 - History of recurrent bacterial infections, and
 - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A), and
 - Any of the following pre-treatment laboratory findings:
 - Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
 - Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
 - Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
 - IgG subclass deficiency: IgG1, IgG2, or IgG3 ≥ 2 SD below mean for age assessed on at least 2 occasions; normal IgG (total) and IgM levels, normal/low IgA levels
 - Specific antibody deficiency: normal IgG, IgA and IgM levels
- Other predominant antibody deficiency disorders must meet all of the following:
 - History of recurrent bacterial infections, and
 - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A), and
 - A pre-treatment laboratory finding of hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
- Other combined immunodeficiency must meet all of the following:
 - Diagnosis confirmed by genetic or molecular testing (if applicable), and
 - History of recurrent bacterial infections (e.g., pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
 - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)

Re-authorization of 12 months may be granted when the following criteria are met:

- A reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy, AND
- IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication),³⁵ OR

- The prescriber will re-evaluate the dose of IG and consider a dose adjustment (when appropriate).

Myasthenia Gravis

- Authorization of 1 month may be granted to members who are prescribed IG for worsening weakness, acute exacerbation, or in preparation for surgery.
 - Worsening weakness includes an increase in any of the following symptoms: diplopia, ptosis, blurred vision, difficulty speaking (dysarthria), difficulty swallowing (dysphagia), difficulty chewing, impaired respiratory status, fatigue, and limb weakness. Acute exacerbations include more severe swallowing difficulties and/or respiratory failure
 - Pre-operative management (e.g., prior to thymectomy)
- Authorization of 6 months may be granted to members with refractory myasthenia gravis who have tried and failed 2 or more standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Initial authorization of 3 months may be granted when the following criteria are met:
 - Disease course is progressive or relapsing/remitting for 2 months or longer
 - Moderate to severe functional disability
 - The diagnosis was confirmed by electrodiagnostic studies
- Re-authorization of 6 months may be granted when the following criteria are met:
 - Significant improvement in disability and maintenance of improvement since initiation of IG therapy
 - IG is being used at the lowest effective dose and frequency

Dermatomyositis or Polymyositis

- Initial authorization of 3 months may be granted when the following criteria are met:
 - Member has at least 4 of the following:
 - Proximal muscle weakness (upper or lower extremity and trunk)
 - Elevated serum creatine kinase (CK) or aldolase level
 - Muscle pain on grasping or spontaneous pain
 - Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
 - Positive for anti-synthetase antibodies (e.g., anti-Jo-1, also called histadyl tRNA synthetase)
 - Non-destructive arthritis or arthralgias
 - Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method)

- Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen), and
- Standard first-line treatments (corticosteroids) and second-line treatments (immunosuppressants) have been tried but were unsuccessful or not tolerated, or
- Member is unable to receive standard first-line and second-line therapy because of a contraindication or other clinical reason.
- Re-authorization of 6 months may be granted when the following criterion is met:
 - Significant improvement in disability and maintenance of improvement since initiation of IG therapy

Idiopathic Thrombocytopenic Purpura ITP/(Immune Thrombocytopenia)

- Newly diagnosed ITP (diagnosed within the past 3 months) or initial therapy: authorization of 1 month may be granted when the following criteria are met:
 - Children (< 18 years of age)
 - Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding) or
 - High risk for bleeding (see Appendix B), or
 - Rapid increase in platelets is required (e.g., surgery or procedure)
 - Adults (≥ 18 years of age)
 - Platelet count < 30,000/mcL, or
 - Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required, and
 - Corticosteroid therapy is contraindicated and IG will be used alone or IG will be used in combination with corticosteroid therapy
- Chronic/persistent ITP (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy: authorization of 6 months may be granted when the following criteria are met:
 - Platelet count < 30,000/mcL, or
 - Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required, and
 - Relapse after previous response to IG or inadequate response/intolerance/contraindication to corticosteroid or anti-D therapy
- Adults with refractory ITP after splenectomy: authorization of 6 months may be granted when either of the following criteria is met:
 - Platelet count < 30,000/mcL, or
 - Significant bleeding symptoms
- ITP in pregnant women: authorization through delivery may be granted to pregnant women with ITP.

The member's risk factor(s) for bleeding (see Appendix B) or reason requiring a rapid increase in platelets must be provided.

B-cell Chronic Lymphocytic Leukemia (CLL)

- Initial authorization of 6 months may be granted when all of the following criteria are met:
 - IG is prescribed for prophylaxis of bacterial infections.
 - Member has a history of recurrent sinopulmonary infections requiring intravenous antibiotics or hospitalization.
 - Member has a pretreatment serum IgG level <500 mg/dL.
- Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients

- Initial authorization of up to 6 months may be granted to pediatric members with HIV infection when any of the following criteria are met:
 - IG is prescribed for primary prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL, or
 - IG is prescribed for secondary prophylaxis of bacterial infections for members with a history of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period), or
 - Member has failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine, or
 - Member lives in an area where measles is highly prevalent and who have not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live, or
 - Member has been exposed to measles and request is for a single dose, or
 - Member has chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy
- Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

Bone Marrow Transplant/Hemopoietic Stem Cell Transplant (BMT/HSCT)

- Initial authorization of 6 months may be granted to members who are BMT/HSCT recipients when the following criteria are met:
 - Therapy will be used to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic), septicemia, and other infections (e.g., cytomegalovirus infections [CMV], recurrent bacterial infection).
 - Either of the following:
 - IG is requested within the first 100 days post-transplant.
 - Member has a pretreatment serum IgG < 400 mg/dL.

- Re-authorization of 6 months may be granted when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IG therapy.

Multifocal Motor Neuropathy (MMN)

- Initial authorization of 3 months may be granted when the following criteria are met:
 - Member experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in 2 or more nerves for at least 1 month
 - The diagnosis was confirmed by electrodiagnostic studies
- Re-authorization of 6 months may be granted when significant improvement in disability and maintenance of improvement have occurred since initiation of IG therapy

Guillain-Barre Syndrome (GBS)

Authorization of 1 month total may be granted for GBS when the following criteria are met:

- Member has severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)
- Onset of neurologic symptoms occurred less than 4 weeks from the anticipated start of therapy

Lambert-Eaton Myasthenic Syndrome (LEMS)

- Initial authorization of 6 months may be granted for LEMS when the following criteria are met:
 - Diagnosis has been confirmed by either of the following:
 - Neurophysiology studies (e.g., electromyography)
 - A positive anti- P/Q type voltage-gated calcium channel antibody test
 - Anticholinesterases (eg pyridostigmine) and amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) have been tried but were unsuccessful or not tolerated
 - Weakness is severe or there is difficulty with venous access for plasmapheresis
- Re-authorization of 6 months may be granted when member is responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

Kawasaki Syndrome

Authorization of 1 month may be granted for pediatric members with Kawasaki syndrome.

Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)

Authorization of 6 months may be granted for treatment of F/NAIT.

Parvovirus B19-induced Pure Red Cell Aplasia (PRCA)

Authorization of 6 months may be granted for severe, refractory anemia associated with bone marrow suppression, with parvovirus B19 viremia.

Stiff-person Syndrome

Authorization of 6 months may be granted for stiff-person syndrome when the following criteria are met:

- Diagnosis has been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing
- Member had an inadequate response to first-line treatment (benzodiazepines and/or baclofen)

Management of Immune Checkpoint Inhibitor-Related Toxicities

Authorization of 1 month may be granted for management of immune checkpoint-inhibitor toxicities when all of the following criteria are met:

- Member has experienced a moderate or severe adverse event to a PD-1 or PD-L1 inhibitor (e.g., pembrolizumab, nivolumab, atezolizumab, avelumab, durvalumab)
- The offending medication has been held or discontinued
- Member experienced one or more of the following adverse events: myocarditis, bullous dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, pneumonitis, myasthenia gravis, peripheral neuropathy, encephalitis, transverse myelitis, severe inflammatory arthritis, Guillain-Barre syndrome, or steroid-refractory myalgias or myositis

Acquired Red Cell Aplasia

Authorization of 6 months may be granted for acquired red cell aplasia.

Acute Disseminated Encephalomyelitis

Authorization of 1 month may be granted for acute disseminated encephalomyelitis in members who have had an insufficient response or a contraindication to intravenous corticosteroid treatment.

Autoimmune Mucocutaneous Blistering Disease

Authorization of 6 months may be granted for autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita) when the following criteria are met:

- Diagnosis has been proven by biopsy and confirmed by pathology report, and
- Condition is rapidly progressing, extensive or debilitating, and
- Member has failed or experienced significant complications (e.g., diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents).

Autoimmune Hemolytic Anemia

Authorization of 6 months may be granted for warm-type autoimmune hemolytic anemia in members who do not respond or have a contraindication to corticosteroids or splenectomy.

Autoimmune Neutropenia

Authorization of 6 months may be granted for autoimmune neutropenia where treatment with G-CSF (granulocyte colony stimulating factor) is not appropriate.

Birdshot Retinochoroidopathy

Authorization of 6 months may be granted for birdshot (vitiliginous) retinochoroidopathy that is not responsive to immunosuppressives (e.g., corticosteroids, cyclosporine).

BK Virus Associated Nephropathy

Authorization of 6 months may be granted for BK virus associated nephropathy.

Churg-Strauss Syndrome

Authorization of 6 months may be granted for severe, active Churg-Strauss syndrome as adjunctive therapy for members who have experienced failure, intolerance, or are contraindicated to other interventions.

Enteroviral Meningoencephalitis

Authorization of 6 months may be granted for severe cases of enteroviral meningoencephalitis.

Hematophagocytic Lymphohistiocytosis (HLH) or Macrophage Activation Syndrome (MAS)

Authorization of 6 months may be granted for treatment of hypogammaglobulinemia in HLH or MAS when total IgG is less than 400 mg/dL or two standard deviations below the mean for age.

Hemolytic Disease of Newborn

Authorization of 6 months may be granted for isoimmune hemolytic disease in neonates.

HIV-associated Thrombocytopenia

Authorization of 6 months may be granted for HIV-associated thrombocytopenia when the following criteria are met:

- Pediatric members with IgG < 400 mg/dL and one of the following:
 - 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent, or

- Received 2 doses of measles vaccine and lives in a region with a high prevalence or measles, or
- HIV-associated thrombocytopenia despite anti-retroviral therapy, or
- Chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy, or
- T4 cell count $\geq 200/\text{mm}^3$
- Adult members with significant bleeding, platelet count $< 20,000/\text{mcL}$, and failure of RhIG in Rh-positive patients

Hyperimmunoglobulinemia E Syndrome

Authorization of 6 months may be granted to treat severe eczema in hyperimmunoglobulinemia E syndrome.

Hypogammaglobulinemia from CAR-T therapy

Authorization of 6 months may be granted for members with IgG $< 400 \text{ mg/dL}$ receiving treatment with CAR-T therapy (including but not limited to idecabtagene vicleucel [Abecma], tisagenlecleucel [Kymriah], or axicabtagene ciloleucel [Yescarta]).

Multiple Myeloma

Authorization of 6 months may be granted for multiple myeloma in members who have recurrent, serious infections despite the use of prophylactic antibiotics.

Neonatal Hemochromatosis

Authorization of 6 months may be granted for prophylaxis in members who are pregnant with a history of pregnancy ending in documented neonatal hemochromatosis.

Opsoclonus-myoclonus

Authorization of 6 months may be granted for treatment of either of the following:

- Paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma
- Refractory opsoclonus-myoclonus, as last-resort treatment

Post-transfusion Purpura

Authorization of 1 month may be granted for post-transfusion purpura

Rasmussen Encephalitis

Authorization of 6 months may be granted for Rasmussen encephalitis in members whose symptoms do not improve with anti-epileptic drugs and corticosteroids.

Renal Transplantation

Authorization of 6 months may be granted for a member undergoing renal transplantation from a live donor with ABO incompatibility or positive cross match.

Secondary Immunosuppression Associated with Major Surgery, Hematological Malignancy, Major Burns, and Collagen-Vascular Diseases

Authorization of 6 months may be granted to prevent or modify recurrent bacterial or viral infections in members with secondary immunosuppression (IgG < 400 mg/dL) associated with major surgery, hematological malignancy, extensive burns, or collagen-vascular disease.

Solid Organ Transplantation

Authorization of 6 months may be granted for solid organ transplantation for allosensitized members.

Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome

Authorization of 1 month may be granted for severe cases of toxic epidermal necrolysis or Stevens-Johnson syndrome.

Toxic Shock Syndrome

Authorization of 1 month may be granted for staphylococcal or streptococcal toxic shock syndrome when the infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or the member has persistent oliguria with pulmonary edema.

Systemic Lupus Erythematosus

Authorization of 6 months may be granted for severe, active SLE in members who have experienced inadequate response, intolerance or have a contraindication to first and second line therapies (e.g., hydroxychloroquine, glucocorticoids, anifrolumab, rituximab).

Measles (Rubeola) Prophylaxis

Authorization of 1 month may be granted for postexposure prophylaxis to prevent or modify symptoms of measles (rubeola) in susceptible members exposed to the disease less than 6 days previously.

Tetanus Treatment and Prophylaxis

Authorization of 1 month may be granted for treatment or postexposure prophylaxis of tetanus as an alternative when tetanus immune globulin (TIG) is unavailable.

Varicella Prophylaxis

Authorization of 1 month may be granted for postexposure prophylaxis of varicella in susceptible individuals when varicella-zoster immune globulin (VZIG) is unavailable.

Toxic Necrotizing Fasciitis Due to Group A Streptococcus

Authorization of 1 month may be granted for members with fasciitis due to invasive streptococcal infection.

Continuation of Therapy

Authorization may be granted for continuation of therapy when either the following criteria is met:

- For conditions with reauthorization criteria listed under the coverage criteria section: Members who are currently receiving IG therapy must meet the applicable reauthorization criteria for the member's condition.
- For all other conditions, all members (including new members) must meet the requirements in the coverage criteria.

Appendix

Appendix A: Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine

- Age 2 years and older: impaired antibody response demonstrated to vaccination with a pneumococcal polysaccharide vaccine
- Not established for children less than 2 years of age
- Excludes the therapy initiated in the hospital setting

Appendix B: Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (eg, peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (eg, construction worker, fireman, professional athlete)

References

1. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; April 2019.
2. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; March 2024.
3. Carimune NF [package insert]. Kankakee, IL: CSL Behring LLC; May 2018.
4. Flebogamma 10% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; September 2019.
5. Flebogamma 5% DIF [package insert]. Los Angeles, CA: Grifols Biologicals, Inc.; September 2019.
6. Gammagard Liquid [package insert]. Westlake Village, CA: Baxalta US Inc.; January 2024.
7. Gammagard S/D [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
8. Gammagard S/D IgA less than 1 mcg/mL [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2016.
9. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
10. Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
11. Gammaplex 10% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
12. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
13. Octagam 10% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.
14. Octagam 5% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.
15. Panzyga [package insert]. Hoboken, NJ: Octapharma USA.; February 2021.
16. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.
17. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at <http://www.micromedexsolutions.com> [available with subscription]. Accessed May 7, 2024.
18. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed May 7, 2024.
19. Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: a review of evidence by Work Group Report of the American Academy of Allergy, Asthma, and Immunology. *J Allergy Clin Immunol*. 2017;139:S1-46.
20. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at: <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-oi/guidelines-pediatric-oi.pdf>. Accessed May 7, 2024.

21. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplant recipients: a global perspective. *Biol Blood Marrow Transplant*. 2009;15(10):1143-1238.
22. Feasby T, Banwell B, Bernstead T, et al. Guidelines on the use of intravenous immune globulin for neurologic conditions. *Transfus Med Rev*. 2007;21(2):S57-S107.
23. Donofrio PD, Berger A, Brannagan TH 3rd, et al. Consensus statement: the use of intravenous immunoglobulin in the treatment of neuromuscular conditions report of the AANEM ad hoc committee. *Muscle Nerve*. 2009;40(5):890-900.
24. Elovaara I, Apostolski S, van Doorn P, et al. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases: EFNS task force on the use of intravenous immunoglobulin in treatment of neurological diseases. *Eur J Neurol*. 2008;15(9):893-908.
25. Patwa HS, Chaudhry V, Katzberg H, et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *Neurology*. 2012;78(13):1009-1015.
26. Anderson D, Kaiser A, Blanchette V, et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. *Transfus Med Rev*. 2007;21(2):S9-S56.
27. Picard C, Al-Herz W, Bousfiha A, et al. Primary immunodeficiency diseases: an update on the classification from the International Union of Immunological Societies Expert Committee for Primary Immunodeficiency. *J Clin Immunol*. 2015; 35(8):696-726.
28. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol*. 2015;136(5):1186-205.e1-78.
29. Orange JS, Ballou M, Stiehm ER, et al. Use and interpretation of diagnostic vaccination in primary immunodeficiency: a working group report of the Basic and Clinical Immunology Interest section of the American Academy of Allergy, Asthma and Immunology. *J Allergy Clin Immunol*. 2012;130:S1-S24.
30. Ameratunga R, Woon ST, Gillis D, Koopmans W, Steele R. New diagnostic criteria for common variable immune deficiency (CVID), which may assist with decisions to treat with intravenous or subcutaneous immunoglobulin. *Clin Exp Immunol*. 2013;174(2):203-11.
31. Immune Deficiency Foundation. About primary immunodeficiencies. Specific disease types. <http://primaryimmune.org/about-primary-immunodeficiencies/specific-disease-types/>. Accessed May 7, 2024.
32. European Society for Immunodeficiencies. Diagnostic criteria for PID. <http://esid.org/Working-Parties/Clinical/Resources/Diagnostic-criteria-for-PID2>. Accessed May 7, 2024.
33. Immune Deficiency Foundation. *Diagnostic and Clinical Care Guidelines for Primary Immunodeficiency Diseases*. 3rd edition. Towson, MD: Immune Deficiency Foundation; 2015. <http://primaryimmune.org/wp-content/uploads/2015/03/2015-Diagnostic-and-Clinical-Care-Guidelines-for-PI.pdf>. Accessed May 7, 2024.
34. NCCN Clinical Practice Guidelines in Oncology® Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (Version 3.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed May 7, 2024.
35. Van den Bergh PY, Hadden RD, van Doorn PA, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating

- polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society - second revision. *Eur J Neurol*. 2021;28(11):3556-3583.
36. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Societies guideline on management of multifocal motor neuropathy. *J Peripher Nerv Syst*. 2010;15:295-301.
 37. Olney RK, Lewis RA, Putnam TD, Campellone JV. Consensus criteria for the diagnosis of multifocal motor neuropathy. *Muscle Nerve*. 2003;27:117-121.
 38. Dalakas M. Inflammatory muscle diseases. *N Engl J Med*. 2015;372(18):1734-1747.
 39. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829-3866.
 40. Provan D, Arnold DM, Bussell JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv* 2019;3(22): 3780–3817.
 41. Shearer WT, Dunn E, Notarangelo LD, et al. Establishing diagnostic criteria for severe combined immunodeficiency disease (SCID), leaky SCID, and Omenn syndrome: the Primary Immune Deficiency Treatment Consortium experience. *J Allergy Clin Immunol*. 2014;133(4):1092.
 42. NCCN Clinical Practice Guidelines in Oncology® Management of Immunotherapy-Related Toxicities (Version 1.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed May 7, 2024.
 43. [HIVPeds]Working Group on Antiretroviral Therapy of the National Pediatric HIV Resource Center. Antiretroviral therapy and medical management of pediatric HIV infection. *Pediatrics*. 1998;102;1005-1063.
 44. Center for Medicare and Medicaid Services (CMS). Intravenous immune globulin for autoimmune mucocutaneous blistering diseases. Decision Memorandum. CPG-00109N. Baltimore, MD: CMS; January 22, 2002.
 45. Sawinski D, Goral S. BK virus infection: An update on diagnosis and treatment. *Nephrol Dial Transplant*. 2015;30(2):209-217.
 46. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA)Consensus Task Force recommendations for evaluation and management. *Eur J Intern Med*. 2015;26(7):545-553.
 47. McKinney RE, Katz SL, Wilfert CM. Chronic enteroviral meningoencephalitis in agammaglobulinemic patients. *Rev Infect Dis*. 1987;9(2):334-56.
 48. Sen, E.S., Clarke, SL, Ramanan, A.V. Macrophage Activation Syndrome. *Indian J Pediatr*. 2016;83(3): 248-53.
 49. Kimata H. High-dose intravenous gammaglobulin treatment of hyperimmunoglobulinemia E syndrome. *J Allergy Clin Immunol*. 1995;95:771-774.
 50. Yescarta [package insert]. Santa Monica, CA: Kite Pharma; April 2024.
 51. Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.
 52. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at <https://www.online.lexi.com> [available with subscription]. Accessed May 7, 2024.
 53. Lopriore E., Mearin M.L., Oepkes D., Devlieger R., Whittington P.F. Neonatal hemochromatosis: Management, outcome, and prevention. *Prenat. Diagn*. 2013;33:1221–1225.

Reference number(s)
2042-A

54. Tate ED, Pranzatelli MR, Verhulst SJ, et al. Active comparator-controlled rater-blinded study of corticotropin-based immunotherapies for opsoclonus-myoclonus syndrome. *J Child Neurol*. 2012; 27:875-884.
55. Mutch LS, Johnston DL. Late presentation of opsoclonus-myoclonus-ataxia syndrome in a child with stage 4S neuroblastoma. *J Pediatr Hematol Oncol*. 2005;27(6):341-343.
56. Sonnenday CJ, Ratner LE, Zachary AA, et al. Preemptive therapy with plasmapheresis/intravenous immunoglobulin allows successful live donor renal transplantation in patients with a positive cross-match. *Transplant Proc*. 2002;34(5):1614-1616.
57. Razonable RR, Humar A. Cytomegalovirus in Solid Organ Transplantation. *Am J Transplant*. 2013;13:93-106.
58. Jordan SC, Toyoda M, Kahwaji J, et al. Clinical Aspects of Intravenous Immunoglobulin Use in Solid Organ Transplant Recipients. *Am J Transplant*. 2011;11:196-202
59. Kimberlin DW, Brady MT, Jackson MA, et al. Staphylococcus aureus. American Academy of Pediatrics. Red Book: 2018 Report of the Committee on Infectious Diseases. 2018:733-746
60. Gordon C, Amissah-Arthur MB, Gayed M, et al. British Society for Rheumatology guideline on management of systemic lupus erythematosus in adults. *Rheumatology (Oxford)*. 2018;57:e1-45.
61. Abecma [package insert]. Summit, NJ: Celgene Corporation; April 2024.
62. Alyglo [package insert]. Teaneck, NJ: GC Biopharma USA, Inc.; December 2023.
63. Illinois Statutes Chapter 215. Insurance § 5/356z.24. Immune gamma globulin therapy: <https://www.ilga.gov/legislation/ilcs/documents/021500050K356z.24.htm>
64. Yimmugo [package insert]. Dreieich, Germany: Biotest AG; June 2024.

Initial Prior Authorization

Kerendia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kerendia	finerenone

Indications

FDA-approved Indications

Kerendia is indicated to reduce the risk of:

- sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM).
- cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) $\geq$ 40%.

Coverage Criteria

Chronic Kidney Disease (CKD) Associated with Type 2 Diabetes (T2DM)

Authorization may be granted when the patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2DM) when ONE of the following criteria is met:

Reference number(s)
4871-A

- The patient is currently receiving a maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) OR angiotensin receptor blocker (ARB).
- The patient has experienced an intolerance to an ACEi or ARB.
- The patient has a contraindication that would prohibit a trial of an ACEi or ARB.

Heart Failure with Left Ventricular Ejection Fraction (LVEF) $\geq$ 40%

Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits when the following criteria is met:

- The patient has a diagnosis of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40 percent.

Duration of Approval (DOA)

- 4871-A: DOA: 12 months

References

1. Kerendia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed September 27, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/27/2025).
4. Chronic Kidney Disease and Risk Management: Standards of Medical Care in Diabetes – 2025. Diabetes Care. Jan 2025;48:S239-S251.
5. KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney International. 2022;102(Suppl 5S):S1-S127.

Specialty Guideline Management

Kesimpta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kesimpta	ofatumumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Kesimpta is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing forms of multiple sclerosis¹

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically isolated syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Kesimpta.

Other Criteria

- Members will not use Kesimpta concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Reference

1. Kesimpta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.

Specialty Guideline Management

Kevzara

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kevzara	sarilumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
- Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
- Patients with active polyarticular juvenile idiopathic arthritis (pJIA) who weigh 63 kg or greater.

Compendial Uses¹³

- Immune checkpoint inhibitor-related toxicity - inflammatory arthritis
- Giant cell arteritis (GCA)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polymyalgia rheumatica and immune checkpoint inhibitor-related toxicity

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Polyarticular juvenile idiopathic arthritis

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Giant cell arteritis (GCA)

For continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, polymyalgia rheumatica, polyarticular juvenile idiopathic arthritis, and giant cell arteritis: rheumatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid arthritis (RA)^{1-3,5-8}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.

- Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.

Polymyalgia rheumatica (PMR)¹

Authorization of 12 months may be granted for adult members for treatment of polymyalgia rheumatica when any of the following criteria is met:

- Member has experienced an inadequate response to systemic corticosteroids.
- Member has experienced a disease flare during a taper with systemic corticosteroids.
- Member has experienced an inadequate response to methotrexate.
- Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months may be granted for members weighing 63 kg and greater who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active polyarticular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members weighing 63 kg and greater for treatment of active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

Immune checkpoint inhibitor-related toxicity¹³

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when then member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Giant cell arteritis (GCA)¹³

Authorization of 12 months may be granted for treatment of giant cell arteritis when the member's diagnosis was confirmed by either of the following:

- Temporal artery biopsy or cross-sectional imaging
- Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP])

Continuation of Therapy

Rheumatoid arthritis (RA)^{1-3,5-8}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Polymyalgia rheumatica (PMR)^{1,9}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for PMR and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Morning stiffness
- Hip or shoulder pain
- Hip or shoulder range of motion
- C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

Polyarticular juvenile idiopathic arthritis

Authorization of 12 months may be granted for all members (including new members) weighing 63 kg and greater who are using the requested medication for active polyarticular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Immune checkpoint inhibitor-related toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Giant cell arteritis (GCA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for giant cell arteritis and who achieve or maintain a positive clinical response as

evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Headaches
- Scalp tenderness
- Tenderness and/or thickening of superficial temporal arteries
- Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
- Jaw and/or tongue claudication
- Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication

Other^{1,4}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Methotrexate, Hydroxychloroquine, or Leflunomide¹⁰

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity

- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

References

1. Kevzara [package insert]. Bridgewater, NJ: Sanofi-aventis, U.S. LLC /Regeneron Pharmaceuticals, Inc.; May 2025.
2. Genovese MC, Fleischmann R, Kivitz AJ, et al. Sarilumab plus methotrexate in patients with active rheumatoid arthritis and inadequate response to methotrexate: results of a phase III study. *Arthritis Rheumatol.* June 2015;67(6):1424-37.
3. Strand V, Reaney M, Chen C, et al. Sarilumab improves patient-reported outcomes in rheumatoid arthritis patients with inadequate response/intolerance to tumour necrosis factor inhibitors. *RMD Open.* 2017; 3:e000416. doi: 10.1136/rmdopen-2016-000416.
4. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 11, 2024 from: <https://www.cdc.gov/tb/testing/>.
5. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis.* 2023;82:3-18.
6. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum.* 2010;62(9):2569-81.
7. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
8. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2021;0:1-16.
9. Dasgupta B, Cimmino MA, Kremers HM, et al. 2012 provisional classification criteria for polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. *Arthritis Rheum.* 2012 Apr;64(4):943-54.

10. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486.
11. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *American College of Rheumatology.* 2019;1-18.
12. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
13. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 11, 2024.

Specialty Guideline Management

Kineret

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Kineret	anakinra

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs)
- Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Compendial Uses

- Systemic juvenile idiopathic arthritis (sJIA)³
- Adult-onset Still's disease (AOSD)⁴⁻⁵
- Multicentric Castleman disease⁶
- Recurrent pericarditis (RP)¹⁶
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)¹⁷⁻¹⁹
- Schnitzler syndrome^{2,20,21}

- Gout and pseudogout (calcium pyrophosphate deposition)^{2,25-27}
- Chimeric antigen receptor (CAR) T-cell-related toxicities⁶
- Erdheim-Chester Disease⁶
- Immune checkpoint inhibitor-related toxicity—immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome⁶

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid Arthritis (RA)

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (sJIA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Continuation requests: Chart notes, medical record documentation, or laboratory results supporting positive clinical response.

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Initial requests: IL1RN gene variant status

Recurrent Pericarditis (RP)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Initial requests: Chart notes, medical record documentation, or laboratory result (if applicable) indicating number of active flares within the last 6 months and Physician's Global Assessment (PGA) score or C-reactive protein (CRP) level.

Gout and Pseudogout Flares, CAR T-Cell-Related Toxicities, and Immune Checkpoint Inhibitor-Related Toxicity

Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis (RA), adult-onset Still's disease (AOSD), systemic juvenile idiopathic arthritis (sJIA), gout, and pseudogout: rheumatologist
- Cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), deficiency of interleukin-1 receptor antagonist (DIRA), and hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD): rheumatologist or immunologist
- Recurrent pericarditis (RP): cardiologist, rheumatologist, or immunologist
- Schnitzler syndrome: rheumatologist, dermatologist, or immunologist

- Multicentric Castleman disease, CAR T-cell-related toxicities, Erdheim-Chester disease, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Coverage Criteria

Rheumatoid Arthritis (RA)^{1,7-11,31,32}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days.

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following criteria are met:

- Member meets either of the following criteria:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide,

hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).

- Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.

Adult-Onset Still's Disease (AOSD)^{4,5,14,15,23,24,34}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for active AOSD.

Authorization of 12 months may be granted for treatment of active AOSD when both of the following criteria are met:

- Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
- Member meets any of the following:
 - Member has had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs).
 - Member has had an inadequate response to a trial of corticosteroids.
 - Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

Systemic Juvenile Idiopathic Arthritis (sJIA)^{3,12,13,35}

Authorization of 12 months may be granted for members who have previously received a biologic indicated for active sJIA.

Authorization of 12 months may be granted for treatment of active sJIA when the member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)¹

Authorization of 12 months may be granted for treatment of cryopyrin-associated periodic syndromes (CAPS), including NOMID (also known as chronic infantile neurologic cutaneous and articular [CINCA] syndrome).

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)^{1,29}

Authorization of 12 months may be granted for treatment of genetically confirmed deficiency of interleukin-1 receptor antagonist (DIRA) due to IL1RN gene variants.

Recurrent Pericarditis (RP)^{16,33,37}

Authorization of 12 months may be granted for treatment of recurrent pericarditis when both of the following criteria are met:

- Member has had at least two episodes of pericarditis.
- Member has failed at least two agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids).

Multicentric Castleman Disease⁶

Authorization of 12 months may be granted for treatment of multicentric Castleman disease when both of the following criteria are met:

- The requested medication will be used as a single agent.
- The disease has progressed following treatment of relapsed/refractory or progressive disease.

Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)¹⁷⁻¹⁹

Authorization of 12 months may be granted for treatment of HIDS/MKD when both of the following criteria are met:

- Member has had active flares within the last 6 months.
- Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

Schnitzler Syndrome^{2,20,21}

Authorization of 12 months may be granted for treatment of Schnitzler syndrome when both of the following criteria are met:

- Member has an urticarial rash, monoclonal IgM (or IgG) gammopathy, and at least two of the following signs and symptoms: fever, joint pain or inflammation, bone pain, lymphadenopathy, hepatomegaly, splenomegaly, leukocytosis, elevated erythrocyte sedimentation rate (ESR), or abnormalities on bone morphological study (e.g., increased bone density).
- Other possible causes of the signs and symptoms have been ruled out, including but not limited to: hyperimmunoglobulin D syndrome, adult-onset Still's disease, hypocomplementemic urticarial vasculitis, acquired C1 inhibitor deficiency, and cryoglobulinemia.

Gout and Pseudogout Flares²⁵⁻³⁸

Authorization of 12 months may be granted for adult members for treatment of flares for gout and pseudogout (also known as calcium pyrophosphate deposition disease) when both of the following criteria are met:

- Member has experienced at least three gout flares in the last 12 months.
- Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

Chimeric Antigen Receptor (CAR) T-Cell-Related Toxicities⁶

Authorization of 1 month may be granted for management of chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome when either of the following criteria is met:

- Cytokine release syndrome is refractory to high-dose corticosteroids and anti-IL-6 therapy.
- Kineret will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

Authorization of 3 months may be granted for the prophylaxis of CAR T-cell-induced toxicity in members at high risk of developing high-grade immune effector cell-associated neurotoxicity syndrome (ICANS).

Erdheim-Chester Disease⁶

Authorization of 12 months may be granted for the treatment of Erdheim-Chester disease.

Immune Checkpoint Inhibitor-Related Toxicity⁶

Authorization of 6 months may be granted for the treatment of immune checkpoint inhibitor-related toxicity when the member has immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome and either of the following criteria is met:

- Member has had an inadequate response to systemic corticosteroids.

- Member has an intolerance or contraindication to corticosteroids.

Continuation of Therapy

Rheumatoid Arthritis (RA)^{1,7-11,31-32}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (sJIA)^{3-5,12-15,23,24,34}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for adult-onset Still's disease or systemic juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability
- Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)^{1,30}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for CAPS, including NOMID (also known as CINCA), and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Fever
- Skin rash
- Joint pain and/or inflammation
- Central nervous system (CNS) symptoms (e.g., meningitis, headache, cerebral atrophy, uveitis, hearing loss)
- Inflammatory markers (e.g., serum amyloid A [SAA], C-reactive protein [CRP], erythrocyte sedimentation rate [ESR])

Recurrent Pericarditis (RP)^{16,33}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for recurrent pericarditis and who achieve or maintain a positive clinical response as evidenced by decreased recurrence of pericarditis or improvement in signs and symptoms of the condition when there is improvement in any of the following:

- Pericarditic or pleuritic chest pain
- Pericardial or pleural rubs
- Electrocardiogram (ECG)
- Pericardial effusion
- C-reactive protein (CRP)

Multicentric Castleman Disease

Authorization of 12 months may be granted for continued treatment of multicentric Castleman disease in members requesting reauthorization who have not experienced disease progression or an unacceptable toxicity.

CAR T-Cell-Related Toxicities and Immune Checkpoint Inhibitor-Related Toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All Other Indications

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,22}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide³⁶

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); September 2024.
2. Micromedex® [electronic version]. Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed April 18, 2025.
3. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013;65:2499-2512.
4. Laskari K, Tzioufas AG, Moutsopoulos HM. Efficacy and long-term follow-up of IL-1R inhibitor anakinra in adults with Still's disease: a case-series study. *Arthritis Res Ther*. 2011;13(3):R91.
5. Lequerre T, Quartier P, Rosellini D, et al. Interleukin-1 receptor antagonist (anakinra) treatment in patients with systemic-onset juvenile idiopathic arthritis or adult onset Still disease: preliminary experience in France. *Ann Rheum Dis*. 2008;67:302-308.

6. The NCCN Drugs & Biologics Compendium™. National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 15, 2025.
7. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
8. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2012;64(5):625-639.
9. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
10. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid Arthritis Classification Criteria. An American College of Rheumatology/European League Against Rheumatism Collaborative Initiative. *Arthritis Rheum*. 2010;62:2569-2581.
11. Anderson J, Caplan L, Yazdany J, et al. Rheumatoid Arthritis Disease Activity Measures: American College of Rheumatology Recommendations for Use in Clinical Practice. *Arthritis Rheum*. 2010;64:640-647.
12. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
13. Quartier P, Allantaz F, Cimaz R, et al. A multicentre, randomized, double-blind, placebo-controlled trial with the interleukin-1 receptor antagonist anakinra in patients with systemic-onset juvenile idiopathic arthritis (ANAJIS trial). *Ann Rheum Dis*. 2011;70:747-754.
14. Efthimiou P, Paik PK, Bielory L. Diagnosis and Management of Adult-Onset Still's Disease. *Ann Rheum Dis*. 2006;65(5):564-72. Epub 2005 Oct 11.
15. National Organization for Rare Disorders. Adult-Onset Still's Disease. URL: <https://rarediseases.org/rare-diseases/adult-onset-stills-disease>. Accessed November 18, 2024.
16. Adler Y, Charron P, Imazio M, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC) Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2015;36(42):2921-64.
17. Kostjukovits S, Kallikokoski L, Antila K, et al. Treatment of hyperimmunoglobulinemia D Syndrome with biologics in children: review of the literature and Finnish experience. *Eur J Pediatr*. 2015;174(6):707-14.
18. National Organization for Rare Disorders. Mevalonate Kinase Deficiency. <http://rarediseases.org/rare-diseases/hyper-igd-syndrome>. Accessed November 18, 2024.
19. American College of Rheumatology. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (Juvenile). <https://rheumatology.org/patients/hyperimmunoglobulin-d-syndrome-hids-mevalonate-kinase-deficiency-mkd-juvenile>. Accessed November 18, 2024.
20. Simon A, Asli B, Braun-Falco M, et al. Schnitzler's syndrome: diagnosis, treatment, and follow-up. *Allergy*. 2013;68:562-568.
21. Lipsker D. The Schnitzler syndrome. *Orphanet J Rare Dis*. 2010;5:38.

22. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 14, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
23. Lyseng-Williamson KA. Anakinra in Still's disease: A profile of its use. *Drugs Ther Perspect*. 2018;34(12):543-553.
24. Yoo DH. Biologics for the treatment of adult-onset still's disease. *Expert Opin Biol Ther*. 2019;19(11):1173-1190.
25. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Ann Rheum Dis*. 2017;76:29–42.
26. Zhang W, Doherty M, Pascual E, et al. EULAR recommendations for calcium pyrophosphate deposition. Part II: Management. *Ann Rheum Dis*. 2011;70:571–575.
27. Ottaviani S., Brunier L, Sibilia J, et al. Efficacy of anakinra in calcium pyrophosphate crystal-induced arthritis: A report of 16 cases and review of the literature. *Joint Bone Spine*. 2013;80:178-182.
28. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in *Arthritis Care Res (Hoboken)*. 2020;72(8):1187]. *Arthritis Care Res (Hoboken)*. 2020;72(6):744-760.
29. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. *N Engl J Med*. 2009;360(23):2426-37.
30. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *J Allergy Clin Immunol*. 2015;136(5):1186-205.
31. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis disease activity and physical function. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed November 18, 2024.
32. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2021;73(7):924-939.
33. Chiabrando JG, Bonaventura A, Vecchié A, et al. Management of acute and recurrent pericarditis: JACC State-of-the-art review. *J Am Coll Cardiol*. 2020;75(1):76-92.
34. Efthimiou P, Kontzias A, Hur P, et al. Adult-onset Still's disease in focus: Clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. *Semin Arthritis Rheum*. 2021;51(4):858-874.
35. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
36. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
37. Kumar S, Furqan M, Kafil T, et al. (2023). The paradigm shift in the management of recurrent pericarditis. *American College of Cardiology*. <https://www.acc.org/Latest-in-Cardiology/Articles/2022/12/19/14/52/The-Paradigm-Shift-in-the-Management-of-Recurrent-Pericarditis>.

Prior Authorization Policy

Long-Acting Injectable Antipsychotics

Brand Name	Generic Name
Abilify Asimtufii®	aripiprazole monohydrate
Abilify Maintena®	aripiprazole
Aristada®	aripiprazole lauroxil
Aristada Initio®	aripiprazole lauroxil
Erzofri®	Paliperidone palmitate
Invega Sustenna®	paliperidone palmitate
Invega Trinza®	paliperidone palmitate
Invega Hafyera®	paliperidone palmitate
Perseris®	risperidone
Risperdal Consta®	risperidone microspheres
Risperidone ER injectable suspension	risperidone
Rykindo®	risperidone
Uzedy®	risperidone
Zyprexa Relprevv®	olanzapine pamoate

Covered Indications and Required Documentation

To support review of a prior authorization request, documentation should clearly identify:

- Member diagnosis
- Member age
- Requested medication and dosing regimen
- Relevant chart notes supporting the clinical need for therapy
- Documentation of oral antipsychotic tolerability when required
- Documentation of prior treatment history when applicable
- Documentation of positive clinical response for continuation requests

- Documentation of compliance with outpatient follow-up appointments when applicable

Coverage Criteria by Indication

Schizophrenia, Schizoaffective Disorder, or Bipolar I Disorder

Authorization of 12 months may be granted when:

- The patient has a diagnosis of schizophrenia, schizoaffective disorder, or bipolar I disorder consistent with the medication's FDA-approved labeling.
- The patient has a documented history of nonadherence to oral antipsychotic therapy or documented stabilization on a long-acting injectable antipsychotic while in a mental health facility.
- The patient has demonstrated oral tolerability to the active ingredient of the requested long-acting injectable antipsychotic according to FDA labeling.
- The requested treatment regimen is consistent with the medication's FDA-approved labeling.
- No contraindications or significant drug interactions are identified.

Continuation of Therapy

Authorization of 12 months may be granted when:

- The prescriber attests that the patient is tolerating the requested medication.
- The patient has demonstrated a documented clinical response to therapy.
- The patient has maintained compliance with outpatient follow-up appointments.
- The patient is 18 years of age or older.

Paliperidone Long-Acting Injection Agents

Authorization of 12 months may be granted when the following medication-specific criteria are met.

Invega Sustenna®

Authorization of 12 months may be granted when:

- The patient has demonstrated established tolerability with oral paliperidone or oral risperidone.

Invega Trinza®

Authorization of 12 months may be granted when:

- The patient has completed a documented trial of Invega Sustenna for at least 4 months.

Invega Hafyera®

Authorization of 12 months may be granted when:

- The patient has completed a documented trial of Invega Sustenna for at least 4 months, or
- The patient has completed a documented trial of Invega Trinza for at least one 3-month dosing cycle.

Preferred Long-Acting Injectable Antipsychotics

Authorization of 12 months may be granted when:

- The requested medication is a preferred long-acting injectable antipsychotic.

Non-Preferred Long-Acting Injectable Antipsychotics

Authorization of 12 months may be granted when:

- The patient has a documented clinically significant treatment failure, intolerance, or contraindication to preferred long-acting injectable antipsychotic agents.

Authorization Duration

All authorizations are issued for **12 months**.

Specialty Guideline Management

ledipasvir-sofosbuvir, Harvoni

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Harvoni	ledipasvir-sofosbuvir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV):

- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

Reference number(s)
Policy: 2134-A
Qsets: 5920-A, 6284-A

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin¹⁻⁵

Genotype 1 infection

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis when any of the following criteria is met:
 - Member is less than 18 years of age.
 - Member has human immunodeficiency virus (HIV) co-infection.
 - Member has pre-treatment HCV RNA greater than or equal to 6 million international units per milliliter (IU/mL).
- Authorization of up to 8 weeks total may be granted for treatment-naïve members without cirrhosis who have pre-treatment HCV RNA below 6 million IU/mL and do not have HIV co-infection.
- Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor.
- Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Genotype 4 or 5 infection

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Genotype 6 infection

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria is met:

- Member is treatment-naïve and does not have genotype 6e subtype.
- Member has failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)

Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection who have decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Appendix).

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis.

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

Hepatitis C Virus Infection, in combination with Ribavirin¹⁻⁵

Genotype 1 infection

Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Decompensated cirrhosis (CTP class B or C)

- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV, sofosbuvir plus PEG-IFN and RBV, sofosbuvir plus simeprevir with or without RBV).

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis who are treatment naïve or have failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Hepatitis C Virus and HIV coinfection^{1,2,5}

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

Reference number(s)
Policy: 2134-A
Qsets: 5920-A, 6284-A

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness
 - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
 - Hepatitis B virus screening results
 - Metavir/Fibrosis score

Appendix: Ribavirin (RBV) Ineligibility^{3,4}

Ribavirin (RBV) ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

References

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences; December 2024.
2. Ledipasvir and sofosbuvir tablet [package insert]. Foster City, CA: Asegua Therapeutics LLC; March 2020.
3. Ribavirin capsule [package insert] . East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.
4. Ribavirin tablet [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
5. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Guideline Management

leuprolide depot products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot 1-Month 7.5 mg	leuprolide acetate depot 1-Month 7.5 mg
Lupron Depot 3-Month 22.5 mg	leuprolide acetate depot 3-Month 22.5 mg
Lupron Depot 4-Month 30 mg	leuprolide acetate depot 4-Month 30 mg
Lupron Depot 6-Month 45 mg	leuprolide acetate depot 6-Month 45 mg
Lutrate Depot 3-Month 22.5 mg	leuprolide acetate 3-Month 22.5 mg

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻³

Lupron Depot 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, leuprolide acetate depot 3-month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg, and Lutrate Depot 3-Month 22.5 mg are indicated for the treatment of advanced prostate cancer.

Compendial Uses

- Prostate cancer⁴
- Ovarian cancer - Malignant sex cord-stromal tumors (7.5 mg and 22.5 mg)⁴

- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)⁵⁻⁷
- Breast cancer (7.5 mg and 22.5 mg)^{4,10}

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties⁹

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

Coverage Criteria

Prostate Cancer¹⁻⁴

Authorization of 12 months may be granted for treatment of prostate cancer.

Gender Dysphoria⁵⁻⁷

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Ovarian Cancer (7.5 mg and 22.5 mg only)⁴

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors (granulosa cell tumors) as a single agent.

Breast Cancer (7.5 mg and 22.5 mg only)⁴

Authorization of 12 months may be granted for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer at higher risk for recurrence (e.g., young age, high-grade tumor, lymph-node involvement) when used in combination with endocrine therapy.

Continuation of Therapy

Ovarian Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Prostate Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

Breast Cancer¹⁰

Authorization of 12 months may be granted (up to 5 years total) for continued treatment in members requesting reauthorization who were premenopausal at diagnosis and are still undergoing treatment with endocrine therapy.

Gender Dysphoria⁹

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

References

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.
2. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2024.
3. Lutrate Depot 22.5 mg [package insert]. New Jersey: Avyxa Pharma, LLC.; November 2024.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed February 12, 2025.
5. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869–3903.
6. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
7. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
8. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017;5:816-26.
9. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals>.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 21, 2025.

Specialty Guideline Management

leuprolide

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Generic Name	Dosage Form
leuprolide acetate	injection solution

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer.

Compendial Uses

- Central precocious puberty (CPP)^{2-7,17}
- Use as a stimulation test to confirm the diagnosis of CPP³⁻⁶
- Use in combination with growth hormone for children with growth failure and advancing puberty⁸⁻¹²
- Prostate cancer¹³
- Inhibition of premature luteinizing hormone (LH) surges in members undergoing ovulation induction or assisted reproductive technology^{14,15}
- Triggering of oocyte maturation and ovulation in assisted reproductive technology cycle¹⁶

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for central precocious puberty: laboratory report or medical record of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

Coverage Criteria

Central Precocious Puberty (CPP)^{2-7,17}

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
 - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
 - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 mutations]).

Stimulation Test for CPP Diagnosis^{3-6,17}

Authorization of one dose may be granted for use as a stimulation test to confirm the diagnosis of CPP.

Advancing Puberty and Growth Failure⁸⁻¹²

Authorization of 12 months may be granted for treatment of advancing puberty and growth failure in a pediatric member when leuprolide acetate is used in combination with growth hormone.

Prostate Cancer^{1,13}

Authorization of 12 months may be granted for treatment of prostate cancer.

Inhibition of Premature Luteinizing Hormone (LH) Surges^{†14,15}

Authorization of 12 months may be granted for the inhibition of premature LH surges in members undergoing ovulation induction or assisted reproductive technology (ART).

Oocyte Maturation and Ovulation Trigger^{‡16,18}

Authorization of 12 months may be granted for members undergoing ovulation induction or assisted reproductive technology (ART).

‡ Specialty Guideline Management coverage review will be bypassed for leuprolide if it is being requested for a procedure that has been approved under a member's medical benefit plan. Such members will be exempt from the requirements listed in the coverage criteria. A medical authorization number and confirmation of the approved procedure(s) will be required. NOTE: Some plans may opt-out of medical benefit alignment. Members receiving coverage under such plans must meet the requirements listed in the coverage criteria.

Continuation of Therapy

Central Precocious Puberty^{2-7,17}

Authorization of up to 12 months may be granted for continued treatment for CPP when the member meets all of the following criteria:

- The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

Prostate Cancer

Authorization of 12 months may be granted for continued treatment of prostate cancer in members requesting authorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

References

1. Leuprolide acetate injection [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; February 2025.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. URL: <http://www.clinicalpharmacology.com>. Accessed May 15, 2025.

3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Bangalore Krishna K, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: Update by an international consortium. *Horm Res Paediatr*. 2019;91(6):357-372.
5. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr*. 2015;54:414-424.
6. Bangalore Krishna K, Silverman LA. Diagnosis of central precocious puberty. *Endocrinol Metab Clin North Am*. 2024;53(2):217-227.
7. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.
8. Kamp GA, Mul D, Waelkens JJ, et al. A randomized controlled trial of three years growth hormone and gonadotropin-releasing hormone agonist treatment in children with idiopathic short stature and intrauterine growth retardation. *J Clin Endocrinol Metab*. 2001;86:2969-2975.
9. Mericq V, Cajardo H, Effers M, et al. Effects of treatment with GH alone or in combination with LHRH analog on bone mineral density in pubertal GH-deficient patients. *J Clin Endocrinol Metab*. 2002;87:84-89.
10. Mul D, Wit JM, Oostdijk W, et al. The effect of pubertal delay by GnRH agonist in GH-deficient children on final height. *J Clin Endocrinol Metab*. 2001;86:4655-4656.
11. Quintos JB, Vogiatzi MG, Harbison MD, et al. Growth hormone therapy alone or in combination with gonadotropin-releasing hormone analog therapy to improve the height deficit in children with congenital adrenal hyperplasia. *J Clin Endocrinol Metab*. 2001;86:1511-1517.
12. Tanaka T, Satoh M, Yasunaga T, et al. GH and GnRH analog treatment in children who enter puberty at short stature. *J Pediatr Endocrinol Metab*. 1997;10:623-628.
13. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 20, 2025.
14. Urman B, Yakin K. Ovulatory disorders and infertility. *J Reprod Med*. 2006;51(4):267-282.
15. National Institute for Health and Clinical Excellence (NICE). Guideline on assessment and treatment for people with fertility problems. NICE 2017 Feb 6:CG156.
16. Casper RF. Reducing the Risk of OHSS by GnRH Agonist Triggering. *J Clin Endocrinol Metab*. 2015;100(12):4396-8.
17. Cheuiche AV, da Silveira LG, de Paula LCP, et al. Diagnosis and management of precocious sexual maturation: an updated review. *Eur J Pediatr*. 2021;180(10):3073-3087.
18. Practice Committee of the American Society for Reproductive Medicine. Prevention and treatment of moderate and severe ovarian hyperstimulation syndrome: a guideline. *Fertil & Steril*. 2016. 106(7):1634-1647.
19. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2.2024. Accessed February 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.
20. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. *Front Pediatr*. 2022;10:968485. doi:10.3389/fped.2022.968485

Initial Prior Authorization with Quantity Limit Libervant, Valtoco

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Libervant	diazepam	buccal film
Valtoco	diazepam	nasal spray

Indications

FDA-approved Indications

Libervant

Libervant is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age.

Valtoco

Valtoco is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 years of age and older.

Coverage Criteria

Intermittent, Stereotypic Episodes of Frequent Seizure Activity

Authorization may be granted when the requested drug is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern in a patient with epilepsy when ONE of the following criteria is met:

- The request is for Libervant (diazepam buccal film) and the following criteria is met:
 - The patient is 2 to 5 years of age.
- The request is for Valtoco (diazepam nasal spray) and the following criteria is met:
 - The patient is 2 years of age or older.

Quantity Limits Apply

Quantity Limit

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Libervant (diazepam buccal film)	10 individual pouches / 25 days	30 individual pouches / 75 days
Valtoco (diazepam nasal spray)	10 blister packs / 25 days	30 blister packs / 75 days

Duration of Approval (DOA)

- 3517-C: DOA: 12 months

References

1. Libervant [package insert]. Warren, NJ: Aquestive Therapeutics; April 2024.
2. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; April 2025.
3. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 2, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/02/2025).

Initial Prior Authorization with Quantity Limit

Lidocaine, Lidocaine-Prilocaine, Lidocaine-Tetracaine Dermatological Topical

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are included.

Brand Name	Generic Name	Dosage Form
lidocaine HCl 2% (all brands)	lidocaine HCl 2%	gel
lidocaine HCl-collagen-aloe vera 2% (all brands)	lidocaine HCl-collagen-aloe vera 2%	gel
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel prefilled syringe
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	solution
lidocaine 5% (all brands)	lidocaine 5%	ointment
lidocaine 2.5% and prilocaine 2.5% (all brands)	lidocaine 2.5% and prilocaine 2.5%	cream
Pliaglis	lidocaine and tetracaine 7-7%	cream
Synera	lidocaine and tetracaine 70-70 mg	patch

Reference number(s)
1331-C

Indications

FDA-approved Indications

Lidocaine HCl 2% Gel

For the local management of skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl 4% Gel

Lidocaine 4% Gel is indicated for the following:

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

Lidocaine HCl Urethral/Mucosal 2% Gel

Lidocaine HCl 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl Urethral/Mucosal 2% Gel Prefilled Syringe

Lidocaine HCl jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Reference number(s)
1331-C

Lidocaine HCl 4% Topical Solution

Lidocaine hydrochloride is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

Lidocaine 5% Ointment

Lidocaine 5% ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx.

It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

Lidocaine 2.5% and Prilocaine 2.5% Cream

Lidocaine and prilocaine cream, 2.5%/2.5% (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on:

- normal intact skin for local analgesia.
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

Lidocaine and prilocaine cream, 2.5%/2.5% is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

Pliaglis (lidocaine and tetracaine 7-7% cream)

Pliaglis is indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

Synera (lidocaine and tetracaine 70-70 mg patch)

Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions.

Coverage Criteria

Authorization may be granted for the requested product when it will NOT be used as part of a compound and ONE of the following criteria is met:

- Lidocaine-prilocaine 2.5-2.5 percent cream is being prescribed as a topical anesthetic for use on EITHER: normal intact skin for local analgesia OR genital mucous membranes for superficial minor surgery or as pretreatment for infiltration anesthesia

- Lidocaine 5 percent ointment is being prescribed for ANY of the following: production of anesthesia of accessible mucous membranes of the oropharynx; as an anesthetic lubricant for intubation; temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, or insect bites
- Lidocaine urethral/mucosal 2 percent gel is being prescribed for ANY of the following: prevention and control of pain in procedures involving the urethra; topical treatment of painful urethritis; as an anesthetic lubricant for endotracheal intubation (oral or nasal)
- Lidocaine-tetracaine 7-7 percent cream (Pliaglis) is being prescribed for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, or laser-assisted tattoo removal
- Lidocaine 4 percent topical solution is being prescribed for the production of topical anesthesia of accessible mucous membranes of the oral or nasal cavities or proximal portions of the digestive tract
- Lidocaine-tetracaine 70-70 mg patch (Synera) is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access or superficial dermatological procedures such as excision, electrodesiccation or shave biopsy of skin lesions
- Lidocaine 2 percent gel OR Lidocaine-collagen-aloe vera 2 percent gel is being prescribed for the local management of painful skin wounds for ANY of the following: pressure ulcers, venous stasis ulcers, superficial wounds or scrapes, 1st or 2nd degree burns, AND the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, or contraindication to ALL available FDA-approved drugs and over-the-counter (OTC) products for their medical condition
- Lidocaine 4 percent gel is being prescribed for ANY of the following: stage I - IV pressure ulcers; venous stasis ulcers; ulcerations caused by mixed vascular etiologies; diabetic skin ulcers; first or second degree burns; post-surgical incisions, cuts or abrasions; AND the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, or contraindication to ALL available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

Quantity Limits Apply

Quantity Limit

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Reference number(s)
1331-C

The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

These products are for short-term acute use; therefore, the intent is for prescriptions of the requested product to be filled one month at a time; there should be no 3 month supplies filled.

Product	1 Month Limit	3 Month Limit
lidocaine HCl 2% gel	85 gm or mL / 25 days	Does Not Apply
lidocaine HCl-collagen-aloe vera 2% gel	85 gm or mL / 25 days	Does Not Apply
lidocaine HCl 4% gel	90 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel	125 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel prefilled syringe	125 mL / 25 days	Does Not Apply
lidocaine HCl 4% topical solution	100 mL / 25 days	Does Not Apply
lidocaine 5% ointment	100 gm / 25 days	Does Not Apply
lidocaine-prilocaine 2.5-2.5% cream	60 gm / 25 days	Does Not Apply
Pliaglis 7-7% (lidocaine-tetracaine cream)	60 gm / 25 days	Does Not Apply
Synera 70-70 mg (lidocaine-tetracaine patch)	10 patches / 25 days	Does Not Apply

Duration of Approval (DOA)

- 1331-C: DOA: 3 months

References

1. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
4. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; September 2022.

Reference number(s)
1331-C

6. Lidocaine HCl 4% topical solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.
7. Lidocaine 5% ointment [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; October 2023.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2018.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
10. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
11. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.
12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
13. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
14. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
15. Human Drug Compounding. Available at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. Accessed September 2024.
16. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed September 2024.

Post Limit Prior Authorization

Lidocaine, Lidocaine-Prilocaine, Lidocaine-Tetracaine

Dermatological Topical

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are included.

Brand Name	Generic Name	Dosage Form
lidocaine HCl 2% (all brands)	lidocaine HCl 2%	gel
lidocaine HCl-collagen-aloe vera 2% (all brands)	lidocaine HCl-collagen-aloe vera 2%	gel
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel prefilled syringe
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	solution
lidocaine 5% (all brands)	lidocaine 5%	ointment
lidocaine 2.5% and prilocaine 2.5% (all brands)	lidocaine 2.5% and prilocaine 2.5%	cream
Pliaglis	lidocaine and tetracaine 7-7%	cream
Synera	lidocaine and tetracaine 70-70 mg	patch

Indications

FDA-approved Indications

Lidocaine HCl 2% Gel

For the local management of skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl 4% Gel

Lidocaine 4% Gel is indicated for the following:

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

Lidocaine HCl Urethral/Mucosal 2% Gel

Lidocaine HCl 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl Urethral/Mucosal 2% Gel Prefilled Syringe

Lidocaine HCl jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl 4% Topical Solution

Lidocaine hydrochloride is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

Lidocaine 5% Ointment

Lidocaine 5% ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx.

It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

Lidocaine 2.5% and Prilocaine 2.5% Cream

Lidocaine and prilocaine cream, 2.5%/2.5% (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on:

- normal intact skin for local analgesia.
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

Lidocaine and prilocaine cream, 2.5%/2.5% is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

Pliaglis (lidocaine and tetracaine 7-7% cream)

Pliaglis is indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

Synera (lidocaine and tetracaine 70-70mg patch)

Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions.

Coverage Criteria

Authorization may be granted for the requested product when it will NOT be used as part of a compound and ONE of the following criteria is met:

- Lidocaine-prilocaine 2.5-2.5 percent cream is being prescribed as a topical anesthetic for use on EITHER: normal intact skin for local analgesia OR genital mucous membranes for superficial minor surgery or as pretreatment for infiltration anesthesia
- Lidocaine 5 percent ointment is being prescribed for ANY of the following: production of anesthesia of accessible mucous membranes of the oropharynx; as an anesthetic lubricant for

intubation; temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, or insect bites

- Lidocaine urethral/mucosal 2 percent gel is being prescribed for ANY of the following: prevention and control of pain in procedures involving the urethra; topical treatment of painful urethritis; as an anesthetic lubricant for endotracheal intubation (oral or nasal)
- Lidocaine-tetracaine 7-7 percent cream (Pliaglis) is being prescribed for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, or laser-assisted tattoo removal
- Lidocaine 4 percent topical solution is being prescribed for the production of topical anesthesia of accessible mucous membranes of the oral or nasal cavities or proximal portions of the digestive tract
- Lidocaine-tetracaine 70-70 mg patch (Synera) is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access or superficial dermatological procedures such as excision, electrodesiccation or shave biopsy of skin lesions
- Lidocaine 2 percent gel OR Lidocaine-collagen-aloe vera 2 percent gel is being prescribed for the local management of painful skin wounds for ANY of the following: pressure ulcers, venous stasis ulcers, superficial wounds or scrapes, 1st or 2nd degree burns, AND the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, or contraindication to ALL available FDA-approved drugs and over-the-counter (OTC) products for their medical condition
- Lidocaine 4 percent gel is being prescribed for ANY of the following: stage I - IV pressure ulcers; venous stasis ulcers; ulcerations caused by mixed vascular etiologies; diabetic skin ulcers; first or second degree burns; post-surgical incisions, cuts or abrasions; AND the following criteria is met:
 - The patient experienced an inadequate treatment response, intolerance, or contraindication to ALL available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

Quantity Limits Apply

Post Limit Quantity

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period to allow time for refill processing.

These products are for short-term acute use; therefore, the intent is for prescriptions of the requested product to be filled one month at a time; there should be no 3 month supplies filled.

Product	1 Month Limit	3 Month Limit
lidocaine HCl 2% gel	85 gm or mL / 25 days	Does Not Apply
lidocaine HCl-collagen-aloe vera 2% gel	85 gm or mL / 25 days	Does Not Apply
lidocaine HCl 4% gel	90 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel	125 mL / 25 days	Does Not Apply
lidocaine HCl urethral/mucosal 2% gel prefilled syringe	125 mL / 25 days	Does Not Apply
lidocaine HCl 4% topical solution	100 mL / 25 days	Does Not Apply
lidocaine 5% ointment	100 gm / 25 days	Does Not Apply
lidocaine-prilocaine 2.5-2.5% cream	60 gm / 25 days	Does Not Apply
Pliaglis 7-7% (lidocaine-tetracaine cream)	60 gm / 25 days	Does Not Apply
Synera 70-70 mg (lidocaine-tetracaine patch)	10 patches / 25 days	Does Not Apply

Duration of Approval (DOA)

- 1330-J: DOA: 3 months

References

1. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
4. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; September 2022.
6. Lidocaine HCl 4% topical solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.
7. Lidocaine 5% ointment [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; October 2023.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2018.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
10. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
11. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.

Reference number(s)
1330-J

12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
13. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
14. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
15. Human Drug Compounding. Available at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>. Accessed September 2024.
16. Medical Devices. Available at: <https://www.fda.gov/medical-devices>. Accessed September 2024.

Initial Prior Authorization

Linzess

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Linzess	linaclotide

Indications

FDA-approved Indications

Linzess is indicated for the treatment of:

- irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older
- chronic idiopathic constipation (CIC) in adults
- functional constipation (FC) in pediatric patients 6 years of age and older

Coverage Criteria

Chronic Idiopathic Constipation (CIC)

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic idiopathic constipation (CIC) in an adult patient.

Reference number(s)
843-A, 1023-A

Functional Constipation (FC)

Authorization may be granted when the requested drug is being prescribed for the treatment of functional constipation (FC) when the following criteria is met:

- The request is for a pediatric patient 6 years of age or older.

Irritable Bowel Syndrome with Constipation (IBS-C)

Authorization may be granted when the requested drug is being prescribed for the treatment of irritable bowel syndrome with constipation (IBS-C) when the following criteria is met:

- The request is for a patient 7 years of age or older.

Duration of Approval (DOA)

- 843-A: DOA: 12 months
- 1023-A: DOA: 36 months

References

1. Linzess [package insert]. North Chicago, IL: AbbVie, Inc.; Boston, MA: Ironwood Pharmaceuticals, Inc.; November 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed August 11, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/11/2025).

Specialty Guideline Management

Lupron Depot

Endometriosis-Fibroid

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot 3.75 mg Lupron Depot-3 Month 11.25 mg	leuprolide acetate for depot suspension

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Endometriosis

Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot 3.75 mg monthly and Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily are also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Use of norethindrone acetate in combination with Lupron Depot 3.75 mg and Lupron Depot 11.25 mg is referred to as add-back therapy, and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of Lupron Depot 3.75 mg and Lupron Depot 11.25 mg.

Limitations of Use

For endometriosis: The total duration of therapy with Lupron Depot 3.75 mg and 11.75 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids)

When used concomitantly with iron therapy, Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Consider a one-month trial period on iron alone, as some women will respond to iron alone. Lupron Depot may be added if the response to iron alone is considered inadequate.

Limitations of Use

For uterine leiomyomata (fibroids): Lupron Depot 3.75 mg and 11.25 mg are not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

This section of the document is organized by the drug or drugs covered by this criteria. Limitations of use for the drug are also identified here.

Compendial Uses

- Breast cancer³
- Ovarian cancer – Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer, and less common ovarian cancers (grade 1 endometrioid carcinoma, low-grade serous carcinoma, carcinosarcoma [malignant mixed Müllerian tumors], mucinous carcinoma of the ovary, or clear cell carcinoma of the ovary)³
- Recurrent androgen receptor positive salivary gland tumors^{3,15}
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)⁶⁻⁸
- Preservation of ovarian function^{9,10}
- Prevention of recurrent menstrual related attacks in acute porphyria^{11,12}
- Uterine Sarcoma³

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties^{11,12-14}

Gender Dysphoria

The medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

The medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

Coverage Criteria

Endometriosis^{1,2}

Authorization of up to 6 months (one treatment course) may be granted to members for initial treatment of endometriosis.

Uterine Leiomyomata (Fibroids)^{1,2,4,5}

Authorization of up to 3 months may be granted for initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:

- Member has anemia due to uterine leiomyomata,
- Lupron Depot will be used prior to surgery for uterine leiomyomata.

Breast Cancer³

Authorization of 12 months may be granted for treatment of hormone receptor-positive breast cancer.

Ovarian Cancer³

Authorization of 12 months may be granted for treatment of persistent disease or recurrence of any of the following types of ovarian cancer when used as a single agent:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer
- Grade 1 endometrioid carcinoma
- Low-grade serous carcinoma
- Carcinosarcoma (malignant mixed Müllerian tumors)
- Mucinous carcinoma of the ovary
- Clear cell carcinoma of the ovary

Salivary Gland Tumors^{3,15}

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent or in combination with abiraterone and prednisone when the tumor is androgen receptor positive.

Gender Dysphoria^{6-8,13}

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Preservation of Ovarian Function^{9,10}

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria^{11,12}

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

Uterine Sarcoma³

Authorization of 12 months may be granted for treatment of uterine sarcoma in combination with an aromatase inhibitor (e.g. anastrozole, letrozole, exemestane) when the member is premenopausal and not suitable for surgery.

Continuation of Therapy

Endometriosis^{1,2}

Authorization of up to 6 months (for a lifetime maximum of 12 months total) may be granted for retreatment of endometriosis when both of the following criteria are met:

- The member has had a recurrence of symptoms.
- The member has a bone mineral density within normal limits.

Uterine Leiomyomata (Fibroids)^{1,2,4,5}

Authorization of up to 3 months (for a lifetime maximum of 6 months total) may be granted when either of the following criteria is met:

- Member has anemia due to uterine leiomyomata.
- Lupron Depot will be used prior to surgery for uterine leiomyomata.

Breast Cancer, Ovarian Cancer, Salivary Gland Tumors, and Uterine Sarcoma³

Authorization of 12 months may be granted for continued treatment of breast cancer, ovarian cancer, salivary gland tumors, and uterine sarcoma in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Gender Dysphoria^{13,14}

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Preservation of Ovarian Function and Prevention of Recurrent Menstrual Related Attacks in Acute Porphyria

All members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section.

Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

References

1. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
2. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 14, 2025.
4. Management of symptomatic uterine leiomyomas: ACOG Practice Bulletin No. 228. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2021 June 1;137(6):e100-e115.
5. Marret H, Fritel X, Ouldamer L, et al. Therapeutic management of uterine fibroid tumors: updated French guidelines. *European Journal of Obstetrics and Gynecology and Reproductive Biology*. 2012;165:156-164.
6. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
7. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
8. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender, and gender-diverse people, version. 8. 2022 ;23(Suppl 1): S1-S259. doi: 10.1080/26895269.2022.2100644
9. Oktay K, Harvey BE, Partridge AH, et al. Fertility preservation in patients with cancer: ASCO Clinical Practice Guideline Update. *J Clin Oncol*. 2018 Jul 1;36(19):1994-2001.
10. Clowse MEB, Behera MA, Anders CK, et al. Ovarian preservation by GnRH agonists during chemotherapy: a meta-analysis. *J Womens Health (Larchmt)*. 2009 Mar; 18(3): 311-319. doi:10.1089/jwh.2008.0857
11. Stein P, Badminton M, Barth J, et al. British and Irish Porphyria Network. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. *Ann Clin Biochem*. 2013 May;50(Pt 3):217-23.
12. Innala E, Bäckström T, Bixo M, et al. C. Evaluation of gonadotrophin-releasing hormone agonist treatment for prevention of menstrual-related attacks in acute porphyria. *Acta Obstet Gynecol* 2010;89:95-100.
13. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017; 5: 816-26.
14. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals>.
15. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2.2025. Accessed February 15, 2025. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.

Specialty Guideline Management

Lupron Depot-PED

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot-PED	leuprolide acetate depot suspension

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Lupron Depot-PED is indicated for the treatment of pediatric patients with central precocious puberty (CPP).

Compendial Uses⁷⁻⁹

Gender dysphoria (also known as transgender and gender diverse [TGD] persons)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty, laboratory report or medical record of a pubertal response to a gonadotropin

releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

Prescriber Specialties¹²

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

Coverage Criteria

Central Precocious Puberty (CPP)^{1-6,10}

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
 - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
 - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 mutations]).

Gender Dysphoria⁷⁻⁹

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Continuation of Therapy

Central Precocious Puberty (CPP)^{2,4,10}

Authorization of up to 12 months may be granted for continued treatment for CPP when the member meets all of the following criteria:

- The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

Gender Dysphoria¹¹

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.

- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

References

1. Lupron Depot-PED [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr*. 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Bangalore Krishna K, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: Update by an international consortium. *Horm Res Paediatr*. 2019;91(6):357-372.
5. Bangalore Krishna K, Silverman LA. Diagnosis of central precocious puberty. *Endocrinol Metab Clin North Am*. 2024;53(2):217-227.
6. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
8. Gender Identity Research and Education Society. Guidance for GPs and other clinicians on the treatment of gender variant people. UK Department of Health. Published March 10, 2008.
9. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
10. Cheuiche AV, da Silveira LG, de Paula LCP, et al. Diagnosis and management of precocious sexual maturation: an updated review. *Eur J Pediatr*. 2021;180(10):3073-3087.
11. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty Suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017; 5: 816-26.
12. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals>.
13. Popovic J, Geffner ME, Rogol AD, et al. Gonadotropin-releasing hormone analog therapies for children with central precocious puberty in the United States. *Front Pediatr*. 2022;10:968485. doi:10.3389/fped.2022.968485

CountyCare IL: MAVENCLAD (cladribine)

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CountyCare.

CRITERIA FOR APPROVAL

1. What is the diagnosis?
 - a. Relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) → **Go to #2**
 - b. Clinically isolated syndrome of multiple sclerosis → **Deny**
 - c. Other, please specify. _____ → **Deny**
2. Will the patient be taking the requested drug concomitantly with other disease modifying multiple sclerosis (MS) agents? Note: Ampyra and Nuedexta are not disease modifying.
 - a. Yes → **Deny**
 - b. No → **Go to #3**
3. Is the requested drug being prescribed by or in consultation with a neurologist?
 - a. Yes → **Go to #4**
 - b. No → **Deny**
4. Is the patient 18 years of age or older?
 - a. Yes → **Go to #6**
 - b. No → **Go to #5**
5. Has the prescriber evaluated the risks and benefits of treatment and attests the benefits outweigh the risks?
 - a. Yes → **Go to #6**
 - b. No → **Deny**
6. Is the request for continuation of therapy with the requested drug?
 - a. Yes → **Go to #10**
 - b. No → **Go to #50**

Continuation

Relapsing form of multiple sclerosis

10. How many cycles of the requested drug has the patient received previously? Note: The requested drug is administered based on weight over 4 to 5 days. This 4 to 5 day administration period is a cycle. Two cycles administered three to four weeks apart are a course. A maximum of two courses is allowed.
 - a. One cycle → **Go to #11**
 - b. Two cycles → **Go to #11**
 - c. Three cycles → **Go to #11**
 - d. Four cycle or more → **Deny**
11. Has the patient received a complete course (two 4-5 day cycles) of the requested drug in the last 43 weeks? Note: One course is two 4 to 5 day cycles administered 3 to 4 weeks apart.
 - a. Yes → **Deny**
 - b. No → **Approve for 45 days**

Reference number(s)
C29901-A

Initial

Relapsing form of multiple sclerosis

50. Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with at least TWO of the preferred disease modifying products: A) Rebif, B) Betaseron, C) Gilenya, D) Copaxone, E) Glatopa, F) dimethyl fumarate, or G) Tecfidera?

ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried.

- a. Yes → Go to #51
- b. No → Deny

51. Has the patient received any cycles of the requested drug previously? Note: The requested drug is administered based on weight over 4 to 5 days. This 4 to 5 day administration period is a cycle. Two cycles administered three to four weeks apart are a course. A maximum of two courses is allowed.

- a. No → Approve for 45 days
- b. One cycle → Approve for 45 days
- c. Two cycles → Approve for 45 days
- d. Three cycles → Approve for 45 days
- e. Four cycle or more → Deny

REFERENCE

1. CountyCare Prior Authorization Guidelines. Mavenclad (cladribine).

Document History

Created: SD 10/2025
Revised:

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

_____*Ashley M Robinson PharmD*_____
Signature Date 10/23/25

CountyCare
Client Name

Specialty Guideline Management

Mavyret

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Mavyret	glecaprevir-pibrentasvir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Mavyret is indicated for the treatment of adult and pediatric patients 3 years and older with:

- Acute or chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C).

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin^{1,2}

Genotype 1 infection

- Authorization of up to 8 weeks total may be granted for treatment-naïve members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and ribavirin [RBV], simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria is met:
 - Member has failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and has not received an NS3/4A protease inhibitor.
 - Member has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and has not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Genotype 3 infection

- Authorization of up to 8 weeks total may be granted for treatment-naïve members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A

protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.

- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following is met:
 - Member has failed prior treatment with an interferon-based regimen with or without RBV and has not received an NS3/4A protease inhibitor or NS5A inhibitor.
 - Member has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon) without sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) or prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Genotype 4 infection

- Authorization of up to 8 weeks total may be granted for treatment-naïve members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis and human immunodeficiency virus (HIV) coinfection.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Genotype 2, 5, or 6 infection

- Authorization of up to 8 weeks total may be granted for treatment-naïve members without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A

inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.

- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, or telaprevir in combination with peginterferon and RBV, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
- Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
- Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

Unknown genotype/genotype could not be determined²

Authorization of up to 8 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis or with compensated cirrhosis who are treatment-naïve and do not have any of the following characteristics:

- Compensated cirrhosis with end-stage renal disease (i.e., estimated glomerular filtration rate [eGFR] < 30 mL/min)
- Hepatitis B surface antigen (HBsAG) positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Note: Genotype testing is required for members with any of the characteristics listed.

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis.
- Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 1 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 3 infection post liver transplantation without cirrhosis or with compensated cirrhosis who have not received an NS3/4A protease inhibitor or NS5A inhibitor when either of following criteria is met:

Reference number(s)
Policy: 2242-A
Qsets: 5920-A, 6284-A

- Member has failed prior treatment with peginterferon alfa (PEG-IFN) and RBV.
- Member has failed prior treatment with sofosbuvir and RBV with or without PEG-IFN.

Kidney transplant recipients

- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.
- Authorization of up to 16 weeks total may be granted for members with HCV genotype 1 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir [Mavyret]) and who have not received an NS3/4A protease inhibitor.
- Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who have not received an NS3/4A protease inhibitor or NS5A inhibitor when either of the criteria is met:
 - Member has failed prior treatment with PEG-IFN and RBV.
 - Member has failed prior treatment with sofosbuvir and RBV with or without PEG-IFN.

Organ recipient from HCV-viremic donor

- Authorization of up to 12 weeks total may be granted for members who have received a liver transplant from an HCV-viremic donor.
- Authorization of up to 8 weeks total may be granted for members who have received a non-liver organ transplant from an HCV-viremic donor when treatment is initiated in the first week after transplant.
- Authorization of up to 12 weeks total may be granted for members who have received a non-liver organ transplant from an HCV-viremic donor when treatment is initiated more than one week after transplant.

Hepatitis C Virus Infection, in combination with Sofosbuvir and Ribavirin²

Authorization of up to 16 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis when either of the following criteria is met:

- Member has failed prior treatment with glecaprevir/pibrentasvir (Mavyret). Authorization of up to 24 weeks total may be granted for members following failure with sofosbuvir with glecaprevir/pibrentasvir (Mavyret).
- Member has failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi). Authorization of up to 24 weeks total may be granted for members with extremely difficult cases (e.g., genotype 3 with cirrhosis).

Hepatitis C Virus and HIV Coinfection^{1,2}

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness
 - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
 - Hepatitis B virus screening results
 - Metavir/Fibrosis score

References

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; June 2025.
2. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). HCV guidance: Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Guideline Management

Mayzent

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Mayzent	siponimod

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Mayzent is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing forms of multiple sclerosis¹

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically isolated syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Mayzent.

Other Criteria

- Members will not use Mayzent concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Reference

1. Mayzent [package insert]. East Hanover, NJ: Novartis; July 2024.

Prior Authorization Policy

Methylphenidate Products

Products Referenced by this document

Brand Name	Generic Name
Azstarys®	serdexmethylphenidate / dexmethylphenidate
Focalin®	dexmethylphenidate
Adhansia®	methylphenidate
Aptensio®	methylphenidate
Concerta®	methylphenidate
Cotempla®	methylphenidate
Daytrana®	methylphenidate
Jornay PM®	methylphenidate
Methylin®	methylphenidate
Methylphenidate	methylphenidate
Quillichew®	methylphenidate
Quillivant®	methylphenidate
Relexxii®	methylphenidate
Ritalin®	methylphenidate

Required Documentation

To support review of a prior authorization request, documentation should clearly identify:

- Member diagnosis
 - Member age
 - Requested medication, strength, and formulation
 - Relevant chart notes supporting the clinical need for therapy
 - Documentation of positive clinical response for continuation requests
 - Documentation of cardiac risk screening when applicable
 - Documentation supporting quantity requests when exceeding plan limits
-

Coverage Criteria by Indication

ADHD — Adults (≥ 18 years)

Authorization of 12 months may be granted when:

- ADHD diagnosis is documented, and
- For continuation requests, documentation shows positive clinical response*

ADHD — Pediatrics (< 18 years)

Authorization of 12 months may be granted when:

- ADHD diagnosis is documented, and
- Medication use is age-appropriate based on FDA labeling or compendia support.

Narcolepsy

Authorization of 12 months may be granted when:

- Diagnosis of narcolepsy is documented,
- Member is ≥ 18 years old,
- Diagnosis is confirmed by sleep study,
- For continuation requests, documentation shows positive clinical response*

Idiopathic Hypersomnia / Klein-Levin Syndrome / Secondary Hypersomnia

Authorization of 12 months may be granted when:

- Member is ≥ 18 years old,
 - Diagnosis is confirmed by sleep study,
 - For continuation requests, documentation shows positive clinical response*
-

Formulary Exception Criteria

Non-Preferred Agents

Authorization of 12 months may be granted when:

- ADHD/ADD- Previous trial of at least 2 preferred products
- Narcolepsy- Previous trial of at least 1 preferred product
- For continuation requests, documentation shows positive clinical response* and reassessment within the past year

Formulation Exceptions (ODT, chewable, oral solution, patch)

Authorization of 12 months may be granted when:

- Documentation shows difficulty swallowing tablets/capsules or medical need for alternate formulation

Quantity Limit Override

Authorization of 12 months for the requested quantity may be granted when:

- The requested dose is within FDA-approved dosing
- Supported by clinical literature or recognized treatment guidelines.

Authorization Duration

All authorizations are issued for 12 months.

*Positive Clinical Response: **ADD/ADHD Examples:** Improvement in hyperactivity, impulsivity, inattention, organization skills, time management, sleep patterns, emotional management, or self-esteem. **Narcolepsy Examples:** improvement in excessive daytime sleepiness, improvement in work/school performance/attendance, improvement in quality of life.

Specialty Guideline Management

mifepristone-Korlym

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Korlym	mifepristone

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Limitations of Use:

Should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: pretreatment hemoglobin A1C level (for initial requests)

Coverage Criteria

Cushing's Syndrome/Disease¹⁻⁴

Authorization of 6 months may be granted for treatment of Cushing's syndrome/disease when all of the following criteria are met:

- Member has type 2 diabetes mellitus or glucose intolerance
- The requested drug is being prescribed to control hyperglycemia secondary to hypercortisolism
- Member has had surgery that was not curative OR member is not a candidate for surgery
- If the member is able to become pregnant, a negative pregnancy test is required before initiating therapy

Continuation of Therapy

Cushing's Syndrome/Disease¹⁻⁴

Authorization of 12 months may be granted if the member has achieved or maintained an adequate positive response, or there is improvement in signs and symptoms of the condition.

References

1. Korlym [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; September 2024.
2. Mifepristone [package insert]. Menlo Park, CA: Corcept Therapeutics Incorporated; September 2024.
3. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818
4. Fleseriu M, Auchus R, Bancos I, et al. Consensus on Diagnosis and Management of Cushing's Disease: A Guideline Update. Lancet Diabetes Endocrinol. 2021;9(12):847-875. doi:10.1016/S2213-8587(21)00235-7

Initial Prior Authorization

Myfembree

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Myfembree	Relugolix/estradiol/norethindrone acetate

Indications

FDA-approved Indications

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas

Myfembree is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Moderate to Severe Pain Associated with Endometriosis

Myfembree is indicated for the management of moderate to severe pain associated with endometriosis in premenopausal women.

Limitations of Use

Use of Myfembree should be limited to 24 months due to the risk of continued bone loss that may not be reversible.

Coverage Criteria

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas (Fibroids)

Authorization may be granted when the requested drug is being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) when ALL the following criteria is met:

- The patient is premenopausal.
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient must not have already received ANY of the following:
 - Greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree).
 - Greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily.

Moderate to Severe Pain Associated with Endometriosis

Authorization may be granted when the requested drug is being prescribed for the management of moderate to severe pain associated with endometriosis when ALL the following criteria are met:

- The patient is premenopausal.
- The patient has NOT received the maximum recommended treatment course of 12 months of Lupron Depot or Lupaneta Pack OR 6 months of Synarel or Zoladex.
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient must not have already received ANY of the following:
 - Greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree).
 - Greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily.

Duration of Approval (DOA)

- 4752-A: Total additive duration: 24 months (see chart)

Cumulative months of prior treatment with an elagolix- and/or relugolix-containing product	Duration of Approval (in months)
No prior treatment	12

Cumulative months of prior treatment with an elagolix- and/or relugolix-containing product	Duration of Approval (in months)
≤ 12	12
13	11
14	10
15	9
16	8
17	7
18	6
19	5
20	4
21	3
22	2
23	1

References

1. Myfembree [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc.; July 2024.
2. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc.; June 2015.
3. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
4. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
5. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
6. Synarel [package insert]. New York, NY: Pfizer Inc.; January 2023.
7. Zoladex 3.6 mg [package insert]. Deerfield, IL: TerSera Therapeutics LLC; March 2023.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 29, 2024.
9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2024).
10. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. Am Fam Physician. 2013;87(2):107.
11. Management of endometriosis. Practice Bulletin No. 114. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2010;116:223-236.
12. Edi R, Cheng T. Endometriosis: Evaluation and Treatment. Am Fam Physician. 2022;106(4):397-404.

Initial Prior Authorization with Quantity Limit Nayzilam

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Nayzilam	midazolam	nasal spray

Indications

FDA-approved Indications

Nayzilam is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

Coverage Criteria

Intermittent, Stereotypic Episodes of Frequent Seizure Activity

Authorization may be granted when the requested drug is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern in a patient with epilepsy when the following criteria is met:

Reference number(s)
3102-C

- The patient is 12 years of age or older.

Quantity Limits Apply

10 nasal spray units per 25 days or 30 nasal spray units per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3102-C: DOA: 12 months

References

1. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; January 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 2, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/02/2025).

Specialty Guideline Management

Nemluvio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nemluvio	nemolizumab-ilto

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

- Treatment of adult patients with prurigo nodularis (PN).
- Treatment of adult and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Atopic dermatitis

Initial requests

- Chart notes or medical record documentation showing affected area(s) and body surface area (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prurigo nodularis (PN)

Initial requests

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
- Chart notes, medical record documentation, or claims history supporting previous therapies tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

Coverage Criteria

Atopic dermatitis

Authorization of 4 months may be granted for members 12 years of age or older who have previously received a biologic (e.g., Adbry, Dupixent, Ebglyss) or systemic targeted synthetic drug (e.g., Cibinqo, Rinvoq) indicated for moderate-to-severe atopic dermatitis in the past year. The requested medication must be prescribed in combination with a low potency to medium potency topical corticosteroid (see Appendix A) or topical calcineurin inhibitor, unless the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 12 years of age or older when all of the following criteria are met:

- Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- Member meets either of the following:
 - Member has had an inadequate treatment response with one of the following in the past year:
 - A medium potency to super-high potency topical corticosteroid (see Appendix A)
 - A topical calcineurin inhibitor
 - A topical Janus kinase (JAK) inhibitor
 - A topical phosphodiesterase-4 (PDE-4) inhibitor
 - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, and topical PDE-4 inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
- Member is prescribed the requested medication in combination with a low potency to medium potency topical corticosteroid (see Appendix A) or topical calcineurin inhibitor or the use of a low potency to medium potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

Prurigo Nodularis (PN)

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for prurigo nodularis in the past year.

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

- Member has pruritus lasting at least 6 weeks.
- Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
 - Member has had an inadequate response to one of the following:
 - A medium to super-high potency topical corticosteroid (see Appendix A)
 - A topical calcineurin inhibitor
 - Phototherapy (e.g., UVB, PUVA)
 - Pharmacologic treatment with methotrexate or cyclosporine
 - Member has had an intolerance or a clinical reason to avoid either of the following:
 - Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor

- Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

Continuation of Therapy

Atopic dermatitis

Authorization of 12 months may be granted for members 12 years of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Prurigo Nodularis (PN)

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by either of the following:

- Low disease activity (i.e., clear or almost clear skin)
- Reduction in pruritis intensity and improvement in extent and severity of nodular lesions

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Appendix

Appendix A: Table. Relative Potency of Select Topical Corticosteroid Products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%

Potency	Drug	Dosage form	Strength
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Nemluvio [package insert]. Dallas, TX: Galderma Laboratories; December 2024.
2. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 18, 2024. Accessed November 9, 2024.
3. Ständer HF, Elmariah S, Zeidler C, et al. Diagnostic and treatment algorithm for chronic nodular prurigo. J Am Acad Dermatol. 2020;82(2):460-468.
4. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84(3):747-760.
5. Cyclosporine. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; August 15, 2024. Accessed August 25, 2024.
6. Methotrexate. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; July 30, 2024. Accessed August 25, 2024.
7. Eichenfield LF, Tom WL, Chamlin SL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-351.
8. Sidbury R, Alikhan A, Bercovitch L, et. al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
9. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. J Am Acad Dermatol. 2024 Feb;90(2):e43-e56.

Specialty Guideline Management

Neulasta and pegfilgrastim biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Neulasta	pegfilgrastim
Fulphila	pegfilgrastim-jmdb
Fylnetra	pegfilgrastim-pbbk
Nyvepria	pegfilgrastim-apgf
Stimufend	pegfilgrastim-fpgk
Udenyca	pegfilgrastim-cbqv
Ziextenzo	pegfilgrastim-bmez

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Neulasta

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Fulphila

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Fulphila is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

Udenyca

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Udenyca is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Udenyca is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Ziextenzo

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Ziextenzo is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Ziextenzo is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Nyvepria

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Nyvepria is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Fylnetra

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Fylnetra is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Stimufend

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Stimufend is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Compendial Use

- Stem cell transplantation-related indications
- Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
- Hematopoietic Acute Radiation Syndrome
- Hairy cell leukemia, neutropenic fever

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Primary Prophylaxis of Febrile Neutropenia

- Documentation must be provided of the member's diagnosis and chemotherapeutic regimen.
- If chemotherapeutic regimen has a low or intermediate risk of febrile neutropenia (less than 20%), documentation must be provided outlining the member's risk factors that confirm the member is at high risk for febrile neutropenia.

Coverage Criteria

Prevention of Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy

Authorization of 6 months may be granted for prevention of febrile neutropenia when all of the following criteria are met :

- The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
- The member will not receive chemotherapy at the same time as they receive radiation therapy.

- The requested medication will not be administered with weekly chemotherapy regimens.
- One of the following criteria is met :
 - The requested medication will be used for primary prophylaxis in members with a solid tumor or non-myeloid malignancies who have received, are currently receiving, or will be receiving any of the following:
 - Myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia (FN) (See Appendix A).
 - Myelosuppressive anti-cancer therapy that is expected to result in 10 – 19% risk of FN (See Appendix B) and who are considered to be at high risk of FN because of bone marrow compromise, co-morbidities, or other patient specific risk factors (See Appendix C).
 - Myelosuppressive anti-cancer therapy that is expected to result in less than 10% risk of FN and who have at least 2 patient-related risk factors (See Appendix C).
 - The requested medication will be used for secondary prophylaxis in members with solid tumors or non-myeloid malignancies who experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy, with the same dose and scheduled planned for the current cycle (for which primary prophylaxis was not received).

Other Indications

Authorization of 6 months may be granted for members with any of the following indications:

- Stem cell transplantation-related indications
 - Hematopoietic Subsyndrome of Acute Radiation Syndrome
 - Treatment for radiation-induced myelosuppression following a radiological/nuclear incident
 - Hairy cell leukemia
- Members with hairy cell leukemia with neutropenic fever following chemotherapy

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Appendix

APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Acute Lymphoblastic Leukemia

Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)

Bladder Cancer

Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

Bone Cancer

- VAIA (vincristine, doxorubicin, ifosfamide, and dactinomycin)
- VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
- Cisplatin/doxorubicin
- VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
- VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)

Breast Cancer

- Dose-dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel
- TAC (docetaxel, doxorubicin, cyclophosphamide)
- TC (docetaxel, cyclophosphamide)
- TCH (docetaxel, carboplatin, trastuzumab)

Head and Neck Squamous Cell Carcinoma

TPF (docetaxel, cisplatin, 5-fluorouracil)

Hodgkin Lymphoma

- Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
- Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)

Kidney Cancer

Doxorubicin/gemcitabine

Non-Hodgkin's Lymphoma

- CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin

- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) ± rituximab
- ICE (ifosfamide, carboplatin, etoposide) ± rituximab
- Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
- MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± rituximab
- DHAP (dexamethasone, cisplatin, cytarabine) ± rituximab
- ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) ± rituximab
- HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
- Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone)

Melanoma

Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma

- VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
- DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)

Ovarian Cancer

- Topotecan ± bevacizumab
- Docetaxel

Soft Tissue Sarcoma

- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
- Doxorubicin
- Ifosfamide/doxorubicin

Small Cell Lung Cancer

Topotecan

Testicular Cancer

- VelP (vinblastine, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)

Gestational Trophoblastic Neoplasia

- EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
- EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
- EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
- TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)

Reference number(s)
1931-A

- BEP (bleomycin, etoposide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- ICE (ifosfamide, carboplatin, etoposide)

Wilms Tumor

- Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
- Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Occult Primary – Adenocarcinoma

Gemcitabine/docetaxel

Breast Cancer

- Docetaxel ± trastuzumab
- AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
- AC + sequential docetaxel + trastuzumab
- Paclitaxel every 21 days ± trastuzumab
- TC (docetaxel, cyclophosphamide)

Cervical Cancer

- Irinotecan
- Cisplatin/topotecan
- Paclitaxel/cisplatin ± bevacizumab
- Topotecan

Colorectal Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Esophageal and Gastric Cancers

Irinotecan/cisplatin

Non-Hodgkin's Lymphomas

- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin

- CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
- Bendamustine

Non-Small Cell Lung Cancer

- Cisplatin/paclitaxel
- Cisplatin/vinorelbine
- Cisplatin/docetaxel
- Cisplatin/etoposide
- Carboplatin/paclitaxel
- Docetaxel

Ovarian Cancer

Carboplatin/docetaxel

Pancreatic Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Prostate Cancer

Cabazitaxel

Small Cell Lung Cancer

Etoposide/carboplatin

Testicular Cancer

- BEP (bleomycin, etoposide, cisplatin)
- Etoposide/cisplatin

Uterine Sarcoma

Docetaxel

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

APPENDIX C: Patient Risk Factors

This list is not all-inclusive.

- Active infections, open wounds, or recent surgery
- Age greater than or equal to 65 years
- Bone marrow involvement by tumor producing cytopenias
- Previous chemotherapy or radiation therapy
- Poor nutritional status
- Poor performance status
- Previous episodes of FN

- Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
- Persistent neutropenia

References

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
2. Fulphila [package insert]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
3. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
4. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; February 2024.
5. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
6. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
7. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
8. The NCCN Drugs & Biologics Compendium © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> Accessed June 5, 2024.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf Accessed June 6, 2024.
10. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at <https://www.micromedexsolutions.com> (Accessed: June 6, 2024).
11. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199-3212.
12. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hairy Cell Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf Accessed June 6, 2024.
13. Smith TJ, Khatcheressian J, Lyman GH, et al. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol. 2006;24(19):3187-3205.
14. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gestational Trophoblastic Neoplasia. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/gtn.pdf Accessed June 5, 2024.
15. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma). Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/wilms_tumor.pdf Accessed June 6, 2024.

Initial Prior Authorization with Logic Nexletol, Nexlizet

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nexletol	bempedoic acid
Nexlizet	bempedoic acid/ezetimibe

Indications

FDA-approved Indications

Nexletol

Nexletol is indicated:

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

Nexlizet

Nexlizet, a combination of bempedoic acid and ezetimibe, is indicated:

Reference number(s)
3648-D

- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

The bempedoic acid component of Nexlizet is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with:
 - established cardiovascular disease (CVD), or
 - a high risk for a CVD event but without established CVD

Screen out Logic

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of a generic or brand statin or statin combination within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the screen out logic, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Primary Hyperlipidemia, Including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet.
- The patient meets ONE of the following:
 - The requested drug will be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies.
 - Concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is NOT possible.

Risk Reduction of Myocardial Infarction and Coronary Revascularization

Authorization may be granted when the requested drug is being prescribed to reduce the risk of myocardial infarction and coronary revascularization in an adult when ALL of the following criteria are met:

- The patient has ANY of the following: established cardiovascular disease (CVD), a high risk for a CVD event but without established CVD.
- The patient meets ONE of the following:
 - The patient experienced an intolerance to the recommended statin therapy.
 - The patient has a contraindication that would prohibit use of statin therapy.

Continuation of Therapy

Primary Hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet.
- The patient has achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline.

Risk Reduction of Myocardial Infarction and Coronary Revascularization

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

Duration of Approval (DOA)

- 3648-D: DOA: 36 months

References

1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.

Reference number(s)
3648-D

3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/24/2024).
5. McGowan MP, Dehkordi SHH, Moriarty PM et. al. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. *J AM Heart Assoc.* 2019;8:e013225. DOI: 10.1161/JAHA. 119.013225.
6. Grundy SM, Stone NJ, Bailey AL, et al. 2018
AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation* 2019 Jun 18;139(25):e1082-1143.
7. Handelsman Y, Jellinger PS, Guerin CK, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia and Prevention of Cardiovascular Disease Algorithm -2020 Executive Summary. *Endocr Pract.* 2020;26(10):1196-1224.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol.* 2022;80:1366-1418.

Specialty Guideline Management

Nucala

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nucala	mepolizumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Nucala is indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Nucala is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.
- Nucala is indicated for the add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Nucala is indicated for the add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitations of Use:

- Not for relief of acute bronchospasm or status asthmaticus

Reference number(s)
1655-A

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Asthma

Initial requests

- Chart notes or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

EGPA

Initial requests

- Chart notes or medical record showing pretreatment blood eosinophil count or percentage of blood eosinophil level (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting beneficial response to treatment.

HES

Initial requests

- FIP1L1-PDGFR fusion gene test results.
- Chart notes or medical record showing pretreatment blood eosinophil count.

Continuation requests

- FIP1L1-PDGFR fusion gene test results.
- Chart notes or medical record documentation supporting improvement in HES control.

CRSwNP

Initial requests

- Chart notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., polyps location, size), Meltzer Clinical Score, or endoscopic nasal polyps score (NPS) (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

COPD

Initial requests

- Chart notes or medical record documentation demonstrating classic signs and/or symptoms of COPD (where applicable).
- Chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).
- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication (where applicable).
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Exclusions

Coverage will not be provided for treatment of HES for members with any of the following exclusions:

- HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus [HIV] infection, non-hematologic malignancy).
- FIP1L1-PDGFR kinase-positive HES.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Asthma: allergist/immunologist or pulmonologist
- Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist

Coverage Criteria

Asthma^{1-7,16}

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Dupixent, Cinqair) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Member meets either of the following criteria:
 - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
 - Member is dependent on systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s).
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - High-dose inhaled corticosteroid.
 - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline).
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)^{1,8-11,17}

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Fasenra) indicated for EGPA in the past year.

Authorization of 12 months may be granted for treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
- Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
- Member has at least two of the following disease characteristics of EGPA:^{8,9}
 - Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - Pulmonary infiltrates, non-fixed
 - Sino-nasal abnormality
 - Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - Alveolar hemorrhage (by bronchoalveolar lavage)
 - Palpable purpura
 - Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
- Member has had at least one relapse (i.e., requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication or has refractory disease.

Hypereosinophilic Syndrome (HES)^{1,12,13}

Authorization of 12 months may be granted for treatment of HES when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
- Member will not use the requested medication as monotherapy.
- Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
- Member has had HES for at least 6 months.
- Member has experienced at least two HES flares within the past 12 months.

Chronic Rhinosinusitis with Nasal Polyps^{1,14,15,18-20}

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent, Xolair) indicated for CRSwNP in the past year.

Authorization of 6 months may be granted for treatment of chronic rhinosinusitis with nasal polyps when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- The member has CRSwNP despite one of the following:
 - Prior sino-nasal surgery.
 - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated.
- Member has one of the following:
 - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
 - Meltzer Clinical Score of 2 or higher in both nostrils.
 - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - Rhinorrhea (anterior/posterior).
 - Reduction or loss of smell.
 - Facial pain or pressure.
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Chronic Obstructive Pulmonary Disease (COPD)^{1,21-23}

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for COPD in the past year.

Authorization of 12 months may be granted for treatment of COPD in members when all of the following criteria are met:

- Member is 18 years of age or older.
- Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV₁)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.
- Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
- Member has an absolute blood eosinophil count of at least 150 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing either of the following in the last year:

- At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.
- One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets either of the following:
 - Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and long-acting beta₂-agonist [LABA]).
 - Member is currently receiving a LAMA and LABA, and has a contraindication to ICS.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Continuation of Therapy

Asthma^{1-7,16}

Authorization of 12 months may be granted for continuation of treatment of severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations.
 - A reduction in the daily maintenance oral corticosteroid dose.⁷
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)^{1,8-11,17}

Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has beneficial response to treatment with the requested medication as demonstrated by any of the following:
 - A reduction in the frequency of relapses.
 - A reduction or discontinuance of daily oral corticosteroid dose.
 - No active vasculitis.

Hypereosinophilic Syndrome (HES)¹

Authorization of 12 months may be granted for continuation of treatment of HES when both of the following criteria are met:

- Member is 12 years of age or older.
- Member has experienced a reduction in HES flares since starting treatment with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps^{1,14,15}

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis when all of the following are met:

- Member is 18 years of age or older.
- Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Chronic Obstructive Pulmonary Disease (COPD)^{1,21-23}

Authorization of 12 months may be granted for continuation of treatment of COPD when all of the following criteria are met:

- Members is 18 years of age or older.
- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV₁) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

References

1. Nucala [package insert]. Durham, NC: GlaxoSmithKline; May 2025.
2. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1198-1207.
3. Bel EH, Wenzel SE, Thompson PJ, et al. Oral glucocorticoid-sparing effect of mepolizumab in eosinophilic asthma. *N Engl J Med*. 2014;371(13):1189-1197.
4. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Asthma Management Guidelines: Focused Updates 2020. Bethesda, MD: National Heart Lung and Blood Institute; December 2020. Available at: <https://www.nhlbi.nih.gov/sites/default/files/publications/AsthmaManagementGuidelinesReport-2-4-21.pdf>. Accessed March 1, 2025.
5. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
6. Kew KM, Karner C, Mindus SM. Combination formoterol and budesonide as maintenance and reliever therapy versus combination inhaler maintenance for chronic asthma in adults and children (review). *Cochrane Database Syst Rev*. 2013;12:CD009019.
7. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: <https://annualmeeting.aaaai.org/>. Accessed March 8, 2025.
8. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med*. 2017;18;376(20):1921-1932.
9. GlaxoSmithKline. A Study to Investigate Mepolizumab in the Treatment of Eosinophilic Granulomatosis With Polyangiitis. Available from <https://clinicaltrials.gov/ct2/show/record/NCT02020889>. NLM identifier: NCT02020889. Accessed March 14, 2025.
10. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force Recommendations for evaluation and management. *Eur J Intern Med*. 2015;26(7):545-553.
11. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis*. 2024 Jan 2;83(1):30-47.
12. Shomali W, Gotlib J. World Health Organization and International Consensus Classification of eosinophilic disorders: 2024 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2024 May;99(5):946-968.
13. Butt NM, Lambert J, Ali S, et al. Guideline for the investigation and management of eosinophilia. *Br J Haematol*. 2017;176(4):553-572.
14. Han JK, Bachert C, Fokkens W, et al. Mepolizumab for chronic rhinosinusitis with nasal polyps (SYNAPSE): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med*. 2021;9(10):1141-1153.
15. Bachert C, Han JK, Wagenmann M, et al. EUFOREA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRSwNP) and biologics: Definitions and management. *J Allergy Clin Immunol*. 2021;147(1):29-36.

16. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.
17. American College of Rheumatology. 2021 American college of rheumatology/vasculitis foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. Arthritis & Rheumatology. <https://vasculitisfoundation.org/wp-content/uploads/2024/01/2021-ACR-VF-Guideline-for-Management-of-ANCA-Associated-Vasculitis.pdf>. Accessed March 16, 2025.
18. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. Rhinology. 2020;58(Suppl S29):1-464.
19. Hopkins C. Chronic Rhinosinusitis with Nasal Polyps. N Engl J Med. 2019;381(1):55-63.
20. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. 2023 Feb;151(2):386-398.
21. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2024 Report). Available at: <https://goldcopd.org/2024-gold-report/>. Accessed May 30, 2025.
22. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT04133909. Mepolizumab as Add-on Treatment IN Participants With COPD Characterized by Frequent Exacerbations and Eosinophil Level (MATINEE). Last updated December 11, 2024. Accessed 2025 June 2. Available from: <https://clinicaltrials.gov/study/NCT04133909>.
23. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT02105948. Study to Evaluate Efficacy and Safety of Mepolizumab for Frequently Exacerbating Chronic Obstructive Pulmonary Disease (COPD) Patients. Last updated August 31, 2018. Accessed 2025 June 2. Available from: <https://clinicaltrials.gov/study/NCT02105948>.

Specialty Guideline Management

Ocrevus-Ocrevus Zunovo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ocrevus	ocrelizumab
Ocrevus Zunovo	ocrelizumab and hyaluronidase-ocsq

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

- Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Treatment of primary progressive MS, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis^{1,2,4}

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome^{1,2,4}

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

Primary Progressive Multiple Sclerosis^{1,2,4}

Authorization of 12 months may be granted to members for treatment of primary progressive multiple sclerosis.

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria who are experiencing disease stability or improvement while receiving the requested drug.

Other Criteria

- Members will not use the requested drug concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.³

References

1. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Ocrevus Zunovo [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
3. Pediatric MS. National Multiple Sclerosis Society. Updated March 2023. Accessed March 20, 2025. <https://www.nationalmssociety.org/for-professionals/for-healthcare-professionals/managing-and-treating-ms/pediatric-ms>.
4. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology*. 2018;90(17):777-788.

Specialty Guideline Management

Ofev

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ofev	nintedanib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Treatment of adults with idiopathic pulmonary fibrosis (IPF).

Treatment of adults with chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review (where applicable):

- Result of a chest high-resolution computed tomography (HRCT) study.
- Pathology report of lung biopsy (if performed).

Coverage Criteria

Idiopathic Pulmonary Fibrosis (IPF)^{1,2}

Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes both of the following:

- Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded .
- The member meets either of the following:
 - Member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern.
 - Member has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype^{1,2,5}

Authorization of 12 months may be granted for treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype (progressive pulmonary fibrosis [PPF]) when the member meets both of the following:

- The member has completed a high-resolution computed tomography (HRCT) study of the chest that shows fibrosis affecting at least 10 percent of the lungs.
- The member has progressive disease (e.g., forced vital capacity [FVC] decline greater than or equal to 10% of the predicted value, worsening respiratory symptoms, increased extent of fibrosis on HRCT).

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)^{1,3,4,6,7}

Authorization of 12 months may be granted for treatment of systemic sclerosis-associated interstitial lung disease when the member's diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy for an indication listed in the coverage criteria section may be granted an authorization of 12 months when the member is currently receiving treatment with Ofev.

Other

Note: If the member is a current smoker, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking cessation options.

References

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. October 2024.
2. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults: An official ATS/ERS/JRS/ALAT clinical practice guideline. *Am J Respir Crit Care Med*. 2022;205(9):e18-e47.
3. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for systemic sclerosis-associated interstitial lung disease. *N Engl J Med*. 2019;380(26):2518-2528.
4. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. *Arthritis Rheum*. 2013;65(11):2737-47.
5. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. *N Engl J Med*. 2019;381(18):1718-1727.
6. Rahaghi FF, Hsu VM, Kaner RJ, et al. Expert consensus on the management of systemic sclerosis-associated interstitial lung disease. *Respir Res*. 2023;24(1):6-16.
7. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Ann Rheum Dis*. 2024;0:1-12.

Specialty Guideline Management

Olumiant

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Olumiant	baricitinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.
- Treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
- Treatment of adult patients with severe alopecia areata.

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving Olumiant for the treatment of COVID-19 will be managed according to the member's inpatient benefit.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Alopecia areata

Initial requests

Chart notes or medical record documentation supporting at least 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis: rheumatologist
- Alopecia areata: dermatologist

Coverage Criteria

Rheumatoid arthritis (RA)^{1,3,4}

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor.

Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active RA.

Alopecia areata^{1,5,6}

Authorization of 12 months may be granted for adult members who have previously received a targeted synthetic drug (e.g., Leqselvi, Litfulo) indicated for treatment of severe alopecia areata in the past year.

Authorization of 12 months may be granted for adult members for treatment of severe alopecia areata when both of the following criteria are met:

- Member has at least 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
- Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).

Continuation of Therapy

Rheumatoid arthritis (RA)^{1,3,4}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Alopecia areata^{1,5}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for severe alopecia areata and who achieve or maintain a positive clinical response as evidenced by an improvement in signs and symptoms of the condition from baseline (e.g., increased scalp hair coverage, 80% total scalp hair coverage [SALT score of 20 or less]).

Other^{1,2}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
2. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 4, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
5. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18):1687-1699.
6. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18)(suppl):1-77.

Initial Step Therapy; Initial Limit; Post Limit Prior Authorization Extended-Release Opioid Analgesics Step Therapy with Morphine Milliequivalent (MME) Limit and Post Limit

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Belbuca	buprenorphine	buccal film
Butrans	buprenorphine	transdermal system
ConZip	tramadol hydrochloride extended-release	capsules
fentanyl (all brands)	fentanyl	transdermal system
hydrocodone bitartrate extended-release (generic Zohydro ER – brand unavailable)	hydrocodone bitartrate extended-release	capsules
hydromorphone hydrochloride extended-release (generic Exalgo – brand unavailable)	hydromorphone hydrochloride extended-release	tablets
Hysingla ER	hydrocodone bitartrate extended-release	tablets

Reference number(s)
2219-M

Brand Name	Generic Name	Dosage Form
methadone 5 mg, 10 mg (all brands)	methadone hydrochloride	tablets
Methadone 200 mg/20 mL	methadone hydrochloride	injection
Methadone Intensol 10 mg/mL	methadone hydrochloride	oral concentrate
methadone 5 mg/5 mL & 10 mg/5 mL (all brands)	methadone hydrochloride	oral solution
morphine extended-release (generic Avinza – brand unavailable)	morphine extended-release	capsules
morphine extended-release (generic Kadian – brand unavailable)	morphine extended-release	capsules
MS Contin	morphine extended-release	tablets
Nucynta ER	tapentadol extended-release	tablets
OxyContin	oxycodone hydrochloride extended-release	tablets
oxymorphone hydrochloride extended-release (generic Opana ER – brand unavailable)	oxymorphone hydrochloride extended-release	tablets
tramadol hydrochloride extended-release (generic Ryzolt – brand unavailable)	tramadol hydrochloride extended-release	tablets
tramadol hydrochloride extended-release (generic Ultram ER – brand unavailable)	tramadol hydrochloride extended-release	tablets
Xtampza ER	oxycodone extended-release	capsules

Indications

FDA-approved Indications

Belbuca, Butrans (buprenorphine)

Belbuca, Butrans are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Belbuca, Butrans for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Belbuca, Butrans are not indicated as an as-needed (prn) analgesic.

ConZip (tramadol hydrochloride extended-release)

ConZip is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve ConZip use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- ConZip is not indicated as an as-needed (prn) analgesic.

Fentanyl Transdermal System

Fentanyl transdermal system is indicated for the management of severe and persistent pain in opioid tolerant patients, that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Patients considered opioid-tolerant are those who are taking, for one week or longer, at least 60 mg morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve fentanyl transdermal system for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-

release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- Fentanyl transdermal system is not indicated as an as-needed (prn) analgesic.

Hydrocodone Bitartrate Extended-Release

Hydrocodone bitartrate extended-release capsules are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve hydrocodone bitartrate extended-release capsules for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hydrocodone bitartrate extended-release capsules are not indicated as an as-needed (prn) analgesic.

Hydromorphone Hydrochloride Extended-Release

Hydromorphone hydrochloride extended-release tablets are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Patients considered opioid tolerant are those who are receiving, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve hydromorphone hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hydromorphone hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Hysingla ER (hydrocodone bitartrate extended-release)

Hysingla ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Hysingla ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Hysingla ER is not indicated as an as-needed (prn) analgesic.

Methadone Hydrochloride Injection

Methadone Hydrochloride Injection is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Methadone Hydrochloride Injection for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Injection is not indicated as an as-needed (prn) analgesic.

For use in temporary treatment of opioid dependence in patients unable to take oral medication.

Limitations of Use

- Injectable methadone products are not approved for the outpatient treatment of opioid dependence. In this patient population, parenteral methadone is to be used only for patients unable to take oral medication, such as hospitalized patients.

Methadone Intensol

Methadone Hydrochloride oral concentrate (Intensol) contains methadone, an opioid agonist indicated for the:

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve Methadone Hydrochloride Intensol for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone Hydrochloride Intensol is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).

- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Limitations of Use

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 21 CFR, Title 42, Sec. 8.

Methadone Oral Solution

Methadone hydrochloride oral solution is indicated for the:

- Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve methadone hydrochloride oral solution for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or opioid combination products) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone hydrochloride oral solution is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Limitations of Use

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

Methadone Tablets

Methadone hydrochloride tablets are indicated for the:

- Management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve methadone hydrochloride tablets for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone hydrochloride tablets are not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Limitations of Use

- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction

Code of Federal Regulations, Title 42, Sec 8

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment.

Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment

During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction [pursuant to 21CFR 1306.07(c)], to facilitate the treatment of the primary admitting diagnosis.

During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility [pursuant to 21CFR 1306.07(b)].

Morphine Sulfate Extended-Release

Morphine Sulfate Extended-Release Capsules are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Morphine Sulfate Extended-Release Capsules for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Morphine Sulfate Extended-Release Capsules are not indicated as an as-needed (prn) analgesic.

MS Contin (morphine extended-release)

MS Contin is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve MS Contin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- MS Contin is not indicated as an as-needed (prn) analgesic.

Nucynta ER (tapentadol extended-release)

Nucynta ER (tapentadol) is indicated for the management of:

- Severe and persistent pain in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
- Severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Nucynta ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Nucynta ER is not indicated as an as-needed (prn) analgesic.

OxyContin (oxycodone hydrochloride extended-release)

OxyContin is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate in:

- Adults; and
- Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Oxycontin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are

ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

- OxyContin is not indicated as an as-needed (prn) analgesic.

Oxymorphone Hydrochloride Extended-Release

Oxymorphone hydrochloride extended-release tablets are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve oxymorphone hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Oxymorphone hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Tramadol Hydrochloride Extended-Release

Tramadol hydrochloride extended-release tablets are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Tramadol hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Xtampza ER (oxycodone extended-release)

Xtampza ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Xtampza ER is not indicated as an as-needed (prn) analgesic.

Screen out Logic

If the patient has filled a prescription for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

Initial Step Therapy

For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:

If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics ER Quantity Limits Chart below).

If the patient has filled a prescription for at least a 30-day supply of an extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics ER Quantity Limits Chart below).

If the patient does not have at least an 8-day supply of an IR opioid agent indicated for the management of pain OR at least a 30-day supply of an ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., the patient has not used an IR opioid prior to the ER opioid OR the patient is not already stable on an ER opioid), then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

[NOTE: These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of extended-release/long-acting opioids and how to mitigate the associated risks.]

Pain associated with Cancer, Sickle Cell Disease, a Terminal Condition, or Pain being managed through Hospice or Palliative Care

Authorization may be granted when the requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care.

Chronic Pain

Authorization may be granted when the requested drug is being prescribed for CHRONIC pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid when ALL of the following criteria are met:

[Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

- The patient can safely take the requested dose based on their history of opioid use. [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder.
- The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety. [NOTE: Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.]
- The patient meets ONE of the following:
 - This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days.
 - The patient has taken an immediate-release opioid for at least one week.
- If the request is for a methadone product, then it is NOT being prescribed for detoxification treatment or as part of a maintenance treatment plan for opioid/substance abuse or addiction.

Quantity Limits may Apply

Opioid Analgesics ER Quantity Limits Chart

Coverage is provided without prior authorization for a 30-day or 90-day supply of an extended-release opioid for a quantity that corresponds to ≤ 90 morphine milligram equivalents (MME)/day (when Step Therapy criteria met). Coverage for quantities that correspond to ≤ 200 MME/day (unless FDA-labeled

Reference number(s)
2219-M

strength/dose/frequency exceeds 200 MME/day) for a 30-day or 90-day supply is provided through prior authorization when coverage conditions are met.

These quantity limits should accumulate across all drugs of the same unit limit (i.e., drugs with 30 units accumulate together, drugs with 60 units accumulate together, etc.).

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing. Limits are set up both as quantity versus time and daily dose edits.

The post limit quantity is less than or equal to 200 MME per day, unless the minimum FDA-labeled strength/dose/frequency exceeds 200 MME/day.

For any drug with zero (0) listed in column A and column B, the initial limit is zero. All requests for this drug and strength will be considered through post limit prior authorization.

For methadone 10 mg/mL Intensol solution, in order to accommodate unbreakable packaging and refill processing, the fill limit is set up as a maximum quantity of 45 mL with a daily dose edit of 1.5 mL per day for column A only.

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Belbuca 75 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (4.5 MME/day)	180 films/3 months 2 films/day (4.5 MME/day)	90 films/month 3 films/day (6.75 MME/day)	270 films/3 months 3 films/day (6.75 MME/day)
Belbuca 150 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (9 MME/day)	180 films/3 months 2 films/day (9 MME/day)	90 films/month 3 films/day (13.5 MME/day)	270 films/3 months 3 films/day (13.5 MME/day)
Belbuca 300 mcg	once every 12 hours, MAX 900 mcg/12 hrs	60 films/month 2 films/day (18 MME/day)	180 films/3 months 2 films/day (18 MME/day)	90 films/month 3 films/day (27 MME/day)	270 films/3 months 3 films/day (27 MME/day)
Belbuca 450 mcg	once every 12 hours, MAX	60 films/month 2 films/day	180 films/3 months	90 films/month 3 films/day	270 films/3 months

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
	900 mcg/12 hrs	(27 MME/day)	2 films/day (27 MME/day)	(40.5 MME/day)	3 films/day (40.5 MME/day)
Belbuca 600 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (36 MME/day)	180 films/3 months 2 films/day (36 MME/day)
Belbuca 750 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (45 MME/day)	180 films/3 months 2 films/day (45 MME/day)
Belbuca 900 mcg	once every 12 hours, MAX 900 mcg/12 hrs	0	0	60 films/month 2 films/day (54 MME/day)	180 films/3 months 2 films/day (54 MME/day)
Butrans 5 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (9 MME/day)	12 patches/3 months 0.144 patch/day (9 MME/day)	8 patches/month 0.287 patch/day (18 MME/day)	24 patches/3 months 0.287 patch/day (18 MME/day)
Butrans 7.5 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (13.5 MME/day)	12 patches/3 months 0.144 patch/day (13.5 MME/day)	8 patches/month 0.287 patch/day (27 MME/day)	24 patches/3 months 0.287 patch/day (27 MME/day)
Butrans 10 mcg/hr	once every 7 days, MAX 20 mcg/hr	4 patches/month 0.144 patch/day (18 MME/day)	12 patches/3 months 0.144 patch/day (18 MME/day)	8 patches/month 0.287 patch/day (36 MME/day)	24 patches/3 months 0.287 patch/day (36 MME/day)
Butrans 15 mcg/hr	once every 7 days, MAX 20 mcg/hr	0	0	4 patches/month 0.144 patch/day (27 MME/day)	12 patches/3 months 0.144 patch/day (27 MME/day)

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Butrans 20 mcg/hr	once every 7 days, MAX 20 mcg/hr	0	0	4 patches/month 0.144 patch/day (36 MME/day)	12 patches/3 months 0.144 patch/day (36 MME/day)
ConZip 100 mg	once daily, MAX 300 mg/day	30 capsules/month 1 capsule/day (20 MME/day)	90 capsules/3 months 1 capsule/day (20 MME/day)	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)
ConZip 200 mg	once daily, MAX 300 mg/day	0	0	30 capsules/month 1 capsule/day (40 MME/day)	90 capsules/3 months 1 capsule/day (40 MME/day)
ConZip 300 mg	once daily, MAX 300 mg/day	0	0	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)
Fentanyl transdermal 12 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (28.8 MME/day)	30 patches/3 months 0.334 patch/day (28.8 MME/day)	20 patches/month 0.667 patch/day (57.6 MME/day)	60 patches/3 months 0.667 patch/day (57.6 MME/day)
Fentanyl transdermal 25 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (60 MME/day)	30 patches/3 months 0.334 patch/day (60 MME/day)	20 patches/month 0.667 patch/day (120 MME/day)	60 patches/3 months 0.667 patch/day (120 MME/day)
Fentanyl transdermal 37.5 mcg/hr	once every 72 hours	10 patches/month 0.334 patch/day (90 MME/day)	30 patches/3 months 0.334 patch/day (90 MME/day)	20 patches/month 0.667 patch/day (180 MME/day)	60 patches/3 months 0.667 patch/day (180 MME/day)
Fentanyl transdermal 50 mcg/hr	once every 72 hours	0	0	10 patches/month	30 patches/3 months

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
				0.334 patch/day (120 MME/day)	0.334 patch/day (120 MME/day)
Fentanyl transdermal 62.5 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (150 MME/day)	30 patches/3 months 0.334 patch/day (150 MME/day)
Fentanyl transdermal 75 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (180 MME/day)	30 patches/3 months 0.334 patch/day (180 MME/day)
Fentanyl transdermal 87.5 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (210 MME/day)	30 patches/3 months 0.334 patch/day (210 MME/day)
Fentanyl transdermal 100 mcg/hr	once every 72 hours	0	0	10 patches/month 0.334 patch/day (240 MME/day)	30 patches/3 months 0.334 patch/day (240 MME/day)
Hydrocodone ER (generic Zohydro ER) 10 mg	once every 12 hours	60 capsules/month 2 capsules/day (20 MME/day)	180 capsules/3 months 2 capsules/day (20 MME/day)	90 capsules/month 3 capsules/day (30 MME/day)	270 capsules/3 months 3 capsules/day (30 MME/day)
Hydrocodone ER (generic Zohydro ER) 15 mg	once every 12 hours	60 capsules/month 2 capsules/day (30 MME/day)	180 capsules/3 months 2 capsules/day (30 MME/day)	90 capsules/month 3 capsules/day (45 MME/day)	270 capsules/3 months 3 capsules/day (45 MME/day)
Hydrocodone ER (generic Zohydro ER) 20 mg	once every 12 hours	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)	90 capsules/month 3 capsules/day (60 MME/day)	270 capsules/3 months 3 capsules/day (60 MME/day)

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Hydrocodone ER (generic Zohydro ER) 30 mg	once every 12 hours	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Hydrocodone ER (generic Zohydro ER) 40 mg	once every 12 hours	60 capsules/month 2 capsules/day (80 MME/day)	180 capsules/3 months 2 capsules/day (80 MME/day)	90 capsules/month 3 capsules/day (120 MME/day)	270 capsules/3 months 3 capsules/day (120 MME/day)
Hydrocodone ER (generic Zohydro ER) 50 mg	once every 12 hours	0	0	60 capsules/month 2 capsules/day (100 MME/day)	180 capsules/3 months 2 capsules/day (100 MME/day)
Hydromorphone ER (generic Exalgo) 8 mg	once daily	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)
Hydromorphone ER (generic Exalgo) 12 mg	once daily	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)	60 tablets/month 2 tablets/day (120 MME/day)	180 tablets/3 months 2 tablets/day (120 MME/day)
Hydromorphone ER (generic Exalgo) 16 mg	once daily	30 tablets/month 1 tablet/day (80 MME/day)	90 tablets/3 months 1 tablet/day (80 MME/day)	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Hydromorphone ER (generic Exalgo) 32 mg	once daily	0	0	30 tablets/month 1 tablet/day (160 MME/day)	90 tablets/3 months 1 tablet/day (160 MME/day)
Hysingla ER 20 mg	once every 24 hours	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Hysingla ER 30 mg	once every 24 hours	30 tablets/month 1 tablet/day (30 MME/day)	90 tablets/3 months 1 tablet/day (30 MME/day)	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Hysingla ER 40 mg	once every 24 hours	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)
Hysingla ER 60 mg	once every 24 hours	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)	60 tablets/month 2 tablets/day (120 MME/day)	180 tablets/3 months 2 tablets/day (120 MME/day)
Hysingla ER 80 mg	once every 24 hours	30 tablets/month 1 tablet/day (80 MME/day)	90 tablets/3 months 1 tablet/day (80 MME/day)	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Hysingla ER 100 mg	once every 24 hours	0	0	60 tablets/month 2 tablets/day (200 MME/day)	180 tablets/3 months 2 tablets/day (200 MME/day)
Hysingla ER 120 mg	once every 24 hours	0	0	30 tablets/month 1 tablet/day (120 MME/day)	90 tablets/3 months 1 tablet/day (120 MME/day)
Methadone 5 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (70.5 MME/day)	270 tablets/3 months 3 tablets/day (70.5 MME/day)	120 tablets/month 4 tablets/day (94 MME/day)	360 tablets/3 months 4 tablets/day (94 MME/day)
Methadone 10 mg	once every 8 to 12 hours	30 tablets/month 1 tablet/day (47 MME/day)	90 tablets/3 months 1 tablet/day (47 MME/day)	90 tablets/month 3 tablets/day (141 MME/day)	270 tablets/3 months 3 tablets/day (141 MME/day)
Methadone 200 mg/20 mL injection	once every 8 to 12 hours	20 mL/month (1 multidose vial) 0.667 mL/day (31.3 MME/day)	60 mL/3 months (3 multidose vials) 0.667 mL/day (31.3 MME/day)	40 mL/month (2 multidose vials) 1.334 mL/day (62.7 MME/day)	120 mL/3 months (6 multidose vials) 1.334 mL/day (62.7 MME/day)

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Methadone 10 mg/mL Intensol solution	once every 8 to 12 hours	45 mL/month 1.5 mL/day (70.5 MME/day)	135 mL/3 months 1.5 mL/day (70.5 MME/day)	90 mL/month 3 mL/day (141 MME/day)	270 mL/3 months 3 mL/day (141 MME/day)
Methadone 5 mg/5 mL Oral solution	once every 8 to 12 hours	450 mL/month 15 mL/day (70.5 MME/day)	1350 mL/3 months 15 mL/day (70.5 MME/day)	600 mL/month 20 mL/day (94 MME/day)	1800 mL/month 20 mL/day (94 MME/day)
Methadone 10 mg/5 mL Oral solution	once every 8 to 12 hours	225 mL/month 7.5 mL/day (70.5 MME/day)	675 mL/3 months 7.5 mL/day (70.5 MME/day)	450 mL/month 15 mL/day (141 MME/day)	1350 mL/3 months 15 mL/day (141 MME/day)
Morphine ER (generic Avinza) 30 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (30 MME/day)	90 capsules/3 months 1 capsule/day (30 MME/day)	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)
Morphine ER (generic Avinza) 45 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (45 MME/day)	90 capsules/3 months 1 capsule/day (45 MME/day)	60 capsules/month 2 capsules/day (90 MME/day)	180 capsules/3 months 2 capsules/day (90 MME/day)
Morphine ER (generic Avinza) 60 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)	60 capsules/month 2 capsules/day (120 MME/day)	180 capsules/3 months 2 capsules/day (120 MME/day)
Morphine ER (generic Avinza) 75 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (75 MME/day)	90 capsules/3 months 1 capsule/day (75 MME/day)	60 capsules/month 2 capsules/day (150 MME/day)	180 capsules/3 months 2 capsules/day (150 MME/day)
Morphine ER (generic Avinza) 90 mg	once every 24 hours, MAX 1600 mg/day	30 capsules/month 1 capsule/day (90 MME/day)	90 capsules/3 months 1 capsule/day (90 MME/day)	60 capsules/month 2 capsules/day (180 MME/day)	180 capsules/3 months 2 capsules/day (180 MME/day)
Morphine ER (generic Avinza) 120 mg	once every 24 hours, MAX 1600 mg/day	0	0	30 capsules/month 1 capsule/day (120 MME/day)	90 capsules/3 months 1 capsule/day (120 MME/day)

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
Morphine ER (generic Kadian) 10 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (20 MME/day)	180 capsules/3 months 2 capsules/day (20 MME/day)	90 capsules/month 3 capsules/day (30 MME/day)	270 capsules/3 months 3 capsules/day (30 MME/day)
Morphine ER (generic Kadian) 20 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (40 MME/day)	180 capsules/3 months 2 capsules/day (40 MME/day)	90 capsules/month 3 capsules/day (60 MME/day)	270 capsules/3 months 3 capsules/day (60 MME/day)
Morphine ER (generic Kadian) 30 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Morphine ER (generic Kadian) 40 mg	once every 12 to 24 hours	60 capsules/month 2 capsules/day (80 MME/day)	180 capsules/3 months 2 capsules/day (80 MME/day)	90 capsules/month 3 capsules/day (120 MME/day)	270 capsules/3 months 3 capsules/day (120 MME/day)
Morphine ER (generic Kadian) 50 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (50 MME/day)	90 capsules/3 months 1 capsule/day (50 MME/day)	60 capsules/month 2 capsules/day (100 MME/day)	180 capsules/3 months 2 capsules/day (100 MME/day)
Morphine ER (generic Kadian) 60 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (60 MME/day)	90 capsules/3 months 1 capsule/day (60 MME/day)	60 capsules/month 2 capsules/day (120 MME/day)	180 capsules/3 months 2 capsules/day (120 MME/day)
Morphine ER (generic Kadian) 80 mg	once every 12 to 24 hours	30 capsules/month 1 capsule/day (80 MME/day)	90 capsules/3 months 1 capsule/day (80 MME/day)	60 capsules/month 2 capsules/day (160 MME/day)	180 capsules/3 months 2 capsules/day (160 MME/day)
Morphine ER (generic Kadian) 100 mg	once every 12 to 24 hours	0	0	60 capsules/month 2 capsules/day (200 MME/day)	180 capsules/3 months 2 capsules/day (200 MME/day)
MS Contin 15 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)	120 tablets/month 4 tablets/day (60 MME/day)	360 tablets/3 months 4 tablets/day (60 MME/day)

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
MS Contin 30 mg	once every 8 to 12 hours	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)	120 tablets/month 4 tablets/day (120 MME/day)	360 tablets/3 months 4 tablets/day (120 MME/day)
MS Contin 60 mg	once every 8 to 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
MS Contin 100 mg	once every 8 to 12 hours	0	0	60 tablets/month 2 tablets/day (200 MME/day)	180 tablets/3 months 2 tablets/day (200 MME/day)
MS Contin 200 mg	once every 8 to 12 hours	0	0	60 tablets/month 2 tablets/day (400 MME/day)	180 tablets/3 months 2 tablets/day (400 MME/day)
Nucynta ER 50 mg	once every 12 hours, MAX 500 mg/day	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)	90 tablets/month 3 tablets/day (60 MME/day)	270 tablets/3 months 3 tablets/day (60 MME/day)
Nucynta ER 100 mg	once every 12 hours, MAX 500 mg/day	60 tablets/month 2 tablets/day (80 MME/day)	180 tablets/3 months 2 tablets/day (80 MME/day)	90 tablets/month 3 tablets/day (120 MME/day)	270 tablets/3 months 3 tablets/day (120 MME/day)
Nucynta ER 150 mg	once every 12 hours, MAX 500 mg/day	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
Nucynta ER 200 mg	once every 12 hours, MAX 500 mg/day	0	0	60 tablets/month 2 tablets/day (160 MME/day)	180 tablets/3 months 2 tablets/day (160 MME/day)
Nucynta ER 250 mg	once every 12 hours, MAX 500 mg/day	0	0	60 tablets/month 2 tablets/day	180 tablets/3 months 2 tablets/day

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
				(200 MME/day)	(200 MME/day)
OxyContin 10 mg	once every 12 hours	60 tablets/month 2 tablets/day (30 MME/day)	180 tablets/3 months 2 tablets/day (30 MME/day)	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)
OxyContin 15 mg	once every 12 hours	60 tablets/month 2 tablets/day (45 MME/day)	180 tablets/3 months 2 tablets/day (45 MME/day)	90 tablets/month 3 tablets/day (67.5 MME/day)	270 tablets/3 months 3 tablets/day (67.5 MME/day)
OxyContin 20 mg	once every 12 hours	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)
OxyContin 30 mg	once every 12 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	90 tablets/month 3 tablets/day (135 MME/day)	270 tablets/3 months 3 tablets/day (135 MME/day)
OxyContin 40 mg	once every 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
OxyContin 60 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (180 MME/day)	180 tablets/3 months 2 tablets/day (180 MME/day)
OxyContin 80 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (240 MME/day)	180 tablets/3 months 2 tablets/day (240 MME/day)
Oxymorphone ER (generic Opana ER) 5 mg	once every 12 hours	60 tablets/month 2 tablets/day (30 MME/day)	180 tablets/3 months 2 tablets/day (30 MME/day)	90 tablets/month 3 tablets/day (45 MME/day)	270 tablets/3 months 3 tablets/day (45 MME/day)
Oxymorphone ER	once every 12 hours	60 tablets/month	180 tablets/3 months	90 tablets/month	270 tablets/3 months

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
(generic Opana ER) 7.5 mg		2 tablets/day (45 MME/day)	2 tablets/day (45 MME/day)	3 tablets/day (67.5 MME/day)	3 tablets/day (67.5 MME/day)
Oxymorphone ER (generic Opana ER) 10 mg	once every 12 hours	60 tablets/month 2 tablets/day (60 MME/day)	180 tablets/3 months 2 tablets/day (60 MME/day)	90 tablets/month 3 tablets/day (90 MME/day)	270 tablets/3 months 3 tablets/day (90 MME/day)
Oxymorphone ER (generic Opana ER) 15 mg	once every 12 hours	60 tablets/month 2 tablets/day (90 MME/day)	180 tablets/3 months 2 tablets/day (90 MME/day)	90 tablets/month 3 tablets/day (135 MME/day)	270 tablets/3 months 3 tablets/day (135 MME/day)
Oxymorphone ER (generic Opana ER) 20 mg	once every 12 hours	0	0	90 tablets/month 3 tablets/day (180 MME/day)	270 tablets/3 months 3 tablets/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 30 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (180 MME/day)	180 tablets/3 months 2 tablets/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 40 mg	once every 12 hours	0	0	60 tablets/month 2 tablets/day (240 MME/day)	180 tablets/3 months 2 tablets/day (240 MME/day)
Tramadol ER (generic Ryzolt) 100 mg	once daily, MAX 300 mg/day	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Tramadol ER (generic Ultram ER) 100 mg	once daily, MAX 300 mg/day	30 tablets/month 1 tablet/day (20 MME/day)	90 tablets/3 months 1 tablet/day (20 MME/day)	60 tablets/month 2 tablets/day (40 MME/day)	180 tablets/3 months 2 tablets/day (40 MME/day)
Tramadol ER (generic Ryzolt) 200 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day	90 tablets/3 months 1 tablet/day

Reference number(s)
2219-M

Drug/Strength	Labeled Dosing	COLUMN A Initial 1 Month Limit ≤ 90 MME/day (per 25 days)	COLUMN B Initial 3 Month Limit ≤ 90 MME/day (per 75 days)	COLUMN C Post 1 Month Limit ≤ 200 MME/day (per 25 days)	COLUMN D Post 3 Month Limit ≤ 200 MME/day (per 75 days)
				(40 MME/day)	(40 MME/day)
Tramadol ER (generic Ultram ER) 200 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (40 MME/day)	90 tablets/3 months 1 tablet/day (40 MME/day)
Tramadol ER (generic Ryzolt) 300 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)
Tramadol ER (generic Ultram ER) 300 mg	once daily, MAX 300 mg/day	0	0	30 tablets/month 1 tablet/day (60 MME/day)	90 tablets/3 months 1 tablet/day (60 MME/day)
Xtampza ER 9 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (30 MME/day)	180 capsules/3 months 2 capsules/day (30 MME/day)	90 capsules/month 3 capsules/day (45 MME/day)	270 capsules/3 months 3 capsules/day (45 MME/day)
Xtampza ER 13.5 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (45 MME/day)	180 capsules/3 months 2 capsules/day (45 MME/day)	90 capsules/month 3 capsules/day (67.5 MME/day)	270 capsules/3 months 3 capsules/day (67.5 MME/day)
Xtampza ER 18 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (60 MME/day)	180 capsules/3 months 2 capsules/day (60 MME/day)	90 capsules/month 3 capsules/day (90 MME/day)	270 capsules/3 months 3 capsules/day (90 MME/day)
Xtampza ER 27 mg	once every 12 hours, MAX 288 mg/day	60 capsules/month 2 capsules/day (90 MME/day)	180 capsules/3 months 2 capsules/day (90 MME/day)	90 capsules/month 3 capsules/day (135 MME/day)	270 capsules/3 months 3 capsules/day (135 MME/day)
Xtampza ER 36 mg	once every 12 hours, MAX 288 mg/day	0	0	90 capsules/month 3 capsules/day (180 MME/day)	270 capsules/3 months 3 capsules/day (180 MME/day)

Duration of Approval (DOA)

- 2219-M:
 - Pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care: DOA: 12 months
 - Chronic pain: DOA: 6 months

References

1. Belbuca [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; December 2023.
2. Butrans [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
3. ConZip [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC.; December 2023.
4. Fentanyl Transdermal [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; October 2024.
5. Hydrocodone ER capsules [package insert]. Morristown, NJ: Alvogen, Inc.; December 2023.
6. Hydromorphone ER [package insert]. Minneapolis, MN: Padagis; January 2024.
7. Hysingla ER [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
8. Methadone Injection [package insert]. Morgantown, WV: Mylan Institutional LLC; December 2023.
9. Methadone Hydrochloride Oral Concentrate (Intensol) [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; March 2024.
10. Methadone Oral Solution [package insert]. Webster Groves, MO: SpecGx LLC; January 2024.
11. Methadone Tablets [package insert]. Webster Groves, MO: SpecGx, LLC; December 2023.
12. Morphine ER Capsules [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; February 2024.
13. Morphine ER Capsules [package insert]. Parsippany, NJ: Teva Pharmaceuticals; November 2023.
14. MS Contin [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
15. Nucynta ER [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc; December 2023.
16. OxyContin [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
17. Oxymorphone ER [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; August 2022.
18. Tramadol extended-release tablets [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2023.
19. Tramadol extended-release tablets [package insert]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; January 2024.
20. Xtampza ER [package insert]. Cincinnati, OH: Patheon Pharmaceuticals; December 2023.
21. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 20, 2024.
22. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/20/2024).
23. Dowell D, Ragan, KR, Jones, CM, et al; CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022. MMWR Recomm Rep. 2022;71:1–95. Available at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>. Accessed November 21, 2024.

Reference number(s)
2219-M

24. Palliative Care. NCCN Guidelines version 1.2025. Available at:
https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 21, 2024.
25. Adult Cancer Pain. NCCN Guidelines version 3.2024. Available at:
https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 9, 2024.
26. Chou R, Fanciullo G, Fine P, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. 2009;10:113-130.
27. National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_O.pdf. Accessed November 21, 2024.
28. U.S. Food & Drug Administration. FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. April 13, 2023. Available at:
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use>. Accessed November 21, 2024.

Initial Prior Authorization with Quantity Limit Opzelura (Atopic Dermatitis)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Opzelura	ruxolitinib	cream

Indications

FDA-approved Indications

Opzelura is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Limitation of Use:

Use of Opzelura in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

Coverage Criteria

Atopic Dermatitis

Reference number(s)
5556-C

Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 2 years of age or older.
- The patient meets ONE of the following:
 - The patient's disease is not adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
 - Other topical prescription therapies are NOT advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor).
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in a non-immunocompromised patient when ALL of the following criteria are met:

- The requested drug is NOT being prescribed in combination with therapeutic biologics, other janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.
- The request is for an adult or pediatric patient 2 years of age or older.
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)].
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA).
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days.

Quantity Limits Apply

60 grams per 21 days or 180 grams per 63 days.

For larger body surface area (BSA) for pediatric patients 2 to 11 years of age: 120 grams per 21 days or 360 grams per 63 days.

For larger body surface area (BSA) for patients 12 years of age and older: 240 grams per 21 days or 720 grams per 63 days.

The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.

The intent is for prescriptions of the requested drug to be filled one month at a time for new starts; there should be no 3-month supplies filled for new starts.

Duration of Approval (DOA)

- 5556-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

References

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 5, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/05/2025).
4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014; 70:338-51.
5. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014; 71:116-32.
6. Papp K, Szepietowski JC, Kircik L, et. al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: Results from 2 phase 3, randomized, double-blind studies. J Am Acad Dermatol 2021;85:863-72.
7. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. December 26, 2024. Available at: <https://chemm.hhs.gov/burns.htm>. Accessed February 6, 2025.
8. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023; 89(1): e1-e20.

Initial Prior Authorization with Quantity Limit Oral Fentanyl Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

No Technician Approval; criteria requires a pharmacist to approve.

Brand Name	Generic Name	Dosage Form
Actiq	fentanyl citrate	oral transmucosal lozenge
Fentora	fentanyl citrate	buccal tablet

Indications

FDA-approved Indications

Actiq

Actiq is indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Fentora

Fentora is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

For All Oral Fentanyl Products:

Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid. Patients must remain on around-the-clock opioids when taking the requested oral fentanyl product.

Limitations of Use

- Not for use in opioid non-tolerant patients.
- Not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency department.
- As a part of the TIRF REMS, oral fentanyl products may be dispensed by outpatient pharmacies only to outpatients enrolled in the program. For inpatient administration of oral fentanyl products, patient and prescriber enrollment is not required.

Coverage Criteria

Cancer-Related Pain

Authorization may be granted when the requested drug is being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain. The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. [ACTION REQUIRED: Documentation is required for approval. The prescriber must submit chart notes or other documentation supporting a diagnosis of cancer-related pain and list the type of cancer. For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.] In addition, ALL of the following criteria are met:

- The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain.
- The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their current opioid use history. [NOTE: Ensure that the patient can safely take the requested dose based on their current opioid use history. These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks. Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, at least 60 mg of oral hydrocodone per day, or an equianalgesic dose of another opioid.]
- If additional quantities are being requested, then the patient must meet ONE of the following:

Reference number(s)
288-C

- The patient's dose of a concomitant long-acting analgesic is being increased.
- Additional quantities of the requested drug are needed for breakthrough pain because the dose of the patient's long-acting analgesic is unable to be increased.

Quantity Limits Apply

120 units / 25 days OR 360 units / 75 days.

For patients undergoing dose titration (increase) of their concomitant long-acting analgesic or in situations where it is not clinically appropriate to increase the dose of the long-acting analgesic, an additional quantity may be available:

180 units / 25 days OR 540 units / 75 days.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 288-C: DOA: 12 months

References

1. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed December 20, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/20/2024).
5. Adult Cancer Pain. NCCN Guidelines version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 9, 2024.

CountyCare IL Custom Criteria Orencia

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

Signature

Date

Client Name

MDC: REG

CRITERIA FOR APPROVAL

1	What is the diagnosis? ☐ Polyarticular juvenile idiopathic arthritis (If checked, go to 12) ☐ Psoriatic arthritis (If checked, go to 7) ☐ Rheumatoid arthritis (If checked, go to 2) ☐ Other, please specify: _____ (If checked, go to 17)		
2	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication to TWO of the preferred products Cimzia, Enbrel, Xeljanz/Xeljanz XR, or an adalimumab product? [If Yes, then go to 17. If No, then go to 3.]	Yes	No
3	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
5	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 6. If No, then no further questions.]	Yes	No

6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Enbrel, or an adalimumab product? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
7	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication to at least TWO of the preferred products Cimzia, Cosentyx, Enbrel, Xeljanz/Xeljanz XR, or an adalimumab product? [If Yes, then go to 17. If No, then go to 8.]	Yes	No
8	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then go to 10.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
10	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
12	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the preferred products Enbrel, Xeljanz/Xeljanz XR, or an adalimumab product? [If Yes, then go to 17. If No, then go to 13.]	Yes	No
13	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 14. If No, then go to 15.]	Yes	No
14	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
15	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or	Yes	No

risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D)
History of hepatitis B or hepatitis C virus infection, E) History of being
a primary non-responder to a JAK inhibitor?
[If Yes, then go to 16. If No, then no further questions.]

16	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Enbrel or adalimumab product? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 18.]	Yes	No
18	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 22. If No, then go to 19.]	Yes	No
19	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	What were the results of the tuberculosis (TB) test? ☐ Positive for TB (If checked, go to 21) ☐ Negative for TB (If checked, go to 22) ☐ Unknown (If checked, no further questions)		
21	Which of the following applies to the patient? ☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions) ☐ Patient has active TB (If checked, no further questions)		
22	What is the diagnosis? ☐ Rheumatoid arthritis (If checked, go to 23) ☐ Polyarticular juvenile idiopathic arthritis (pJIA) (If checked, go to 37) ☐ Oligoarticular juvenile idiopathic arthritis (If checked, go to 37) ☐ Psoriatic arthritis (If checked, go to 50) ☐ Chronic graft versus host disease (If checked, go to 65)		

☐ Immune checkpoint inhibitor-related toxicity (If checked, go to 71)

☐ Prophylaxis of acute graft versus host disease (If checked, go to 76)

☐ Systemic juvenile idiopathic arthritis (sJIA) (If checked, no further questions)

☐ Other, please specify. _____ (If checked, no further questions)

23	Has the patient been diagnosed with moderately to severely active rheumatoid arthritis (RA)? [If Yes, then go to 24. If No, then no further questions.]	Yes	No

24	Is the patient an adult (18 years of age or older)? [If Yes, then go to 25. If No, then no further questions.]	Yes	No

25	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 26. If No, then no further questions.]	Yes	No

26	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 27. If No, then go to 30.]	Yes	No

27	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 30)

☐ No (If checked, go to 28)

☐ Unknown (If checked, go to 30)

28	Has the patient achieved or maintained a positive clinical response since starting treatment with the requested drug? [If Yes, then go to 29. If No, then no further questions.]	Yes	No

29	Has the patient experienced substantial disease activity improvement (e.g., at least 20% from baseline) in tender joint count, swollen joint count, pain, or disability? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting positive clinical response and substantial disease activity improvement. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 80. If No, then no further questions.]	Yes	No

Tech Note: Percentage of disease activity improvement is per prescriber attestation and does not have to be explicitly stated in chart notes or medical record documentation.

30	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation	Yes	No

[If Yes, then go to 80. If No, then go to 31.]

31	Does the patient meet either of the following: a) the patient was tested for the rheumatoid factor (RF) biomarker and the RF biomarker test was positive, or b) the patient was tested for the anti-cyclic citrullinated peptide (anti-CCP) biomarker and the anti-CCP biomarker test was positive? ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing. <i>ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 33. If No, then go to 32.]

32	Has the patient been tested for all of the following biomarkers: a) rheumatoid factor (RF), b) anti-cyclic citrullinated peptide (anti-CCP), and c) C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)? ACTION REQUIRED: If Yes, please attach laboratory results, chart notes, or medical record documentation of biomarker testing. <i>ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 33. If No, then no further questions.]

33	Has the patient experienced an inadequate response after at least 3 months of treatment with methotrexate at a dose greater than or equal to 15 mg per week? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. <i>ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 80. If No, then go to 34.]

34	Has the patient experienced an intolerance to methotrexate? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. <i>ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 80. If No, then go to 35.]

35	Does the patient have a contraindication to methotrexate? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. <i>ACTION REQUIRED: Submit supporting documentation</i>	Yes	No

[If Yes, then go to 36. If No, then no further questions.]

36 Please indicate the contraindication to methotrexate.

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 80)

☐ Drug interaction (If checked, go to 80)

☐ Risk of treatment-related toxicity (If checked, go to 80)

☐ Pregnancy or currently planning pregnancy (If checked, go to 80)

☐ Breastfeeding (If checked, go to 80)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 80)

☐ Hypersensitivity (If checked, go to 80)

☐ History of intolerance or adverse event (If checked, go to 80)

☐ Other, please specify. _____ (If checked, no further questions)

37	Has the patient been diagnosed with moderately to severely active articular juvenile idiopathic arthritis? [If Yes, then go to 38. If No, then no further questions.]	Yes	No

38	Is the patient 2 years of age or older? [If Yes, then go to 39. If No, then no further questions.]	Yes	No

39	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 40. If No, then no further questions.]	Yes	No

40	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 41. If No, then go to 44.]	Yes	No

41	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 44)

☐ No (If checked, go to 42)

☐ Unknown (If checked, go to 44)

42	Has the patient achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 43. If No, then no further questions.]	Yes	No

43	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of joints with active arthritis (e.g., swelling, pain, limitation of motion) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 80)

☐ Number of joints with limitation of movement **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 80)

☐ Functional ability **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 80)

☐ None of the above (If checked, no further questions)

44	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Xeljanz) indicated for the treatment of moderately to severely active articular juvenile idiopathic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION	Yes	No

REQUIRED: Submit supporting documentation

[If Yes, then go to 80. If No, then go to 45.]

45	Has the patient had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 80. If No, then go to 46.]	Yes	No
46	Has the patient had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 47. If No, then go to 48.]	Yes	No
47	Does the patient have one of the following risk factors for poor outcome: a) involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ), b) presence of erosive disease or enthesitis, c) delay in diagnosis, d) elevated levels of inflammation markers, or e) symmetric disease? [If Yes, then go to 80. If No, then go to 48.]	Yes	No
48	Does the patient have any of the following risk factors for disease severity and potentially a more refractory disease course: a) positive rheumatoid factor, b) positive anti-cyclic citrullinated peptide antibodies, or c) pre-existing joint damage? [If Yes, then go to 49. If No, then no further questions.]	Yes	No
49	Does the patient meet any of the following: a) high-risk joints are involved (e.g., cervical spine, wrist, or hip), b) high disease activity, or c) high risk for disabling joint disease? [If Yes, then go to 80. If No, then no further questions.]	Yes	No
50	Is the patient 2 years of age or older? [If Yes, then go to 51. If No, then no further questions.]	Yes	No
51	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 52. If No, then no further questions.]	Yes	No
52	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 53. If No, then go to 56.]	Yes	No
53	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		
	☐ Yes (If checked, go to 56)		
	☐ No (If checked, go to 54)		
	☐ Unknown (If checked, go to 56)		

54	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 55. If No, then no further questions.]	Yes	No
55	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. ☐ Number of swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ Number of tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ Dactylitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ Enthesitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ Skin and/or nail involvement ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ Functional status ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ C-reactive protein (CRP) ACTION REQUIRED: Submit supporting documentation (If checked, go to 80) ☐ None of the above (If checked, no further questions)		
56	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 57. If No, then no further questions.]	Yes	No
57	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 80. If No, then go to 58.]	Yes	No
58	What is the patient's disease severity? ☐ Mild to moderate (If checked, go to 59) ☐ Severe (If checked, go to 80)		
59	Does the patient have enthesitis? [If Yes, then go to 80. If No, then go to 60.]	Yes	No
60	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? ACTION REQUIRED: If Yes, please attach chart notes, medical	Yes	No

record documentation, or claims history supporting previous medications tried, including response to therapy. *ACTION REQUIRED: Submit supporting documentation*
[If Yes, then go to 80. If No, then go to 61.]

61	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then go to 62.]	Yes	No

62	Does the patient have a contraindication to methotrexate or leflunomide? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 64. If No, then go to 63.]	Yes	No

63	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then no further questions.]	Yes	No

64	Please indicate the contraindication to methotrexate or leflunomide. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 80) ☐ Drug interaction (If checked, go to 80) ☐ Risk of treatment-related toxicity (If checked, go to 80) ☐ Pregnancy or currently planning pregnancy (If checked, go to 80) ☐ Breastfeeding (If checked, go to 80) ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 80) ☐ Hypersensitivity (If checked, go to 80) ☐ History of intolerance or adverse event (If checked, go to 80) ☐ Other, please specify. _____ (If checked, no further questions)		

65	Is the requested drug being prescribed by or in consultation with an oncologist or hematologist? [If Yes, then go to 66. If No, then no further questions.]	Yes	No

66	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 67. If No, then go to 69.]	Yes	No

67	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 69)

☐ No (If checked, go to 68)

☐ Unknown (If checked, go to 69)

68	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then no further questions.]	Yes	No
69	Has the patient had an inadequate response to systemic corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then go to 70.]	Yes	No
70	Does the patient have an intolerance or contraindication to corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then no further questions.]	Yes	No
71	Is the requested drug being prescribed by or in consultation with an oncologist or hematologist? [If Yes, then go to 72. If No, then no further questions.]	Yes	No
72	Does the patient have myocarditis? [If Yes, then go to 73. If No, then no further questions.]	Yes	No
73	Has the patient had an inadequate response to systemic corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then go to 74.]	Yes	No
74	Does the patient have an intolerance or contraindication to corticosteroids? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 80. If No, then go to 75.]	Yes	No
75	Does the patient have concomitant myositis and the requested drug will be used in combination with ruxolitinib? [If Yes, then go to 80. If No, then no further questions.]	Yes	No

76	Is the patient 2 years of age or older? [If Yes, then go to 77. If No, then no further questions.]	Yes	No
77	Is the requested drug being prescribed by or in consultation with an oncologist or hematologist? [If Yes, then go to 78. If No, then no further questions.]	Yes	No
78	Is the patient undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor? [If Yes, then go to 79. If No, then no further questions.]	Yes	No
79	Will the requested medication be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate? [If Yes, then go to 80. If No, then no further questions.]	Yes	No
80	What is the diagnosis? ☐ Rheumatoid arthritis (If checked, go to 81) ☐ Polyarticular juvenile idiopathic arthritis (pJIA) (If checked, go to 104) ☐ Oligoarticular juvenile idiopathic arthritis (If checked, go to 104) ☐ Psoriatic arthritis (If checked, go to 122) ☐ Chronic graft versus host disease (If checked, go to 142) ☐ Immune checkpoint inhibitor-related toxicity (If checked, go to 149) ☐ Prophylaxis of acute graft versus host disease (If checked, go to 153)		
81	Is the patient currently receiving Orencia? [If Yes, then go to 82. If No, then go to 90.]	Yes	No
82	What is the route of administration? ☐ Intravenous (If checked, go to 83) ☐ Subcutaneous (If checked, go to 88)		
83	Is the prescribed frequency for the maintenance dose more frequent than one dose every four weeks? [If Yes, then no further questions. If No, then go to 84.]	Yes	No
84	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 60 kg _____ (If checked, go to 85) ☐ Greater than or equal to 60 kg to less than or equal to 100 kg _____ (If checked, go to 86) ☐ Greater than 100 kg _____ (If checked, go to 87)		

85	Does the prescribed dose exceed 500 mg? [No further questions]	Yes	No
86	Does the prescribed dose exceed 750 mg? [No further questions]	Yes	No
87	Does the prescribed dose exceed 1000 mg? [No further questions]	Yes	No
88	Does the prescribed maintenance dose exceed 125 mg? [If Yes, then no further questions. If No, then go to 89.]	Yes	No
89	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [No further questions]	Yes	No
90	What is the route of administration? ☐ Intravenous (If checked, go to 91) ☐ Intravenous loading dose followed by subcutaneous maintenance (If checked, go to 96) ☐ Subcutaneous (If checked, go to 102)		
91	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [If Yes, then no further questions. If No, then go to 92.]	Yes	No
92	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 60 kg _____ (If checked, go to 93) ☐ Greater than or equal to 60 kg to less than or equal to 100 kg _____ (If checked, go to 94) ☐ Greater than 100 kg _____ (If checked, go to 95)		
93	Does the prescribed dose exceed a loading dose of 500 mg at week 0, week 2, week 4, and a maintenance dose of 500 mg thereafter? [No further questions]	Yes	No
94	Does the prescribed dose exceed a loading dose of 750 mg at week 0, week 2, week 4, and a maintenance dose of 750 mg thereafter? [No further questions]	Yes	No
95	Does the prescribed dose exceed a loading dose of 1000 mg at week 0, week 2, week 4, and a maintenance dose of 1000 mg thereafter? [No further questions]	Yes	No
96	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 97.]	Yes	No

97	Does the prescribed maintenance dose exceed 125 mg? [If Yes, then no further questions. If No, then go to 98.]	Yes	No
98	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 60 kg _____ (If checked, go to 99) ☐ Greater than or equal to 60 kg to less than or equal to 100 kg _____ (If checked, go to 100) ☐ Greater than 100 kg _____ (If checked, go to 101)		
99	Does the prescribed loading dose exceed 500 mg as an intravenous infusion? [No further questions]	Yes	No
100	Does the prescribed loading dose exceed 750 mg as an intravenous infusion? [No further questions]	Yes	No
101	Does the prescribed loading dose exceed 1000 mg as an intravenous infusion? [No further questions]	Yes	No
102	Does the prescribed dose exceed 125 mg? [If Yes, then no further questions. If No, then go to 103.]	Yes	No
103	Is the prescribed frequency more frequent than one dose every week? [No further questions]	Yes	No
104	What is the route of administration? ☐ Intravenous (If checked, go to 105) ☐ Subcutaneous (If checked, go to 117)		
105	What is the patient's age? ☐ 2 years to less than 6 years of age (If checked, no further questions) ☐ 6 years of age or older (If checked, go to 106)		
106	Is the patient currently receiving Orencia? [If Yes, then go to 107. If No, then go to 112.]	Yes	No
107	Is the prescribed frequency for the maintenance dose more frequent than one dose every four weeks? [If Yes, then no further questions. If No, then go to 108.]	Yes	No
108	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 75 kg _____ (If checked, go to 109)		

☐ Greater than or equal to 75 kg to less than or equal to 100 kg
_____ (If checked, go to 110)

☐ Greater than 100 kg _____ (If checked, go to 111)

109	Does the prescribed dose exceed 10 mg per kg? [No further questions]	Yes	No

110	Does the prescribed dose exceed 750 mg? [No further questions]	Yes	No

111	Does the prescribed dose exceed 1000 mg? [No further questions]	Yes	No

112	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [If Yes, then no further questions. If No, then go to 113.]	Yes	No

113 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than 75 kg _____ (If checked, go to 114)

☐ Greater than or equal to 75 kg to less than or equal to 100 kg
_____ (If checked, go to 115)

☐ Greater than 100 kg _____ (If checked, go to 116)

114	Does the prescribed dose exceed a loading dose of 10 mg per kg at week 0, week 2, week 4, and a maintenance dose of 10 mg per kg thereafter? [No further questions]	Yes	No

115	Does the prescribed dose exceed a loading dose of 750 mg at week 0, week 2, week 4, and a maintenance dose of 750 mg thereafter? [No further questions]	Yes	No

116	Does the prescribed dose exceed a loading dose of 1000 mg at week 0, week 2, week 4, and a maintenance dose of 1000 mg thereafter? [No further questions]	Yes	No

117	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 118.]	Yes	No

118 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than 10 kg _____ (If checked, no further questions)

☐ Greater than or equal to 10 kg to less than 25 kg
_____ (If checked, go to 119)

☐ Greater than or equal to 25 kg to less than 50 kg
_____ (If checked, go to 120)

	☐ Greater than or equal to 50 kg _____ (If checked, go to 121)		
119	Does the prescribed dose exceed 50 mg? [No further questions]	Yes	No
120	Does the prescribed dose exceed 87.5 mg? [No further questions]	Yes	No
121	Does the prescribed dose exceed 125 mg? [No further questions]	Yes	No
122	What is the route of administration? ☐ Intravenous (If checked, go to 123) ☐ Subcutaneous (If checked, go to 135)		
123	What is the patient's age? ☐ 2 years to less than 18 years of age (If checked, no further questions) ☐ 18 years of age or older (If checked, go to 124)		
124	Is the patient currently receiving Orencia? [If Yes, then go to 125. If No, then go to 130.]	Yes	No
125	Is the prescribed frequency for the maintenance dose more frequent than one dose every four weeks? [If Yes, then no further questions. If No, then go to 126.]	Yes	No
126	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 60 kg _____ (If checked, go to 127) ☐ Greater than or equal to 60 kg to less than or equal to 100 kg _____ (If checked, go to 128) ☐ Greater than 100 kg _____ (If checked, go to 129)		
127	Does the prescribed dose exceed 500 mg? [No further questions]	Yes	No
128	Does the prescribed dose exceed 750 mg? [No further questions]	Yes	No
129	Does the prescribed dose exceed 1000 mg? [No further questions]	Yes	No
130	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [If Yes, then no further questions. If No, then go to 131.]	Yes	No
131	What is the patient's weight? Indicate in kilograms (kg).		

	☐ Less than 60 kg _____ (If checked, go to 132)	
	☐ Greater than or equal to 60 kg to less than or equal to 100 kg _____ (If checked, go to 133)	
	☐ Greater than 100 kg _____ (If checked, go to 134)	
132	Does the prescribed dose exceed a loading dose of 500 mg at week 0, week 2, week 4, and a maintenance dose of 500 mg thereafter? [No further questions]	Yes No
133	Does the prescribed dose exceed a loading dose of 750 mg at week 0, week 2, week 4, and a maintenance dose of 750 mg thereafter? [No further questions]	Yes No
134	Does the prescribed dose exceed a loading dose of 1000 mg at week 0, week 2, week 4, and a maintenance dose of 1000 mg thereafter? [No further questions]	Yes No
135	What is the patient's age?	
	☐ 2 years to less than 18 years of age (If checked, go to 136)	
	☐ 18 years of age or older (If checked, go to 140)	
136	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 137.]	Yes No
137	What is the patient's weight? Indicate in kilograms (kg).	
	☐ Less than 10 kg (If checked, no further questions)	
	☐ Greater than or equal to 10 kg to less than 25 kg (If checked, go to 138)	
	☐ Greater than or equal to 25 kg to less than 50 kg (If checked, go to 139)	
	☐ Greater than or equal to 50 kg (If checked, go to 141)	
138	Does the prescribed dose exceed 50 mg? [No further questions]	Yes No
139	Does the prescribed dose exceed 87.5 mg? [No further questions]	Yes No
140	Is the prescribed frequency for the maintenance dose more frequent than one dose every week? [If Yes, then no further questions. If No, then go to 141.]	Yes No
141	Does the prescribed dose exceed 125 mg? [No further questions]	Yes No
142	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN	Yes No

compendia, current treatment guidelines)?
[If Yes, then go to 143. If No, then no further questions.]

143 What is the route of administration?

☐ Intravenous (If checked, go to 144)

☐ Subcutaneous (If checked, no further questions)

144	Is the patient currently receiving Orencia?	Yes	No
	[If Yes, then go to 145. If No, then go to 147.]		

145	Does the prescribed maintenance dose exceed 10 mg per kg?	Yes	No
	[If Yes, then no further questions. If No, then go to 146.]		

146	Is the prescribed frequency for the maintenance dose more frequent than one dose every four weeks?	Yes	No
	[No further questions]		

147	Does the prescribed dose exceed a loading dose of 10 mg per kg at week 0, week 2, and week 4, followed by a maintenance dose of 10 mg per kg thereafter?	Yes	No
	[If Yes, then no further questions. If No, then go to 148.]		

148	Is the prescribed frequency for the maintenance dose more frequent than one dose every four weeks?	Yes	No
	[No further questions]		

149	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)?	Yes	No
	[If Yes, then go to 150. If No, then no further questions.]		

150 What is the route of administration?

☐ Intravenous (If checked, go to 151)

☐ Subcutaneous (If checked, no further questions)

151	Does the prescribed dose exceed 10 mg per kg?	Yes	No
	[If Yes, then no further questions. If No, then go to 152.]		

152	Is the prescribed frequency more frequent than one dose every two weeks?	Yes	No
	[No further questions]		

153 What is the route of administration?

☐ Intravenous (If checked, go to 154)

☐ Subcutaneous (If checked, no further questions)

154 What is the patient's age? Indicate in years.

☐ 2 years to less than 6 years of age _____
(If checked, go to 155)

☐ 6 years of age or older _____ (If checked, go to 156)		
155	Does the prescribed dose exceed 15 mg per kg on the day before transplantation (Day -1) followed by 12 mg per kg on Days 5, 14, and 28 after transplantation? [No further questions]	Yes No
156	Does the prescribed dose exceed 10 mg per kg (maximum 1000 mg) on the day before transplantation (Day -1) and on Days 5, 14, and 28 after transplantation? [No further questions]	Yes No

Mapping Instructions		
	Yes	No
1.	1=12 ;2=7 ;3=2 ;4=17	
2.	Go to 17	Go to 3
3.	Go to 4	Go to 5
4.	Go to 17	Deny OR Pend and Continue to 17
5.	Go to 6	Deny OR Pend and Continue to 6
6.	Go to 17	Deny OR Pend and Continue to 17
7.	Go to 17	Go to 8
8.	Go to 9	Go to 10
9.	Go to 17	Deny OR Pend and Continue to 17
10.	Go to 11	Deny OR Pend and Continue to 11
11.	Go to 17	Deny OR Pend and Continue to 17
12.	Go to 17	Go to 13
13.	Go to 14	Go to 15
14.	Go to 17	Deny OR Pend and Continue to 17
15.	Go to 16	Deny OR Pend and Continue to 16
16.	Go to 17	Deny OR Pend and Continue to 17
17.	Deny OR Pend and Continue to 18	Go to 18
18.	Go to 22	Go to 19
19.	Go to 20	Deny OR Pend and Continue to 20
20.	1=21 ;2=22 ;3=Deny	

21.	1=22 ;2=22 ;3=Deny OR Pend and Continue to 22 ;4=Deny OR Pend and Continue to 22	
22.	1=23 ;2=37 ;3=37 ;4=50 ;5=65 ;6=71 ;7=76 ;8=Deny ;9=Deny	
23.	Go to 24	Deny OR Pend and Continue to 24
24.	Go to 25	Deny OR Pend and Continue to 25
25.	Go to 26	Deny OR Pend and Continue to 26
26.	Go to 27	Go to 30
27.	1=30 ;2=28 ;3=30	
28.	Go to 29	Deny OR Pend and Continue to 29
29.	Go to 80	Deny OR Pend and Continue to 80
30.	Go to 80	Go to 31
31.	Go to 33	Go to 32
32.	Go to 33	Deny OR Pend and Continue to 33
33.	Go to 80	Go to 34
34.	Go to 80	Go to 35
35.	Go to 36	Deny OR Pend and Continue to 36
36.	1=80 ;2=80 ;3=80 ;4=80 ;5=80 ;6=80 ;7=80 ;8=80 ;9=Deny OR Pend and Continue to 37	
37.	Go to 38	Deny OR Pend and Continue to 38
38.	Go to 39	Deny OR Pend and Continue to 39
39.	Go to 40	Deny OR Pend and Continue to 40
40.	Go to 41	Go to 44
41.	1=44 ;2=42 ;3=44	
42.	Go to 43	Deny OR Pend and Continue to 43
43.	1=80 ;2=80 ;3=80 ;4=Deny OR Pend and Continue to 44	
44.	Go to 80	Go to 45
45.	Go to 80	Go to 46
46.	Go to 47	Go to 48

47.	Go to 80	Go to 48
48.	Go to 49	Deny OR Pend and Continue to 49
49.	Go to 80	Deny OR Pend and Continue to 80
50.	Go to 51	Deny OR Pend and Continue to 51
51.	Go to 52	Deny OR Pend and Continue to 52
52.	Go to 53	Go to 56
53.	1=56 ;2=54 ;3=56	
54.	Go to 55	Deny OR Pend and Continue to 55
55.	1=80 ;2=80 ;3=80 ;4=80 ;5=80 ;6=80 ;7=80 ;8=Deny OR Pend and Continue to 56	
56.	Go to 57	Deny OR Pend and Continue to 57
57.	Go to 80	Go to 58
58.	1=59 ;2=80	
59.	Go to 80	Go to 60
60.	Go to 80	Go to 61
61.	Go to 80	Go to 62
62.	Go to 64	Go to 63
63.	Go to 80	Deny OR Pend and Continue to 80
64.	1=80 ;2=80 ;3=80 ;4=80 ;5=80 ;6=80 ;7=80 ;8=80 ;9=Deny OR Pend and Continue to 65	
65.	Go to 66	Deny OR Pend and Continue to 66
66.	Go to 67	Go to 69
67.	1=69 ;2=68 ;3=69	
68.	Go to 80	Deny OR Pend and Continue to 80
69.	Go to 80	Go to 70
70.	Go to 80	Deny OR Pend and Continue to 80
71.	Go to 72	Deny OR Pend and Continue to 72
72.	Go to 73	Deny OR Pend and Continue to 73
73.	Go to 80	Go to 74

Reference number(s)
C29123-A

74.	Go to 80	Go to 75
75.	Go to 80	Deny OR Pend and Continue to 80
76.	Go to 77	Deny OR Pend and Continue to 77
77.	Go to 78	Deny OR Pend and Continue to 78
78.	Go to 79	Deny OR Pend and Continue to 79
79.	Go to 80	Deny OR Pend and Continue to 80
80.	1=81 ;2=104 ;3=104 ;4=122 ;5=142 ;6=149 ;7=153	
81.	Go to 82	Go to 90
82.	1=83 ;2=88	
83.	Deny OR Pend and Continue to 84	Go to 84
84.	1=85 ;2=86 ;3=87	
85.	Deny	Approve, 12 Months, Approve TWO 250 mg vials every 28 days, (Daily limit: 0.072).
86.	Deny	Approve, 12 Months, Approve THREE 250 mg vials every 28 days, (Daily limit: 0.108).
87.	Deny	Approve, 12 Months, Approve FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
88.	Deny OR Pend and Continue to 89	Go to 89
89.	Deny	Approve, 12 Months, Approve FOUR 125 mg syringes/autoinjectors every 28 days (Daily limit: 0.143), and FOUR 87.5 mg syringes every 28 days (Daily limit: 0.1), and FOUR 50 mg syringes every 28 days (Daily limit: 0.058).
90.	1=91 ;2=96 ;3=102	
91.	Deny OR Pend and Continue to 92	Go to 92
92.	1=93 ;2=94 ;3=95	
93.	Deny	Approve, 12 Months, Approve loading dose of SIX 250 mg vials, approval duration 28 days (Daily limit: 0.215), in addition to TWO 250 mg vials every 28 days, (Daily limit: 0.072).
94.	Deny	Approve, 12 Months, Approve loading dose of NINE 250 mg vials, approval duration 28 days (Daily limit: 0.322), in addition to THREE 250 mg vials every 28 days, (Daily limit: 0.108).
95.	Deny	Approve, 12 Months, Approve loading dose of TWELVE 250 mg vials, approval duration 28 days

		(Daily limit: 0.429), in addition to FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
96.	Deny OR Pend and Continue to 97	Go to 97
97.	Deny OR Pend and Continue to 98	Go to 98
98.	1=99 ;2=100 ;3=101	
99.	Deny	Approve, 12 Months, Approve loading dose of TWO 250 mg vials, approval duration 28 days (Daily limit: 0.072), in addition to FOUR 125 mg syringes/autoinjectors every 28 days, (Daily limit: 0.143), and FOUR 87.5 mg syringes every 28 days (Daily limit: 0.1), and FOUR 50 mg syringes every 28 days (Daily limit: 0.058).
100.	Deny	Approve, 12 Months, Approve loading dose of THREE 250 mg vials, approval duration 28 days (Daily limit: 0.108), in addition to FOUR 125 mg syringes/autoinjectors every 28 days, (Daily limit: 0.143), and FOUR 87.5 mg syringes every 28 days (Daily limit: 0.1), and FOUR 50 mg syringes every 28 days (Daily limit: 0.058).
101.	Deny	Approve, 12 Months, Approve loading dose of FOUR 250 mg vials, approval duration 28 days (Daily limit: 0.143), in addition to FOUR 125 mg syringes/autoinjectors every 28 days, (Daily limit: 0.143), and FOUR 87.5 mg syringes every 28 days (Daily limit: 0.1), and FOUR 50 mg syringes every 28 days (Daily limit: 0.058).
102.	Deny OR Pend and Continue to 103	Go to 103
103.	Deny	Approve, 12 Months, Approve FOUR 125 mg syringes/autoinjectors every 28 days (Daily limit: 0.143), and FOUR 87.5 mg syringes every 28 days (Daily limit: 0.1), and FOUR 50 mg syringes every 28 days (Daily limit: 0.058).
104.	1=105 ;2=117	
105.	1=Deny OR Pend and Continue to 106 ;2=106	
106.	Go to 107	Go to 112
107.	Deny OR Pend and Continue to 108	Go to 108
108.	1=109 ;2=110 ;3=111	
109.	Deny	Approve, 12 Months, Approve THREE 250 mg vials every 28 days, (Daily limit: 0.108).
110.	Deny	Approve, 12 Months, Approve THREE 250 mg vials every 28 days, (Daily limit: 0.108).

Reference number(s)
C29123-A

111.	Deny	Approve, 12 Months, Approve FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
112.	Deny OR Pend and Continue to 113	Go to 113
113.	1=114 ;2=115 ;3=116	
114.	Deny	Approve, 12 Months, Approve loading dose of NINE 250 mg vials, approval duration 28 days (Daily limit: 0.322), in addition to THREE 250 mg vials every 28 days, (Daily limit: 0.108).
115.	Deny	Approve, 12 Months, Approve loading dose of NINE 250 mg vials, approval duration 28 days (Daily limit: 0.322), in addition to THREE 250 mg vials every 28 days, (Daily limit: 0.108).
116.	Deny	Approve, 12 Months, Approve loading dose of TWELVE 250 mg vials, approval duration 28 days (Daily limit: 0.429), in addition to FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
117.	Deny OR Pend and Continue to 118	Go to 118
118.	1=Deny ;2=119 ;3=120 ;4=121	
119.	Deny	Approve, 12 Months, Approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
120.	Deny	Approve, 12 Months, Approve FOUR 87.5 mg syringes every 28 days, (Daily limit: 0.1), and approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
121.	Deny	Approve, 12 Months, Approve FOUR 125 mg syringes/autoinjectors every 28 days, (Daily limit: 0.143), and approve FOUR 87.5 mg syringes every 28 days, (Daily limit: 0.1), and approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
122.	1=123 ;2=135	
123.	1=Deny OR Pend and Continue to 124 ;2=124	
124.	Go to 125	Go to 130
125.	Deny OR Pend and Continue to 126	Go to 126
126.	1=127 ;2=128 ;3=129	
127.	Deny	Approve, 12 Months, Approve TWO 250 mg vials every 28 days, (Daily limit: 0.072).
128.	Deny	Approve, 12 Months, Approve THREE 250 mg vials every 28 days, (Daily limit: 0.108).

129.	Deny	Approve, 12 Months, Approve FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
130.	Deny OR Pend and Continue to 131	Go to 131
131.	1=132 ;2=133 ;3=134	
132.	Deny	Approve, 12 Months, Approve loading dose of SIX 250 mg vials, approval duration 28 days (Daily limit: 0.215), in addition to TWO 250 mg vials every 28 days, (Daily limit: 0.072).
133.	Deny	Approve, 12 Months, Approve loading dose of NINE 250 mg vials, approval duration 28 days (Daily limit: 0.322), in addition to THREE 250 mg vials every 28 days, (Daily limit: 0.108).
134.	Deny	Approve, 12 Months, Approve loading dose of TWELVE 250 mg vials, approval duration 28 days (Daily limit: 0.429), in addition to FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
135.	1=136 ;2=140	
136.	Deny OR Pend and Continue to 137	Go to 137
137.	1=Deny ;2=138 ;3=139 ;4=141	
138.	Deny	Approve, 12 Months, Approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
139.	Deny	Approve, 12 Months, Approve FOUR 87.5 mg syringes every 28 days, (Daily limit: 0.1), and approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
140.	Deny OR Pend and Continue to 141	Go to 141
141.	Deny	Approve, 12 Months, Approve FOUR 125 mg syringes/autoinjectors every 28 days, (Daily limit: 0.143), and approve FOUR 87.5 mg syringes every 28 days, (Daily limit: 0.1), and approve FOUR 50 mg syringes every 28 days, (Daily limit: 0.058).
142.	Go to 143	Deny OR Pend and Continue to 143
143.	1=144 ;2=Deny OR Pend and Continue to 144	
144.	Go to 145	Go to 147
145.	Deny OR Pend and Continue to 146	Go to 146
146.	Deny	Approve, 12 Months, Approve FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
147.	Deny OR Pend and Continue to 148	Go to 148

Reference number(s)
C29123-A

148.	Deny	Approve, 12 Months, Approve loading dose of TWELVE 250 mg vials, approval duration 28 days (Daily limit: 0.429), in addition to FOUR 250 mg vials every 28 days, (Daily limit: 0.143).
149.	Go to 150	Deny OR Pend and Continue to 150
150.	1=151 ;2=Deny OR Pend and Continue to 151	
151.	Deny OR Pend and Continue to 152	Go to 152
152.	Deny	Approve, 6 Months, Approve EIGHT 250 mg vials every 28 days, (Daily limit: 0.286).
153.	1=154 ;2=Deny OR Pend and Continue to 154	
154.	1=155 ;2=156	
155.	Deny	Approve, 1 Months, Approve up to SIXTEEN 250 mg vials, approval duration 28 days, (Daily limit: 0.572).
156.	Deny	Approve, 1 Months, Approve up to SIXTEEN 250 mg vials, approval duration 28 days, (Daily limit: 0.572).

Initial Prior Authorization

Oriahnn

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Oriahnn	elagolix/estradiol/norethindrone acetate

Indications

FDA-approved Indications

Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Limitations of Use

Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Coverage Criteria

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas (Fibroids)

Authorization may be granted when the requested drug is being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) when ALL of the following criteria are met:

- The patient is premenopausal.
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient must not have already received ANY of the following:
 - Greater than or equal to 24 cumulative months of treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree).
 - Greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily.

Duration of Approval (DOA)

- 3960-A: Total additive duration: 24 months (see chart)

Cumulative months of prior treatment with an elagolix- and/or relugolix-containing product	Duration of Approval (in months)
No prior treatment	12
≤ 12	12
13	11
14	10
15	9
16	8
17	7
18	6
19	5
20	4
21	3
22	2
23	1

Reference number(s)
3960-A

References

1. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
2. Myfembree [package insert]. Marlborough, MA: Sumitomo Pharma America, Inc.; July 2024.
3. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; June 2023.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed November 29, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2024).

Reference number(s)
C29109-A

CountyCare IL Custom Criteria
Otezla
Otezla XR

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

Signature

Date

Client Name

MDC: REG

CRITERIA FOR APPROVAL

- 1 What is the diagnosis?
 - ☐ Plaque psoriasis (If checked, go to 7)
 - ☐ Psoriatic arthritis (If checked, go to 2)
 - ☐ Other, please specify: _____ (If checked, go to 10)
- 2 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication to at least TWO of the preferred products Cimzia, Cosentyx, Enbrel, Xeljanz/Xeljanz XR, or an adalimumab product? Yes No
 [If Yes, then go to 10. If No, then go to 3.]
- 3 Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? Yes No
 [If Yes, then go to 4. If No, then go to 5.]
- 4 Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? Yes No
 [If Yes, then go to 10. If No, then no further questions.]
- 5 Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being

a primary non-responder to a JAK inhibitor? [If Yes, then go to 6. If No, then no further questions.]		
6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 10. If No, then no further questions.]	Yes No
7	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 10. If No, then go to 8.]	Yes No
8	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then no further questions.]	Yes No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 10. If No, then no further questions.]	Yes No
10	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu) for the same indication? [If Yes, then no further questions. If No, then go to 11.]	Yes No
11	What is the diagnosis? ☐ Plaque psoriasis (If checked, go to 15) ☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 12) ☐ Psoriatic arthritis WITHOUT co-existent plaque psoriasis (If checked, go to 30) ☐ Behcet's disease (If checked, go to 44) ☐ Immune checkpoint inhibitor-related psoriasis and psoriasiform diseases (If checked, go to 52) ☐ Other, please specify _____ (If checked, no further questions)	
12	Is the patient an adult (18 years of age or older)? [If Yes, then go to 13. If No, then no further questions.]	Yes No
13	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 14. If No, then no further questions.]	Yes No
14	What is the primary diagnosis being treated? ☐ Psoriatic arthritis (If checked, go to 32)	

☐ Plaque psoriasis (If checked, go to 17)		
15	Is the patient 6 years of age or older? [If Yes, then go to 16. If No, then no further questions.]	Yes No
16	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 17. If No, then no further questions.]	Yes No
17	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 18. If No, then go to 22.]	Yes No
18	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?	
	☐ Yes (If checked, go to 22)	
	☐ No (If checked, go to 19)	
	☐ Unknown (If checked, go to 22)	
19	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 20. If No, then no further questions.]	Yes No
20	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? <i>ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 59. If No, then go to 21.]	Yes No
21	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? <i>ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 59. If No, then no further questions.]	Yes No
22	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug indicated for the treatment of plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 59. If No, then go to 23.]	Yes No
23	Has the patient experienced an inadequate response or has an intolerance to phototherapy (e.g., UVB, PUVA)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 59. If No, then go to 24.]	Yes No

24	Has the patient experienced an inadequate response or has an intolerance to topical therapies (e.g., medium or higher potency topical corticosteroids, calcineurin inhibitors, vitamin D analogs)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 59. If No, then go to 25.]	Yes	No
25	Does the patient have a contraindication or clinical reason to avoid phototherapy (e.g., UVB, PUVA)? ACTION REQUIRED: If Yes, please attach documentation of contraindication or clinical reason to avoid phototherapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 26. If No, then go to 27.]	Yes	No
26	Does the patient have a contraindication or clinical reason to avoid topical therapies (e.g., medium or higher potency topical corticosteroids, calcineurin inhibitors, vitamin D analogs)? ACTION REQUIRED: If Yes, please attach documentation of contraindication or clinical reason to avoid topical therapies. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 59. If No, then go to 27.]	Yes	No
27	Has the patient experienced an inadequate response, or has an intolerance to pharmacologic treatment with ONE of the following medications: methotrexate, cyclosporine, or acitretin? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 59. If No, then go to 28.]	Yes	No
28	Does the patient have a clinical reason to avoid pharmacologic treatment with ALL of the following medications: methotrexate, cyclosporine, and acitretin? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 29. If No, then no further questions.]	Yes	No
29	Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 59) ☐ Drug interaction (If checked, go to 59) ☐ Risk of treatment-related toxicity (If checked, go to 59) ☐ Pregnancy or currently planning pregnancy (If checked, go to 59) ☐ Breastfeeding (If checked, go to 59) ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 59)		

☐ Hypersensitivity (If checked, go to 59)

☐ History of intolerance or adverse event (If checked, go to 59)

☐ Other, please specify _____ (If checked, no further questions)

30	Is the patient an adult (18 years of age or older)? [If Yes, then go to 31. If No, then no further questions.]	Yes	No

31	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 32. If No, then no further questions.]	Yes	No

32	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 33. If No, then go to 36.]	Yes	No

33	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 36)

☐ No (If checked, go to 34)

☐ Unknown (If checked, go to 36)

34	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 35. If No, then no further questions.]	Yes	No

35	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Number of tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Dactylitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Enthesitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Axial disease ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Skin and/or nail involvement ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ Functional status ACTION REQUIRED: Submit supporting documentation (If checked, go to 64)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 64)

☐ None of the above (If checked, no further questions)

36	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 37. If No, then no further questions.]	Yes	No

37	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 64. If No, then go to 38.]	Yes	No

38	Does the patient have enthesitis? [If Yes, then go to 64. If No, then go to 39.]	Yes	No

39	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 64. If No, then go to 40.]	Yes	No

40	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 64. If No, then go to 41.]	Yes	No

41	Does the patient have a contraindication to methotrexate or leflunomide? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 42. If No, then go to 43.]	Yes	No

42 Please indicate the contraindication to methotrexate or leflunomide.

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 64)

☐ Drug interaction (If checked, go to 64)

☐ Risk of treatment-related toxicity (If checked, go to 64)

☐ Pregnancy or currently planning pregnancy (If checked, go to 64)

☐ Breastfeeding (If checked, go to 64)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If

checked, go to 64)

☐ Hypersensitivity (If checked, go to 64)

☐ History of intolerance or adverse event (If checked, go to 64)

☐ Other (If checked, no further questions)

43	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 60. If No, then no further questions.]	Yes	No
44	Is the patient an adult (18 years of age or older)? [If Yes, then go to 45. If No, then no further questions.]	Yes	No
45	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 46. If No, then no further questions.]	Yes	No
46	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 47. If No, then go to 49.]	Yes	No
47	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 49) ☐ No (If checked, go to 48) ☐ Unknown (If checked, go to 49)		
48	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 64. If No, then no further questions.]	Yes	No
49	Has the patient ever received or is currently receiving a biologic indicated for treatment of Behcet's disease (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 64. If No, then go to 50.]	Yes	No
50	Is this request for the treatment of oral ulcers associated with Behcet's disease? [If Yes, then go to 51. If No, then no further questions.]	Yes	No
51	Has the patient had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation	Yes	No

	[If Yes, then go to 64. If No, then no further questions.]	
52	Is the requested drug being prescribed by or in consultation with a dermatologist, hematologist, or oncologist? [If Yes, then go to 53. If No, then no further questions.]	Yes No
53	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 54. If No, then go to 56.]	Yes No
54	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 56) ☐ No (If checked, go to 55) ☐ Unknown (If checked, go to 56)	
55	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? <i>ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 58. If No, then no further questions.]	Yes No
56	Has the patient had an inadequate response to medium or higher potency topical corticosteroids? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 58. If No, then go to 57.]	Yes No
57	Does the patient have an intolerance or contraindication to medium or higher potency topical corticosteroids? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 58. If No, then no further questions.]	Yes No
58	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? [If Yes, then go to 64. If No, then no further questions.]	Yes No
59	What is the patient's age? ☐ 6 years of age to 17 years of age (If checked, go to 60) ☐ 18 years of age or older (If checked, go to 64)	
60	Is the patient currently receiving the requested drug? [If Yes, then go to 61. If No, then go to 69.]	Yes No
61	What is the patient's weight? Indicate in kilograms (kg).	

☐ Less than 20 kg _____ (If checked, no further questions)

☐ 20 kg to less than 50 kg _____ (If checked, go to 62)

☐ Greater than or equal to 50 kg _____ (If checked, go to 65)

62	Does the prescribed dose exceed 20 mg? [If Yes, then no further questions. If No, then go to 63.]	Yes	No
63	Is the prescribed frequency of the maintenance dose more frequent than one dose twice daily? [No further questions]	Yes	No
64	Is the patient currently receiving the requested drug? [If Yes, then go to 65. If No, then go to 67.]	Yes	No
65	Does the prescribed dose exceed one of the following: 30 mg Immediate Release (IR) tablet OR 75 mg Extended release (XR) tablet? [If Yes, then no further questions. If No, then go to 66.]	Yes	No
66	Is the prescribed frequency of the maintenance dose more frequent than one dose twice daily for 30 mg Immediate release (IR) tablet OR more frequent than one dose once daily for 75 mg Extended release (XR) tablet? [No further questions]	Yes	No
67	Does the prescribed dose exceed 10 mg in the morning on day 1, 10 mg in the morning and evening on day 2, 10 mg in the morning and 20 mg in the evening on day 3, 20 mg in the morning and evening on day 4, 20 mg in the morning and 30 mg in the evening on day 5, and 75 mg thereafter? [If Yes, then no further questions. If No, then go to 68.]	Yes	No
68	Is the prescribed frequency of the maintenance dose more frequent than one dose twice daily? [No further questions]	Yes	No
69	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than 20 kg (If checked, no further questions) ☐ 20 kg to less than 50 kg (If checked, go to 70) ☐ Greater than or equal to 50 kg (If checked, go to 72)		
70	Does the prescribed dose exceed 10 mg in the morning on day 1, 10 mg in the morning and evening on day 2, 10 mg in the morning and 20 mg in the evening on day 3, and 20 mg in the morning and evening thereafter? [If Yes, then no further questions. If No, then go to 71.]	Yes	No
71	Is the prescribed frequency of the maintenance dose more frequent than one dose twice daily? [No further questions]	Yes	No

72	Does the prescribed dose exceed 10 mg in the morning on day 1, 10 mg in the morning and evening on day 2, 10 mg in the morning and 20 mg in the evening on day 3, 20 mg in the morning and evening on days 4 and 5, and 75 mg thereafter? [If Yes, then no further questions. If No, then go to 73.]	Yes	No
73	Is the prescribed frequency of the maintenance dose more frequent than one dose twice daily? [No further questions]	Yes	No

Mapping Instructions

	Yes	No
1.	1=7 ;2=2 ;3=10	
2.	Go to 10	Go to 3
3.	Go to 4	Go to 5
4.	Go to 10	Deny OR Pend and Continue to 10
5.	Go to 6	Deny OR Pend and Continue to 6
6.	Go to 10	Deny OR Pend and Continue to 10
7.	Go to 10	Go to 8
8.	Go to 9	Deny OR Pend and Continue to 9
9.	Go to 10	Deny OR Pend and Continue to 10
10.	Deny OR Pend and Continue to 11	Go to 11
11.	1=15 ;2=12 ;3=30 ;4=44 ;5=52 ;6=Deny	
12.	Go to 13	Deny OR Pend and Continue to 13
13.	Go to 14	Deny OR Pend and Continue to 14
14.	1=32 ;2=17	
15.	Go to 16	Deny OR Pend and Continue to 16
16.	Go to 17	Deny OR Pend and Continue to 17
17.	Go to 18	Go to 22
18.	1=22 ;2=19 ;3=22	
19.	Go to 20	Deny OR Pend and Continue to 20
20.	Go to 59	Go to 21
21.	Go to 59	Deny OR Pend and Continue to 59

22.	Go to 59	Go to 23
23.	Go to 59	Go to 24
24.	Go to 59	Go to 25
25.	Go to 26	Go to 27
26.	Go to 59	Go to 27
27.	Go to 59	Go to 28
28.	Go to 29	Deny OR Pend and Continue to 29
29.	1=59 ;2=59 ;3=59 ;4=59 ;5=59 ;6=59 ;7=59 ;8=59 ;9=Deny OR Pend and Continue to 59	
30.	Go to 31	Deny OR Pend and Continue to 31
31.	Go to 32	Deny OR Pend and Continue to 32
32.	Go to 33	Go to 36
33.	1=36 ;2=34 ;3=36	
34.	Go to 35	Deny OR Pend and Continue to 35
35.	1=64 ;2=64 ;3=64 ;4=64 ;5=64 ;6=64 ;7=64 ;8=64 ;9=Deny OR Pend and Continue to 36	
36.	Go to 37	Deny OR Pend and Continue to 37
37.	Go to 64	Go to 38
38.	Go to 64	Go to 39
39.	Go to 64	Go to 40
40.	Go to 64	Go to 41
41.	Go to 42	Go to 43
42.	1=64 ;2=64 ;3=64 ;4=64 ;5=64 ;6=64 ;7=64 ;8=64 ;9=Deny OR Pend and Continue to 43	
43.	Go to 60	Deny OR Pend and Continue to 60
44.	Go to 45	Deny OR Pend and Continue to 45
45.	Go to 46	Deny OR Pend and Continue to 46
46.	Go to 47	Go to 49
47.	1=49 ;2=48 ;3=49	
48.	Go to 64	Deny OR Pend and Continue to 64

49.	Go to 64	Go to 50
50.	Go to 51	Deny OR Pend and Continue to 51
51.	Go to 64	Deny OR Pend and Continue to 52
52.	Go to 53	Deny OR Pend and Continue to 53
53.	Go to 54	Go to 56
54.	1=56 ;2=55 ;3=56	
55.	Go to 58	Deny OR Pend and Continue to 58
56.	Go to 58	Go to 57
57.	Go to 58	Deny OR Pend and Continue to 58
58.	Go to 64	Deny OR Pend and Continue to 64
59.	1=60 ;2=64	
60.	Go to 61	Go to 69
61.	1=Deny ;2=62 ;3=65	
62.	Deny OR Pend and Continue to 63	Go to 63
63.	Deny	Approve, 12 Months, Approve, 12 Months of Otezla 20mg 66700015000320 with daily dose limit of 2.0
64.	Go to 65	Go to 67
65.	Deny OR Pend and Continue to 66	Go to 66
66.	Deny	Approve, 12 Months, Approve, 12 Months of Otezla 30 mg tablets GPI 66700015000330 Daily Dose limit of 2.0 and 20 mg tablets GPI 66700015000320 Daily Dose limit of 2.0 and Otezla XR 75mg GPI 66700015007530 Daily Dose Limit of 1.0.
67.	Deny OR Pend and Continue to 68	Go to 68
68.	Deny	Approve, 12 Months, Approve initial titration dose of FIFTY-FIVE tablets of the 10/20/30 28-day starter pack, approval duration 28 days(Daily limit: 1.965)GPI 6670001500B720 and initial titration dose of FIFTY-FIVE tablets of the 10/20 28-day starter pack, approval duration 28 days(Daily limit:1.965)GPI 6670001500B710, in addition to SIXTY 30 mg tablets every 30 days(Daily limit:2)GPI 66700015000330 and SIXTY 20 mg tablets every 30 days(Daily limit: 2)GPI 66700015000320 and XR 75mg GPI 667000150007530 Daily Limit 1
69.	1=Deny ;2=70 ;3=72	

Reference number(s)
C29109-A

70.	Deny OR Pend and Continue to 71	Go to 71
71.	Deny	Approve, 12 Months, Approve initial titration dose of FIFTY-FIVE tablets of the 10/20 28-day starter pack GPI 6670001500B710, approval duration 28 days (Daily limit: 1.965), in addition to SIXTY 20 mg tablets GPI 66700015000320 every 30 days (Daily limit: 2)].
72.	Deny OR Pend and Continue to 73	Go to 73
73.	Deny	Approve, 12 Months, Approve initial titration dose of FIFTY-FIVE tablets of the 10/20/30 28-day starter pack, approval duration 28 days (Daily limit: 1.965) GPI 6670001500B720 and initial titration dose of FIFTY-FIVE tablets of the 10/20 28-day starter pack GPI 66700015000B710, approval 28 days(Daily limit: 1.965), in addition to SIXTY 30 mg tablets every 30 days (Daily limit: 2)GPI 66700015000330 and SIXTY 20 mg tablets every 30 days(Daily limit: 2)GPI 66700015000320, and XR 75mg GPI 667000150007530 Daily Limit 1.

Initial Prior Authorization

Pancrelipase

Pancreatic Enzymes

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Creon	pancrelipase
Pancreaze	pancrelipase
Pertzye	pancrelipase
Viokace	pancrelipase
Zenpep	pancrelipase

Indications

FDA-approved Indications

Creon, Pancreaze, Pertzye, Zenpep

These products are indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients.

Viokace

Viokace, in combination with a proton pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy in adults.

Coverage Criteria

Exocrine Pancreatic Insufficiency

Authorization may be granted when the requested drug is being prescribed for the treatment of exocrine pancreatic insufficiency when the following criteria is met:

- If the request is for Viokace, the patient will take Viokace in combination with a proton pump inhibitor (PPI).

Duration of Approval (DOA)

- 3134-A: DOA: 12 months

References

1. Creon [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
2. Pancreaze [package insert]. Campbell, CA: Vivus LLC; February 2024.
3. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; February 2024.
4. Viokace [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; February 2024.
5. Zenpep [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; February 2024.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 3, 2024.
7. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 3, 2024.
8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/03/2024).

Specialty Guideline Management

Pegasys

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pegasys	peginterferon alfa-2a

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications ¹

Chronic Hepatitis C (CHC)

- In combination therapy with other hepatitis C virus (HCV) drugs for adults with compensated liver disease. Pegasys monotherapy is indicated only if the patient has contraindication or significant intolerance to other HCV drugs.
- In combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease

Limitations of Use

- Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa.
- Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

Chronic Hepatitis B

- Treatment of adults with HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation
- Treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT)

Compendial Uses^{2,3}

- Chronic hepatitis E virus infection
- Myeloproliferative neoplasms (i.e., essential thrombocythemia, polycythemia vera, or symptomatic lower-risk myelofibrosis)
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Hairy cell leukemia
- Erdheim-Chester disease
- Chronic myeloid leukemia

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Chronic Hepatitis C Virus (HCV) Infection^{1,4}

Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

Chronic Hepatitis B Virus (HBV) Infection (including hepatitis D virus [HDV] coinfection)^{1,5}

Authorization of up to 48 weeks total may be granted for treatment of chronic HBV infection, including HDV coinfection.

Chronic Hepatitis E Virus (HEV) Infection in Liver Transplant Recipients^{2,6,7}

Authorization of 12 months may be granted for treatment of chronic HEV infection when both of the following criteria are met:

- Member is a liver transplant recipient.
- Member has had an inadequate response, intolerance, or contraindication to ribavirin.

Myeloproliferative Neoplasms²

Authorization of 12 months may be granted for treatment of myeloproliferative neoplasms (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis).

Systemic Mastocytosis²

Authorization of 12 months may be granted for treatment of systemic mastocytosis.

Adult T-Cell Leukemia/Lymphoma²

Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.

Mycosis Fungoides/Sezary Syndrome²

Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders²

Authorization of 12 months may be granted for treatment of primary cutaneous CD30+ T-cell lymphoproliferative disorders.

Hairy Cell Leukemia²

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

Erdheim-Chester Disease²

Authorization of 12 months may be granted for treatment of Erdheim-Chester disease.

Chronic Myeloid Leukemia²

Authorization of 12 months may be granted for treatment of chronic myeloid leukemia in pregnancy.

Continuation of Therapy

Chronic HCV Infection, Chronic HBV Infection (including HDV coinfection), or Chronic HEV Infection in Liver Transplant Recipients

Reference number(s)
Policy: 2139-A
Qsets: 5920-A, 6284-A

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Myeloproliferative Neoplasm^{2,8}

Authorization of 12 months may be granted if the member is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis).

Systemic mastocytosis^{2,9}

Authorization of 12 months may be granted if the member is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., reduction in serum and urine metabolites of mast cell activation, improvement in cutaneous lesions, skeletal disease, bone marrow mast cell burden).

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in the coverage criteria section, not previously listed, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Pegasys [package insert]. South San Francisco, CA: Genentech, Inc; March 2021.
2. AHFS DI (Adult and Pediatric). Lexicomp.
http://online.lexi.com/lco/action/doc/retrieve/docid/complete/_ashp/414040. Last updated February 17, 2025. Accessed March 15, 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 15, 2025.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
5. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67(4):1560-1599. doi: 10.1002/hep.29800
6. European Association for the Study of the Liver. EASL clinical practice guidelines on hepatitis E virus infection. *J Hepatol*. 2018;68(6):1256-1271. doi: 10.1016/j.jhep.2018.03.005
7. Te H, Doucette K. Viral hepatitis: Guidelines by the American Society of Transplantation Infectious Disease Community of Practice. *Clin Transplant*. 2019;33(9):e13514. doi: 10.1111/ctr.13514
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 1.2025). <http://www.nccn.org>. Accessed March 15, 2025.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Systemic Mastocytosis (Version 1.2025). <http://www.nccn.org>. Accessed March 15, 2025.

Specialty Guideline Management

Ponvory

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ponvory	ponesimod

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Ponvory is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Reference number(s)
4631-A

Relapsing forms of multiple sclerosis¹

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically isolated syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

Continuation of Therapy

For all indications:

Authorization of 12 months may be granted to members who are experiencing disease stability or improvement while receiving Ponvory

Other

- Members will not use Ponvory concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Reference

1. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; June 2024.

Specialty Guideline Management

Prolia and Biosimilars

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Prolia	denosumab
Bildyos	denosumab-nxxp
Bosaya	denosumab-kyqq
Conexxence	denosumab-bnht
Jubbonti	denosumab-bbdz
Ospomyv	denosumab-dssb
Stoboclo	denosumab-bmwo

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁶

- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy (ADT) for nonmetastatic prostate cancer.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Compendial Uses⁷

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT).
- Treatment in postmenopausal (natural or induced) patients with breast cancer receiving adjuvant aromatase inhibition therapy to maintain or improve bone mineral density and reduce risk of fractures.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Postmenopausal Osteoporosis, Osteoporosis in Men, Glucocorticoid-Induced Osteoporosis

Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) fracture probability (if applicable).

Prostate Cancer

Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy (ADT).

Breast Cancer

Chart notes, medical record documentation, or claims history supporting use of aromatase inhibition therapy.

Coverage Criteria

Postmenopausal Osteoporosis^{1-6,8-10}

Authorization of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position).
- Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B) and meets ANY of the following criteria:
 - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], teriparatide [Forteo], abaloparatide [Tymlos])
 - Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

Osteoporosis in Men^{1-6,8,11,12}

Authorization of 12 months may be granted to male members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member meets BOTH of the following criteria:
 - Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B)
 - Member has had an oral or injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (see Appendix A)

Glucocorticoid-Induced Osteoporosis^{1-6,11,15}

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months.
- Member has had an oral or injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (see Appendix A)

- Member meets ANY of the following criteria:
 - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position).
 - Member has a pre-treatment T-score less than or equal to -2.5
 - Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B)

Prostate Cancer^{1-7,13}

Authorization of 12 months may be granted to members who are receiving androgen deprivation therapy (ADT) for prostate cancer.

Breast Cancer^{1-7,13}

Authorization of 12 months may be granted to members who are receiving adjuvant aromatase inhibition therapy for breast cancer.

Continuation of Therapy¹⁻⁶

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet either of the following:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets both of the following:
 - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
 - Member has not experienced any adverse effects

Appendix

Appendix A: Clinical Reasons to Avoid Oral Bisphosphonate Therapy^{10,16}

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)

- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take oral bisphosphonate at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B: FRAX Fracture Risk Assessment Tool¹³⁻¹⁵

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk $\geq$ 20% or hip fracture risk $\geq$ 3%
- 10-year probability; calculation tool available at: <https://frax.shef.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day

References

1. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2025.
2. Bieldos [package insert]. Jersey City, NJ: Organon LLC; August 2025.
3. Bosaya [package insert]. Cambridge, MA: Biocon Biologics Inc.; September 2025.
4. Conexence [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2025
5. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
6. Ospomyv [package insert]. Incheon, South Korea: Samsung Bioepis; February 2025.
7. Stoboclo [package insert]. Incheon, South Korea: Celltrion Inc.; February 2025.
8. The NCCN Drugs & Biologics Compendium® 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 5, 2025.
9. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022;33(10):2049-2102.
10. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 update. *Endocr Pract*. 2020;26 (Suppl 1):1-46.
11. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2020;105(3):587-594.
12. Carey JJ. What is a 'failure' of bisphosphonate therapy for osteoporosis? *Cleve Clin J of Med*. 2005;72(11):1033-1039.

Reference number(s)
2026-A

13. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocr Metab*. 2012;97(6):1802-1822.
14. Gralow JR, Biermann JS, Farooki A, et al. NCCN Task Force Report: Bone Health in Cancer Care. *J Natl Compr Canc New*. 2013;11(Suppl 3):S1-50.
15. FRAX® Fracture Risk Assessment Tool. © Osteoporosis Research Ltd, UK. Available online: <https://fraxplus.org>. Accessed September 5, 2025.
16. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2012.
17. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med*. 2017;167(03):ITC17-ITC32.

Specialty Guideline Management

Promacta-Alvaiz

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Promacta	eltrombopag olamine
Alvaiz	eltrombopag choline

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Promacta is indicated for:

- Treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- First-line treatment of severe aplastic anemia in adult and pediatric patients 2 years and older in combination with standard immunosuppressive therapy.
- Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Alvaiz is indicated for:

- Treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
- Treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy.
- Treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

Compendial Uses

- MYH9-related disease with thrombocytopenia (Promacta only)
- Myelodysplastic syndromes (MDS) (Promacta only)
- Thrombocytopenia post-hematopoietic cell transplant

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Persistent or chronic immune thrombocytopenia (ITP):
 - For initial requests: pretreatment platelet count
 - For continuation requests: current platelet count
- Aplastic anemia continuation of therapy: current platelet count

Exclusions

Coverage will not be provided when the requested drug will be used concomitantly with other thrombopoietin receptor agonists (e.g., Nplate, Doptelet, Mulpleta) or with spleen tyrosine kinase inhibitors (e.g., Tavalisse).

Prescriber Specialties

This medication must be prescribed by or in consultation with either of the following:

- Persistent or chronic immune thrombocytopenia (ITP), aplastic anemia, MYH9-related disease with thrombocytopenia, myelodysplastic syndromes, and thrombocytopenia post-hematopoietic cell transplant: hematologist or oncologist

- Thrombocytopenia with hepatitis C: hematologist or a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant

Coverage Criteria

Persistent or chronic immune thrombocytopenia (ITP)

Authorization of 6 months may be granted for treatment of persistent or chronic ITP when both of the following criteria are met:

- Member has had an inadequate response or intolerance to prior therapy with corticosteroids, immunoglobulins, or splenectomy.
- Member has an untransfused platelet count at any point prior to the initiation of the requested medication of either of the following:
 - Less than $30 \times 10^9/L$
 - $30 \times 10^9/L$ to $50 \times 10^9/L$ with symptomatic bleeding (e.g., significant mucous membrane bleeding, gastrointestinal bleeding or trauma) or risk factors for bleeding (see Appendix)

Thrombocytopenia associated with chronic hepatitis C

Authorization of 12 months may be granted to members who are prescribed the requested drug for the initiation and maintenance of interferon-based therapy for the treatment of thrombocytopenia associated with chronic hepatitis C.

Severe aplastic anemia

Promacta

- Authorization of 6 months may be granted for first-line treatment of severe aplastic anemia when the requested drug will be used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin [h-ATG] and cyclosporine).
- Authorization of 6 months may be granted for treatment of severe aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.

Alvaiz

Authorization of 6 months may be granted for treatment of severe aplastic anemia in members who have had an insufficient response to immunosuppressive therapy.

MYH9-related disease with thrombocytopenia (Promacta only)

Authorization of 12 months may be granted to members with thrombocytopenia associated with MYH9-related disease.

Myelodysplastic syndromes (Promacta only)

Authorization of 12 months may be granted for treatment of myelodysplastic syndromes (MDS).

Thrombocytopenia post-hematopoietic cell transplant

Authorization of 6 months may be granted for treatment of prolonged thrombocytopenia in members who are post-allogeneic transplant and have poor graft function.

Continuation of Therapy

Persistent or chronic immune thrombocytopenia (ITP)

- Authorization of 3 months may be granted to members with current platelet count less than $50 \times 10^9/L$ for whom the platelet count is not sufficient to prevent clinically important bleeding and who have not received a maximal dose of the requested drug for at least 4 weeks.
- Authorization of 12 months may be granted to members with current platelet count less than $50 \times 10^9/L$ for whom the current platelet count is sufficient to prevent clinically important bleeding.
- Authorization of 12 months may be granted to members with current platelet count of $50 \times 10^9/L$ to $200 \times 10^9/L$.
- Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ to less than or equal to $400 \times 10^9/L$ for whom dosing for the requested drug will be adjusted to achieve a platelet count sufficient to avoid clinically important bleeding.

Thrombocytopenia associated with chronic hepatitis C

Authorization of 6 months may be granted to members who are continuing to receive interferon-based therapy.

Severe aplastic anemia

- Authorization of up to 16 weeks total may be granted to members with current platelet count less than $50 \times 10^9/L$ who have not received appropriately titrated therapy with the requested drug for at least 16 weeks.
- Authorization of 12 months total may be granted to members with current platelet count less than $50 \times 10^9/L$ who are transfusion-independent.
- Authorization of 12 months may be granted to members with current platelet count of $50 \times 10^9/L$ to $200 \times 10^9/L$.

- Authorization of 12 months may be granted to members with current platelet count greater than $200 \times 10^9/L$ to less than or equal to $400 \times 10^9/L$ for whom dosing for the requested drug will be adjusted to achieve and maintain an appropriate target platelet count.

MYH9-related disease with thrombocytopenia (Promacta only)

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Myelodysplastic syndromes (Promacta only) and thrombocytopenia post-hematopoietic cell transplant

Authorization of 12 months may be granted for continued treatment of myelodysplastic syndromes or thrombocytopenia post-hematopoietic cell transplant in members who experience benefit from therapy (e.g., increased platelet counts, decreased bleeding events, reduced need for platelet transfusions).

Appendix

Examples of risk factors for bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidities for bleeding (e.g., peptic ulcer disease)
- Mandated anticoagulation therapy
- Profession (e.g., construction worker) or lifestyle (e.g., plays contact sports) that predisposes member to trauma

References

1. Promacta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2023.
2. Alvaiz [package insert]. Parsippany, NJ: Teva Pharmaceuticals; May 2024.
3. Pecci A, Gresele P, Klersy C, et al. Eltrombopag for the treatment of the inherited thrombocytopenia deriving from MYH9 mutations. *Blood*. 2010;116(26):5832-7.
4. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2024.
5. The NCCN Clinical Practice Guidelines in Oncology® Myelodysplastic Syndrome (Version 2.2024). © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2024.
6. Nuenert C, Terrel DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019;3(23):3829–3866.

7. Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. *Blood Adv.* 2019;3(22): 3780–3817.
8. Provan D, Stasi R, Newland AC, et al. International consensus report on the investigation and management of primary immune thrombocytopenia. *Blood.* 2010;115(2):168-186.
9. Rodeghiero F, Stasi R, Gernsheimer T, et al. Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group. *Blood.* 2009;113(11):2386-2393.
10. Olnes MJ, Scheinberg P, Calvo KR, et al. Eltrombopag and improved hematopoiesis in refractory aplastic anemia. *N Engl J Med.* 2012;367(1):11-19.
11. Townsley DM, Scheinberg P, Winkler T, et al. Eltrombopag added to standard immunosuppression for aplastic anemia. *N Engl J Med.* 2017;376:1540-1550.
12. Kulasekararaj A, Cavenagh J, Dokal I, et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society for Haematology guideline. *Br J Haematol.* 2024;204(3):784-804.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

ACIPHEX
(rabeprazole)

DEXILANT
(dexlansoprazole)

FIRST-OMEPRAZOLE SUSPENSION
(omeprazole suspension compound kit)

lansoprazole suspension compound kit

NEXIUM
(esomeprazole)

omeprazole suspension compound kit

PREVACID
(lansoprazole)

PRILOSEC
(omeprazole)

PROTONIX
(pantoprazole)

Status: Client Requested Criteria

Type: Initial Prior Authorization

Ref # C25428-A

CRITERIA FOR APPROVAL

1	Is the request for a preferred proton pump inhibitor (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [If yes, then skip to question 20.]	Yes	No
2	Is the patient 21 years of age or older? [If yes, then skip to question 6.]	Yes	No
3	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 5.]	Yes	No
4	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No

5	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No
6	Is this request for continuation of therapy? [If no, then skip to question 13.]	Yes	No
7	Has the patient experienced or maintained a documented positive clinical response to therapy? [If no, then no further questions.]	Yes	No
8	Has the patient previously been through the CountyCare prior authorization process and has received an authorization in the past 12 months? [If yes, then no further questions.]	Yes	No
9	Is the patient on a stable regimen and disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation? [If yes, then no further questions.]	Yes	No
10	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 12.]	Yes	No
11	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No
12	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No
13	Is the patient under the care of a gastroenterologist? [If no, then no further questions.]	Yes	No
14	Does the patient have one of the following conditions: A) GI bleed, B) Erosive esophagitis, C) Pathological hypersecretory syndrome, D) Unhealed gastric, duodenal or peptic ulcer, E) Barret's esophagus, F) Zollinger-Ellison syndrome, G) Helicobacter pylori infection? [If yes, then skip to question 17.]	Yes	No
15	Does the patient have NON-complicated gastroesophageal reflux disease (GERD)? [If yes, then no further questions.]	Yes	No
16	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex	Yes	No

	DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [If no, then no further questions.]		
17	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 19.]	Yes	No
18	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No
19	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No
20	Is the patient 21 years of age or older? [If no, then no further questions.]	Yes	No
21	Is this request for continuation of therapy? [If no, then skip to question 25.]	Yes	No
22	Has the patient experienced or maintained a documented positive clinical response to therapy? [If no, then no further questions.]	Yes	No
23	Has the patient previously been through the CountyCare prior authorization process and has received an authorization in the past 12 months? [If yes, then no further questions.]	Yes	No
24	Is the patient on a stable regimen and disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation? [If yes, then no further questions.]	Yes	No
25	Is the patient under the care of a gastroenterologist? [If no, then no further questions.]	Yes	No
26	Does the patient have one of the following conditions: A) GI bleed, B) Erosive esophagitis, C) Pathological hypersecretory syndrome, D) Unhealed gastric, duodenal or peptic ulcer, E) Barret's esophagus, F) Zollinger-Ellison syndrome, G) Helicobacter pylori infection? [If yes, then no further questions.]	Yes	No
27	Does the patient have NON-complicated gastroesophageal reflux disease (GERD)? [If yes, then no further questions.]	Yes	No
28	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy: Proton Pump Inhibitors. April 2025.

Enhanced Specialty Guideline Management Treatment Of Plaque Psoriasis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Abrilada	adalimumab-afzb
adalimumab (unbranded Humira)	adalimumab
adalimumab-aacf (unbranded Idacio)	adalimumab-aacf
adalimumab-aaty (unbranded Yuflyma)	adalimumab-aaty
adalimumab-adaz (unbranded Hyrimoz)	adalimumab-adaz
adalimumab-adbm (unbranded Cyltezo)	adalimumab-adbm
adalimumab-bwwd (unbranded Hadlima)	adalimumab-bwwd
adalimumab-fkjp (unbranded Hulio)	adalimumab-fkjp
adalimumab-ryvk (unbranded Simlandi)	adalimumab-ryvk
Amjevita	adalimumab-atto
Avsola	infliximab-axxq
Bimzelx	bimekizumab-bkzx
Cimzia	certolizumab pegol
Cosentyx	secukinumab
Cyltezo	adalimumab-adbm
Enbrel	etanercept
Hadlima	adalimumab-bwwd
Hulio	adalimumab-fkjp
Humira	adalimumab
Hyrimoz	adalimumab-adaz

Brand Name	Generic Name
Idacio	adalimumab-aacf
Ilumya	tildrakizumab
Imuldosa	ustekinumab-srlf
Inflectra	infliximab-dyyb
infliximab (unbranded Remicade)	infliximab
Otezla	apremilast
Otezla XR	apremilast extended release
Otulf	ustekinumab-aaaz
Pyzchiva	ustekinumab-ttwe
Remicade	infliximab
Renflexis	infliximab-abda
Selarsdi	ustekinumab-aekn
Siliq	brodalumab
Simlandi	adalimumab-ryvk
Skyrizi	risankizumab-rzaa
Sotyktu	deucravacitinib
Starjemza	ustekinumab-hmny
Stelara	ustekinumab
Steqeyma	ustekinumab-stba
Taltz	ixekizumab
Tremfya	guselkumab
ustekinumab (unbranded Stelara)	ustekinumab
ustekinumab-aaaz (unbranded Otulf)	ustekinumab-aaaz
ustekinumab-aekn (unbranded Selarsdi)	ustekinumab-aekn
ustekinumab-stba (unbranded Steqeyma)	ustekinumab-stba
ustekinumab-ttwe (unbranded Pyzchiva)	ustekinumab-ttwe
Wezlana	ustekinumab-auub
Yesintek	ustekinumab-kfce
Yuflyma	adalimumab-aaty
Yusimry	adalimumab-aqvh

Program Rationale

This program applies to the following products that are FDA-approved for the treatment of plaque psoriasis (Abrilada, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-bwwd, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia,

Reference number(s)
4179-A

Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Imuldosa, Inflectra, infliximab, Otezla/Otezla XR, Otulfi, Pyzchiva, Remicade, Renflexis, Selarsdi, Siliq, Simlandi, Skyrizi, Sotyktu, Starjemza, Stelara, Steqeyma, Taltz, Tremfya, ustekinumab, ustekinumab-aauz, ustekinumab-aekn, ustekinumab-stba, ustekinumab-ttwe, Wezlana, Yesintek, Yuflyma, Yusimry). Members with coexistent psoriatic arthritis will not be subject to these enhanced criteria. Members less than 18 years of age will not be subject to these enhanced criteria. Coverage will be provided if all coverage criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

The following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation of the following at the time of diagnosis (where applicable): psoriasis involvement of body surface area (BSA), Psoriasis Area Severity Index (PASI) score, and severe psoriasis affected area(s) with significant functional impairment and/or high levels of distress.
- Chart notes, medical record documentation, or claims history of all prior and current use of treatment regimens (e.g., topical agents, phototherapy, systemic non-biological agents, and biological agents) for plaque psoriasis (if applicable), including dosage, duration, and response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of any of the following: current psoriasis involvement percent of BSA, percent improvement of BSA from baseline, percent reduction of PASI from baseline, or Dermatology Life Quality Index (DLQI) score.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist.

Coverage Criteria

Authorization of 12 months may be granted for members who have previously received a biologic or a targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis within the past 120 days.

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis in members when both of the following criteria are met:

- The member has met one of following:
 - At least 10% of body surface area (BSA) is affected.
 - At least 3% of BSA is affected and has a Psoriasis Area Severity Index (PASI) score of ≥ 10 .
 - The affected area is severe at localized sites and associated with significant functional impairment and/or high levels of distress (e.g., nail disease or involvement of high-impact and difficult-to-treat sites such as face, scalp, palms, soles, flexures and genitals).
- The member has had an inadequate response at the maximum tolerated dose with all of the following:
 - Topical pharmacologic therapy (e.g., corticosteroids, calcineurin inhibitors, vitamin D analogs, retinoids) unless the patient has any of the following reasons to avoid topical pharmacologic therapies:
 - BSA > 10% is affected.
 - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 - Failure of topical pharmacologic therapy at the maximum tolerated dose and specified duration from any of the following classes:
 - Medium to super-high potency topical corticosteroid therapy (see Appendix A) for a duration of at least 4 weeks.
 - Topical calcineurin inhibitor therapy for a duration of at least 8 weeks.
 - Topical vitamin D analog therapy for a duration of at least 12 weeks.
 - Topical retinoid therapy for a duration of at least 12 weeks.
 - Topical aryl hydrocarbon receptor agonist therapy for a duration of at least 12 weeks.
 - Topical phosphodiesterase-4 inhibitor therapy for a duration of at least 8 weeks.
 - Phototherapy (e.g., UVB, PUVA) for a duration of at least 3 months unless the member has experienced an intolerable adverse event, has a clinical reason to avoid phototherapy, or the member does not have access to phototherapy.
 - Any of the following:
 - Methotrexate at a dose of at least 25 mg/week or at the maximum tolerated dose for a duration of at least 3 months.
 - Cyclosporine at a dose of at least 5 mg/kg/day or at the maximum tolerated dose for a duration of at least 6 weeks.
 - Acitretin at a dose of at least 50 mg/day or at the maximum tolerated dose for a duration of at least 3 months.
 - The member has a clinical reason to avoid systemic pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix B).

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in the coverage criteria who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following criteria is met:

- Member has a psoriasis involvement of $\leq 3\%$ body surface area (BSA)
- Member has a $\geq 75\%$ BSA improvement from baseline
- Member has at least a 75% reduction in the PASI score from baseline
- Member has at least a 50% reduction in the PASI score from baseline and a Dermatology Life Quality Index (DLQI) score of 5 or less

Other

For all drugs other than Otezla/Otezla XR, member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For Sotyktu, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug. For all other drugs, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A. Table. Relative Potency of Select Topical Corticosteroid Products

Potency	Drug	Dosage form	Strength
I. Super-high potency (group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
I. Super-high potency (group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
I. Super-high potency (group 1)	Fluocinonide	Cream	0.1%
I. Super-high potency (group 1)	Flurandrenolide	Tape	4 mcg/cm ²
I. Super-high potency (group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
II. High potency (group 2)	Augmented betamethasone dipropionate	Cream	0.05%
II. High potency (group 2)	Betamethasone dipropionate	Ointment	0.05%
II. High potency (group 2)	Clobetasol propionate	Cream	0.025%
II. High potency (group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
II. High potency (group 2)	Desoximetasone	Gel	0.05%
II. High potency (group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
II. High potency (group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
II. High potency (group 2)	Halcinonide	Cream, Ointment	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
III. High potency (group 3)	Betamethasone valerate	Foam	0.12%
III. High potency (group 3)	Desoximetasone	Cream, Ointment	0.05%
III. High potency (group 3)	Diflorasone diacetate	Cream	0.05%
III. High potency (group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
III. High potency (group 3)	Fluticasone propionate	Ointment	0.005%
III. High potency (group 3)	Mometasone furoate	Ointment	0.1%
III. High potency (group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
IV. Medium potency (group 4)	Clocortolone pivalate	Cream	0.1%
IV. Medium potency (group 4)	Fluocinolone acetonide	Ointment	0.025%
IV. Medium potency (group 4)	Flurandrenolide	Ointment	0.05%
IV. Medium potency (group 4)	Hydrocortisone valerate	Ointment	0.2%
IV. Medium potency (group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
V. Lower-mid potency (group 5)	Betamethasone valerate	Cream	0.1%

Potency	Drug	Dosage form	Strength
V. Lower-mid potency (group 5)	Desonide	Ointment, Gel	0.05%
V. Lower-mid potency (group 5)	Fluocinolone acetonide	Cream	0.025%
V. Lower-mid potency (group 5)	Flurandrenolide	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Fluticasone propionate	Cream, Lotion	0.05%
V. Lower-mid potency (group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone probutate	Cream	0.1%
V. Lower-mid potency (group 5)	Hydrocortisone valerate	Cream	0.2%
V. Lower-mid potency (group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Lotion	0.1%
V. Lower-mid potency (group 5)	Triamcinolone acetonide	Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
VI. Low potency (group 6)	Betamethasone valerate	Lotion	0.1%
VI. Low potency (group 6)	Desonide	Cream, Lotion, Foam	0.05%
VI. Low potency (group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
VI. Low potency (group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	2.5%

Reference number(s)
4179-A

Potency	Drug	Dosage form	Strength
VII. Least potent (group 7)	Hydrocortisone acetate	Lotion	2%
VII. Least potent (group 7)	Hydrocortisone acetate	Cream	1%

Appendix B. Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin⁵⁷

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Abrilada [package insert]. New York, NY: Pfizer Inc.; April 2024.
2. adalimumab [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
3. adalimumab-aacf [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; November 2023.
4. adalimumab-aaty [package insert]. Jersey City, NJ: Celltrion USA, Inc.; November 2023.
5. adalimumab-adaz [package insert]. Princeton, NJ: Sandoz Inc.; March 2023.
6. adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; September 2023.
7. adalimumab-bwwd [package insert]. Incheon, Republic of Korea: Samsung Bioepis Co., Ltd.; June 2025.
8. adalimumab-fkjp [package insert]. Morgantown, WV: Mylan Specialty L.P.; December 2023.
9. adalimumab-ryvk [package insert]. Leesburg, VA: Alvotek USA Inc.; May 2024.
10. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2023.
11. Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
12. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; October 2023.
13. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; December 2022.
14. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023.
15. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
16. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; October 2023.
17. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; June 2024.
18. Hulio [package insert]. Morgantown, WV: Mylan Specialty L.P.; August 2023.

19. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
20. Hyrimoz [package insert]. Princeton, NJ: Sandoz Inc.; April 2024.
21. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; October 2023.
22. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
23. Imuldosa [package insert]. Raleigh, NC: Accord BioPharma Inc.; October 2024.
24. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
25. Infliximab [packet insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
26. Otezla/Otezla XR [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2025.
27. Otulfi [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2024.
28. Pyzchiva [package insert]. Incheon, Republic of Korea: Samsung Bioepis Co., Ltd.; June 2024.
29. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
30. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; December 2023.
31. Selarsdi [package insert]. Leesburg, VA: Alvotech USA Inc.; April 2024.
32. Siliq [package insert]. Bridgewater, NJ: Bausch Health Companies, Inc.; April 2020.
33. Simlandi [package insert]. Leesburg, VA: Alvotech USA Inc.; February 2024.
34. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
35. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb; September 2022.
36. Starjemza [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2025.
37. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; June 2025.
38. Steqeyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; December 2024.
39. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2024.
40. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2023.
41. ustekinumab [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
42. ustekinumab-aaaz [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; April 2025.
43. ustekinumab-aekn [package insert]. Leesburg, VA: Alvotech USA Inc.; October 2024.
44. ustekinumab-stba [package insert]. Jersey City, NJ: Celltrion USA, Inc.; April 2025.
45. ustekinumab-ttwe [package insert]. Grand Cayman, Cayman Islands: Quallent Pharmaceuticals Health LLC; March 2025.
46. Vtama [package insert]. Long Beach, CA: Dermavant Sciences Inc.; May 2022.
47. Wezlana [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2023.
48. Yesintek [package insert]. Cambridge, MA: Biocon Biologics Inc.; November 2024.
49. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2024.
50. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2023.
51. Zoryve [package insert]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; December 2023.
52. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol. 2017; 76:290-8.
53. C.H. Smith, Z.Z.N. Yiu, T. Bale, et al. British Association of Dermatologists' guidelines for biologic therapy for psoriasis 2020: a rapid update. Br J Dermatol. 2020; 183(4):628-627.
54. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol. 2021; 84(2):432-470.

55. Elmetts CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol.* 2019; 81:775-804.
56. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020; 82:1445-86.
57. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019; 80(4):1029-1072.
58. Torres AE, Lyons AB, Hamzavi IH. Role of phototherapy in the era of biologics. *J Am Acad Dermatol.* 2020; 84(2):479-485.
59. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 18, 2024 from: <https://www.cdc.gov/tb/testing/index.html>.
60. Topical Corticosteroids. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; December 1, 2021. Accessed August 23, 2024.
61. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.

Specialty Guideline Management

Rasuvo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rasuvo	methotrexate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Rheumatoid Arthritis (RA) including Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Rasuvo is indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) or children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

Psoriasis

Rasuvo is indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses.

Reference number(s)
2018-A

Limitations of use

Rasuvo is not indicated for the treatment of neoplastic diseases.

Compendial Use

Microscopic polyangiitis⁶

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes, medical record documentation, or claims history supporting previous use of generic oral methotrexate and inadequate response or intolerance to therapy.
- Chart notes or medical record documentation of member's inability to prepare and administer generic injectable methotrexate.

Coverage Criteria²⁻⁶

Authorization of 12 months may be granted for treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), psoriasis, or microscopic polyangiitis when BOTH of the following criteria are met:

- Member has had an inadequate response or intolerance to generic oral methotrexate.
- Member has an inability to prepare and administer generic injectable methotrexate.

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who meet ALL requirements in the coverage criteria section and achieve or maintain a positive clinical response after at least 3 months of therapy with Rasuvo as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References

1. Rasuvo [package insert]. Chicago, IL: Medexus Pharma Inc.; March 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939.

Reference number(s)
2018-A

3. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
4. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Therapeutic approaches for non-systemic polyarthritis, sacroilitis, and enthesitis. *Arthritis Care Res*. 2019;71(6):717-734.
5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-1486.
6. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/12/2024).

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Reyvow

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Reyvow	lasmiditan

Indications

FDA-approved Indications

Reyvow is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use

Reyvow is not indicated for the preventive treatment of migraine.

Initial Step Therapy with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30-day supply of TWO triptan 5-HT₁ agonists (include combinations) within the past 180 days under a prescription benefit administered by CVS Caremark, then

the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

Initial Limit Criteria

Limits do not accumulate together, patient is allowed the maximum limit for each drug and strength.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Reyvow 50 mg	4 tablets / 25 days	12 tablets / 75 days
Reyvow 100 mg	8 tablets / 25 days	24 tablets / 75 days

Coverage Criteria

Authorization may be granted when the requested drug is being prescribed for the acute treatment of migraine with or without aura in an adult patient when ALL of the following criteria are met:

- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response or an intolerance to TWO triptan 5-HT₁agonists
 - The patient has a contraindication that would prohibit a trial of triptan 5-HT₁ agonists
- If additional quantities are being requested, then ALL of the following criteria are met:
 - Medication overuse headache has been considered AND ruled out
 - The patient meets ONE of the following:
 - The patient is currently using migraine prophylactic therapy [NOTE: Examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, venlafaxine, erenumab, fremanezumab, galcanezumab, eptinezumab, rimegepant, atogepant.]

Reference number(s)
3373-E

- The patient is unable to take migraine prophylactic therapy due to an inadequate treatment response, intolerance, or contraindication [NOTE: Examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, candesartan, amitriptyline, venlafaxine, erenumab, fremanezumab, galcanezumab, eptinezumab, rimegepant, atogepant.]

Quantity Limits Apply

Reyvow 50 mg: 4 tablets per 25 days, 12 tablets per 75 days,

Reyvow 100 mg: 8 tablets per 25 days, 24 tablets per 75 days

Post Limit, If additional quantities are being requested,

Reyvow 50 mg: 8 tablets per 25 days, 24 tablets per 75 days,

Reyvow 100 mg: 16 tablets per 25 days, 48 tablets per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 3373-E: DOA: 12 months

References

1. Reyvow [package insert]. Indianapolis, Indiana: Lilly USA, LLC; September 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed April 1, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 04/1/2024).
4. American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021-1039.
5. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024;00:1-9.
6. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee and the American Academy of Neurology and the American Headache Society. Neurology. 2012;78:1337-1346.

Initial Prior Authorization with Quantity Limit Rhapsido

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rhapsido	remibrutinib

Indications

FDA-approved Indications

Rhapsido is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use

Rhapsido is not indicated for other forms of urticaria.

Coverage Criteria

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic spontaneous urticaria (CSU) in an adult patient when ALL of the following criteria are met:

- The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.

Reference number(s)
7242-C

- The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
- The patient has previously received a biologic drug (e.g., Xolair, Dupixent) indicated for CSU in the past year. [ACTION REQUIRED: Documentation is required for approval.]
- If the patient has NOT received a biologic drug (e.g., Xolair, Dupixent) indicated for CSU in the past year, then ALL of the following criteria are met:
 - The patient has experienced a spontaneous onset of wheals (hives), angioedema, or both for at least 6 weeks.
 - The patient has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
 - The patient remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks. [ACTION REQUIRED: Documentation is required for approval.]

Continuation of Therapy

Authorization may be granted when the requested drug is being prescribed for the treatment of chronic spontaneous urticaria (CSU) in an adult patient when ALL of the following criteria are met:

- The requested drug is being prescribed by or in consultation with an allergist, immunologist or dermatologist.
- The requested drug will NOT be used in combination with any other biologic or targeted synthetic drug for the same indication.
- The patient has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy. [ACTION REQUIRED: Documentation is required for approval.]

Quantity Limits Apply

60 tablets / 25 days or 180 tablets / 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 7242-C: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

References

1. Rhapsido [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; September 2025.
2. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2025.
3. Xolair [package insert]. South San Francisco, CA: Genetech, Inc.; February 2024.
4. Lexicomp Online, Lexi-Drugs Online. Hudson, OH: UpToDate, Inc.; 2025; Accessed October 20, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/20/2025).
6. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar;77(3):734-766.

Enhanced Specialty Guideline

Management

Treatment of Rheumatoid Arthritis

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Abrilada	adalimumab-afzb
Actemra	tocilizumab
adalimumab (unbranded Humira)	adalimumab
adalimumab-aacf (unbranded Idacio)	adalimumab-aacf
adalimumab-aaty (unbranded Yuflyma)	adalimumab-aaty
adalimumab-adaz (unbranded Hyrimoz)	adalimumab-adaz
adalimumab-adbm (unbranded Cyltezo)	adalimumab-adbm
adalimumab-fkjp (unbranded Hulio)	adalimumab-fkjp
adalimumab-ryvk (unbranded Simlandi)	adalimumab-ryvk
Amjevita	adalimumab-atto
Avsola	infliximab-axxq
Avtozma	tocilizumab-anoh
Cimzia	certolizumab
Cyltezo	adalimumab-adbm
Enbrel	etanercept
Hadlima	adalimumab-bwwd
Hulio	adalimumab-fkjp
Humira	adalimumab
Hyrimoz	adalimumab-adaz
Idacio	adalimumab-aacf

Reference number(s)
1987-D

Brand Name	Generic Name
Inflectra	infliximab
infliximab (unbranded Remicade)	infliximab
Kevzara	sarilumab
Kineret	anakinra
Orencia	abatacept
Remicade	infliximab
Renflexis	infliximab-abda
Simlandi	adalimumab-ryvk
Simponi	golimumab
Simponi Aria	golimumab
Tofidence	tocilizumab-bavi
Tyenne	tocilizumab-aazg
Yuflyma	adalimumab-aaty
Yusimry	adalimumab-aqvh

Program Rationale

The intent of the criteria is to provide coverage for biologic drugs for adult members who have maximized the use of conventional synthetic drugs for the treatment of rheumatoid arthritis. This program applies to the following products that are FDA-approved for the treatment of rheumatoid arthritis (Abrilada, Actemra, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Avtozma, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, infliximab, Kevzara, Kineret, Orencia, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, Tofidence, Tyenne, Yuflyma, Yusimry). Coverage will be provided if all approval criteria are met and the member has no exclusions to the prescribed therapy.

Documentation

The following information must be submitted:

Initial requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Reference number(s)
1987-D

- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a rheumatologist.

Coverage Criteria

Authorization of 12 months may be granted when the member has previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days.

Authorization of 12 months may be granted when the member has moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

- Member has moderate to high disease activity.
- Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- The requested product is Actemra, Avtozma, Tofidence, or Tyenne.
- For Avsola, Inflectra, infliximab, Remicade, Renflexis, Simponi, and Simponi Aria requests, member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix).
- For Kineret requests, member has experienced an inadequate response to at least a 3-month trial of a biologic or a targeted synthetic drug (e.g., Rinvoq, Xeljanz) or has an intolerance to a biologic or targeted synthetic drug.

Continuation of Therapy

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or

maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Other

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For Actemra, Avtozma, Kineret, Kevzara, Tofidence, and Tyenne, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug. For all other drugs, member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide⁴⁷

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Abrilada [package insert]. New York, NY: Pfizer Inc.; April 2024.
2. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
3. adalimumab [package insert]. North Chicago, IL: AbbVie Inc.; November 2023.
4. adalimumab-aacf [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; June 2024.
5. adalimumab-aaty [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2025.
6. adalimumab-adaz [package insert]. Princeton, NJ: Sandoz Inc.; November 2024.
7. adalimumab-adbm [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
8. adalimumab-fkjp [package insert]. Cambridge, MA: Biocon Biologics Inc.; December 2023.
9. adalimumab-ryvk [package insert]. Leesburg, VA: Alvotek USA Inc.; February 2025.
10. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2024.
11. Avsola [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
12. Avtozma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; February 2025.
13. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
14. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2024.
15. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corporation; October 2024.
16. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; June 2024.
17. Hulio [package insert]. Cambridge, MA: Biocon Biologics Inc.; February 2025.
18. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
19. Hyrimoz [package insert]. Princeton, NJ: Sandoz Inc.; April 2024.
20. Idacio [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; January 2024.
21. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
22. infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
23. Kevzara [package insert]. Bridgewater, NJ: sanofi-aventis, U.S. LLC /Regeneron Pharmaceuticals, Inc.; August 2024.
24. Kineret [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); September 2024.
25. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.
26. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
27. Renflexis [package insert]. Jersey City, NJ. Organon & Co.; December 2023.
28. Simlandi [package insert]. Leesburg, VA: Alvotek USA Inc.; February 2025.
29. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2019.
30. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2023.
31. Tofidence [package insert]. Cambridge, MA: Biogen MA Inc.; March 2025.
32. Tyenne [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2025.
33. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; January 2024.
34. Yusimry [package insert]. Chicago, IL: Meitheal Pharmaceuticals; October 2024.
35. DRUGDEX® System [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed August 19, 2024.

36. Goekoop-Ruiterman YP, de Vries-Bouwstra JK, Allaart CF, et al. Clinical and radiographic outcomes of four different treatment strategies in patients with early rheumatoid arthritis (the BeSt study): a randomized, controlled trial. *Arthritis Rheum.* 2005;52:3381–90.
37. Graudal N, Jurgens G. Similar effects of disease-modifying antirheumatic drugs, glucocorticoids, and biologic agents on radiographic progression in rheumatoid arthritis: meta-analysis of 70 randomized placebo-controlled or drug-controlled studies, including 112 comparisons. *Arthritis Rheum.* 2010;62:2852–63.
38. Ma MH, Kingsley GH, Scott DL. A systematic comparison of combination DMARD therapy and tumour necrosis inhibitor therapy with methotrexate in patients with early rheumatoid arthritis. *Rheumatology (Oxford).* 2010;49:91–8.
39. Methotrexate tablets [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; August 2021.
40. Moreland LW, O'Dell JR, Paulus HE, et al. A randomized comparative effectiveness study of oral triple therapy versus etanercept plus methotrexate in early aggressive rheumatoid arthritis: the Treatment of Early Aggressive Rheumatoid Arthritis trial. *Arthritis Rheum.* 2012;64:2824–35.
41. O'Dell JR, Mikuls TR, Taylor TH, et al. Therapies for active rheumatoid arthritis after methotrexate failure. *N Engl J Med.* 2013;369:307-18.
42. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1):1-26.
43. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res.* 2012;64:625-39.
44. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;79(6):685-699. doi:10.1136/annrheumdis-2019-216655.
45. Van Vollenhoven RF, Geborek P, Forslind K, et al. Conventional combination treatment versus biological treatment in methotrexate-refractory early rheumatoid arthritis: 2 year follow-up of the randomised, non-blinded, parallel-group Swefot trial. *Lancet.* 2012;379(9827):1712–20.
46. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res.* 2021;0:1-16.
47. Menter, A, Gelfand, JM, Connor, C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-86.

Specialty Guideline Management

Rituxan Hycela

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rituxan Hycela	rituximab and hyaluronidase human

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Adult patients with follicular lymphoma (FL):
 - Relapsed or refractory, follicular lymphoma as a single agent
 - Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
 - Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC)

Limitations of Use

Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.

Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

Compendial Uses²

- B-cell lymphomas:
 - Castleman's disease (CD)
 - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
 - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
 - Marginal zone lymphomas
 - Nodal marginal zone lymphoma
 - Splenic marginal zone lymphoma
 - Extranodal Marginal Zone Lymphoma (Gastric and Nongastric mucosa associated lymphoid tissue {MALT} lymphoma)
 - Mantle cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Hairy cell leukemia
- Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
- Small lymphocytic lymphoma (SLL)
- Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
- Hodgkin lymphoma, nodular lymphocyte-predominant

All other indications are considered experimental/investigational and are not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD20 protein on the surface of the B-cell.

Coverage Criteria

Prior to initiating therapy, all members must receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions.

Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)^{1,2}

Authorization of 12 months may be granted for treatment of CD20 positive CLL or SLL.

Hairy Cell Leukemia (HCL)²

Authorization of 12 months may be granted for treatment of CD20 positive HCL.

B-cell Lymphomas^{1,2}

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

- Castleman's disease (CD)
- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma
- High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Mantle cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Marginal zone lymphomas
 - Nodal marginal zone lymphoma
 - Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
 - Splenic marginal zone lymphoma

Primary Cutaneous B-cell Lymphoma²

Authorization of 12 months may be granted for treatment of CD20 positive primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas).

Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma²

Authorization of 12 months may be granted for treatment of CD20 positive Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma.

Hodgkin Lymphoma, Nodular Lymphocyte-Predominant²

Authorization of 12 months may be granted for treatment of CD20 positive Hodgkin lymphoma, nodular lymphocyte-predominant.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity.

References

1. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 14, 2025.

Specialty Guideline Management

Rituximab Products

Treatment of Hematologic and Oncologic Conditions

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rituxan	rituximab
Ruxience	rituximab-pvvr
Truxima	rituximab-abbs
Riabni	rituximab-arrx

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2,9,10}

Rituxan is indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan, Ruxience, Truxima, and Riabni are indicated for:

- Non-Hodgkin's lymphoma (NHL) in adult patients with:

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.
- Granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) in combination with glucocorticoids (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately- to severely active RA who have inadequate response to one or more TNF antagonist therapies. (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

Rituxan is also indicated for:

- Rituxan is indicated for moderate to severe pemphigus vulgaris in adult patients (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

Compendial Uses³⁻⁸

- Autoimmune hemolytic anemia⁷
- B-cell acute lymphoblastic leukemia (ALL)⁴
- B-cell lymphomas⁴⁻⁶
 - Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas⁴
 - B-cell lymphoblastic lymphoma^{5,6}
 - Burkitt lymphoma⁴
 - Castleman's disease⁴
 - Diffuse Large B-Cell lymphoma⁴
 - Follicular lymphoma⁴
 - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)⁴
 - Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma⁴
 - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements⁴
 - Mantle cell lymphoma⁴
 - Marginal zone lymphomas⁴

- Nodal marginal zone lymphoma
- Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma)
- Splenic marginal zone lymphoma
 - Post-transplant lymphoproliferative disorder (PTLD)⁴
 - Pediatric Aggressive Mature B-Cell Lymphomas⁴
 - Primary Mediastinal Large B-Cell Lymphoma⁴
- Central nervous system (CNS) cancers⁴
 - Leptomeningeal metastases from lymphomas
 - Primary CNS lymphomas
- Chronic graft-versus-host disease (GVHD)⁴
- CLL/Small lymphocytic lymphoma (SLL)⁴
- Hairy cell leukemia⁴
- Rosai-Dorfman disease⁴
- Hodgkin's lymphoma, nodular lymphocyte-predominant⁴
- Immune checkpoint inhibitor-related toxicities⁴
- Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients⁸
- Primary cutaneous B-cell lymphoma⁴
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)⁷
- Thrombotic thrombocytopenic purpura⁷
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/ Bing-Neel syndrome⁴
- Allogeneic transplant conditioning⁴
- For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD20 protein on the surface of the B-cell (if applicable).

Coverage Criteria

Oncologic Indications^{1-6,9,19}

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas:

- HIV-Related B-Cell Lymphomas
- B-cell lymphoblastic lymphoma
- Burkitt lymphoma
- Castleman's disease
- Diffuse large B-cell lymphoma
- Follicular lymphoma
- High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- Mantle cell lymphoma
- Marginal zone lymphomas
 - Nodal marginal zone lymphoma
 - Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
 - Splenic marginal zone lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Pediatric Aggressive Mature B-Cell Lymphomas
- Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers:
 - Leptomeningeal metastases from lymphomas
 - Primary CNS lymphoma
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Rosai-Dorfman disease
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Primary cutaneous B-cell lymphoma
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/Bing-Neel syndrome

Hematologic Indications^{3,7,8}

Authorization of 12 months may be granted for treatment of any of the following indications:

- Refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Autoimmune hemolytic anemia
- Thrombotic thrombocytopenic purpura
- Chronic graft-versus-host disease (GVHD)
- Prevention of Epstein-Barr virus (EBV)-related PTLD
- As part of a non-myeloablative conditioning regimen for allogeneic transplant

Immune Checkpoint Inhibitor-Related Toxicities⁴

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

Continuation of Therapy

Oncologic indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in coverage criteria section when there is no evidence of unacceptable toxicity.

Immune checkpoint inhibitor-related toxicities

Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.

All other indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are experiencing benefit from therapy.

References

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
2. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2022.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed April 15, 2025.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 15, 2025.
5. Arber D, Orazi A, Vardiman J, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. May 19, 2016;127(20):2391-2405.
6. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 3.2024). © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 15, 2025.
7. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> [available with subscription]. Accessed April 15, 2025.
8. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. *Biol Blood Marrow Transplant*. 2009; 15(10):1143-1238. URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103296/pdf/nihms205400.pdf>. Accessed April 30, 2019.
9. Ruxience [package insert]. NY, NY: Pfizer Inc; October 2023.
10. Riabni [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.

Specialty Guideline Management

sildenafil-Revatio-Liqrev

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Revatio	sildenafil
Liqrev	sildenafil

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁴

- Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.
- Indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.

Compendial Uses

- Secondary Raynaud's phenomenon^{8,9}
- PAH (WHO Group I) in pediatric members less than 1 year of age

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist for the diagnosis of pulmonary arterial hypertension (PAH).

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)^{1-7,13-18}

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by either of the following criteria:
 - Pretreatment right heart catheterization with all of the following results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units. For pediatric members, pulmonary vascular resistance index (PVRI) > 3 Wood units x m² is also acceptable.
 - For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

Secondary Raynaud's Phenomenon (oral formulation only)⁸⁻¹²

Authorization of 12 months may be granted for treatment of secondary Raynaud's phenomenon when the member has had an inadequate response to one of the following medications:

- Calcium channel blockers
- Angiotensin II receptor blockers
- Selective serotonin reuptake inhibitors
- Alpha blockers
- Angiotensin-converting enzyme inhibitors
- Topical nitrates

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical

benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)¹⁶

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema

- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)
 - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
 - Non-malignant tumors (e.g., uterine leiomyoma)
 - Arteritis without connective tissue disease
 - Congenital pulmonary artery stenoses
 - Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Revatio [package insert]. Morgantown, WV; Viatris Specialty LLC; December 2024.
2. Liqrev [package insert]. Farmville, NC: CMP Pharma, Inc.; April 2023.
3. Sildenafil [package insert]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; February 2024.
4. Sildenafil for oral suspension [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2024.
5. Barst RJ, Ivy DD, Gaitan G, et al. A randomized, double-blind, placebo-controlled, dose-ranging study of oral sildenafil citrate in treatment-naïve children with pulmonary arterial hypertension. *Circulation*. 2012;125:324-334.
6. Galiè N, Ghofrani HA, Torbicki A, et al. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med*. 2005;353:2148-2157.

7. Rubin LJ, Badesch DB, Fleming RT, et al. Long-term treatment with sildenafil citrate in pulmonary arterial hypertension. *Chest*. 2011;140(5):1274-1283.
8. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed April 1, 2025.
9. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed April 1, 2025.
10. Curtiss P, Svigos K, Schwager Z, Lo Sicco K, Franks AG Jr. Part II: The treatment of primary and secondary Raynaud's phenomenon. *J Am Acad Dermatol*. 2024 Feb;90(2):237-248. doi: 10.1016/j.jaad.2022.05.067
11. Maltez N, Maxwell LJ, Rirash F, et al. Phosphodiesterase 5 inhibitors (PDE5i) for the treatment of Raynaud's phenomenon. *Cochrane Database Syst Rev*. 2023 Nov 6;11(11):CD014089. doi: 10.1002/14651858
12. Del Galdo F, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Annals of the Rheumatic Diseases Published Online First*: 11 October 2024. doi: 10.1136/ard-2024-226430
13. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. doi: 10.1183/13993003.01913-2018
14. Barst RJ, Beghetti M, Pulido T, et al. STARTS-2: long-term survival with oral sildenafil monotherapy in treatment-naïve pediatric pulmonary arterial hypertension. *Circulation*. 2014;129(19):1914-23.
15. Kwan WC, Shavelle DM, Laughrun DR. Pulmonary vascular resistance index: getting the units right and why it matters. *Clin Cardiol*. 2019;42(3):334-338.
16. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
17. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J*. 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
18. Ivy D, Rosenzweig EB, Abman SH, et al. Embracing the challenges of neonatal and paediatric pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401345. doi: 10.1183/13993003.01345-2024

Specialty Guideline Management

Simponi Aria

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Simponi Aria	golimumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) in patients 2 years of age and older
- Adult patients with active ankylosing spondylitis (AS)
- Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Compendial Uses

- Non-radiographic axial spondyloarthritis^{7,14}
- Oligoarticular juvenile idiopathic arthritis¹⁵
- Immune checkpoint inhibitor-related toxicities - inflammatory arthritis¹⁷

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid Arthritis (RA)

Initial Requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), and Immune Checkpoint Inhibitor-Related Toxicity

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Articular Juvenile Idiopathic Arthritis (JIA)

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and articular juvenile idiopathic arthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid Arthritis (RA)^{1-4,11-13}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug indicated for moderately to severely active rheumatoid arthritis (RA) within the past 120 days. The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide (see Appendix A).

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.

- Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix A), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix A), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix A).

Psoriatic Arthritis (PsA)^{1,5,6,9,16}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).

- Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,7,14}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Articular Juvenile Idiopathic Arthritis (JIA)^{1,10,15}

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis.

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when any of the following criteria is met:

- Member has had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
- Member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drug (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
 - Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
 - Presence of erosive disease or enthesitis
 - Delay in diagnosis
 - Elevated levels of inflammation markers
 - Symmetric disease
- Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and the member also meets one of the following:
 - High-risk joints are involved (e.g., cervical spine, wrist, or hip)
 - High disease activity
 - Is judged to be at high risk for disabling joint disease

Immune Checkpoint Inhibitor-Related Toxicity¹⁷

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid Arthritis (RA)^{1-4,11-13}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Psoriatic Arthritis (PsA)^{1,5,6,9,17}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,7}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who

achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Articular Juvenile Idiopathic Arthritis (JIA)^{1,10}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,8}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide¹⁸

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis¹⁶

- Positive rheumatoid factor
- Positive anti-cyclic citrullinated peptide antibodies
- Pre-existing joint damage

References

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
2. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
4. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.

5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
6. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis*. 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531.
7. 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.
8. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 11, 2024 from: <https://www.cdc.gov/tb/testing/>.
9. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32. doi:10.1002/art.40726.
10. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. American College of Rheumatology. 2019;1-18.
11. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
12. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
13. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2021;0:1-16.
14. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76(6):978-991.
15. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
16. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
17. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 13, 2024.
18. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-86.

Specialty Guideline Management

Simponi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Simponi	golimumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Moderately to severely active rheumatoid arthritis (RA) in adults, in combination with methotrexate
- Active psoriatic arthritis (PsA) in adults, alone or in combination with methotrexate
- Active ankylosing spondylitis (AS) in adults
- Moderately to severely active ulcerative colitis (UC) in adults who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine

Compendial Uses

- Non-radiographic axial spondyloarthritis²
- Immune checkpoint inhibitor-related toxicities - inflammatory arthritis²¹

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid Arthritis (RA)

Initial Requests

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), Psoriatic Arthritis (PsA), and Immune Checkpoint Inhibitor-Related Toxicity

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Ulcerative Colitis (UC)

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Ulcerative colitis: gastroenterologist
- Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

Coverage Criteria

Rheumatoid Arthritis (RA)^{1,3-5,16,18,19}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis within the past 120 days. The requested medication must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:

- Member meets either of the following:
 - Member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - Member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- Member meets ONE of the following:
 - Member has failed to achieve a low disease activity after a 3-month trial of methotrexate (MTX) monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:
 - Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
 - Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
 - Member was unable to tolerate a 3-month trial of MTX monotherapy at a maximum titrated dose of at least 15 mg per week and meets any of the following conditions:

- Member has had a documented inadequate response to MTX in combination with at least one other conventional synthetic drug (i.e., hydroxychloroquine and/or sulfasalazine) after a 3-month trial at a maximum tolerated dose(s).
- Member has stopped taking MTX and has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
- Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
- Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
- Member has moderate to high disease activity.
- Member has experienced a documented intolerable adverse event or has a documented contraindication to MTX (see Appendix), discontinues MTX, and meets any of the following conditions:
 - Member has had a documented inadequate response to another conventional synthetic drug (i.e., leflunomide, hydroxychloroquine, and/or sulfasalazine) alone or in combination after a 3-month trial at a maximum tolerated dose(s).
 - Member has experienced a documented intolerable adverse event to leflunomide, hydroxychloroquine, or sulfasalazine.
 - Member has a documented contraindication to leflunomide, hydroxychloroquine (see Appendix), and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
 - Member has moderate to high disease activity.
- Member is prescribed the requested medication in combination with methotrexate or leflunomide or has a clinical reason not to use methotrexate or leflunomide (see Appendix).

Psoriatic Arthritis (PsA)^{1,6-9,14}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:

- Member has mild to moderate disease and meets one of the following criteria:
 - Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
 - Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
 - Member has enthesitis or predominantly axial disease.
- Member has severe disease.

Ankylosing Spondylitis (AS) And Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,2,10,11}

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when either of the following criteria is met:

- Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
- Member has an intolerance or contraindication to two or more NSAIDs.

Ulcerative Colitis (UC)^{1,12,15,17}

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Immune Checkpoint Inhibitor-Related Toxicity²¹

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has moderate or severe immunotherapy-related inflammatory arthritis and meets either of the following:

- Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
- Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

Continuation of Therapy

Rheumatoid Arthritis (RA)^{1,3-5,16,18,19}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Psoriatic Arthritis (PsA)^{1,6-9,14}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,2,10,11}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Ulcerative Colitis (UC)^{1,12,15,17}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation

- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for immunotherapy-related inflammatory arthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other^{1,13}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Hydroxychloroquine, or Leflunomide²⁰

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease

- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Simponi [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
2. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76(6):978-991.
3. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
5. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
7. Gossec L, Baraliakos X, Kerschbaumer A, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
8. Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis* 2005;64(Suppl II):ii14–ii17.
9. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
10. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896–904.
11. 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.
12. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.

Reference number(s)
2014-A

13. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on May 27, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.
14. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32. doi:10.1002/art.40726.
15. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024;167(7):1307-1343.
16. Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
17. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2025;120(6):1187-1224.
18. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
19. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
20. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6):1445-86.
21. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 16, 2024.

CountyCare IL Custom Criteria SKYRIZI (risankizumab-rzaa)

CRITERIA FOR APPROVAL

1	What is the diagnosis? ☐ Crohn's disease (If checked, go to 2) ☐ Plaque psoriasis (If checked, go to 4) ☐ Psoriatic arthritis (If checked, go to 7) ☐ Ulcerative colitis (If checked, go to 12) ☐ Other, please specify: _____ (If checked, go to 17)			
2	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the products: Cimzia or ONE of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)? [If Yes, then go to 17. If No, then go to 3.]	Yes	No	
3	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 17. If No, then no further questions.]	Yes	No	
4	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the products: Cimzia, Cosentyx, Enbrel, or ONE of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)? [If Yes, then go to 17. If No, then go to 5.]	Yes	No	
5	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 6. If No, then no further questions.]	Yes	No	
6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 17. If No, then no further questions.]	Yes	No	
7	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the products: Cimzia, Cosentyx, Enbrel, Xeljanz/Xeljanz XR, or ONE of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)?	Yes	No	

[If Yes, then go to 17. If No, then go to 8.]

8	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then go to 10.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
10	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, and ONE of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
12	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with BOTH of the products: Xeljanz/Xeljanz XR and ONE of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)? [If Yes, then go to 17. If No, then go to 13.]	Yes	No
13	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 14. If No, then go to 15.]	Yes	No
14	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
15	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with ONE of the following	Yes	No

adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi, or Abrilada)?

[If Yes, then go to 17. If No, then no further questions.]

17	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 18.]	Yes	No
18	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 22. If No, then go to 19.]	Yes	No
19	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	What were the results of the TB test? ☐ Positive for TB (If checked, go to 21) ☐ Negative for TB (If checked, go to 22) ☐ Unknown (If checked, no further questions)		
21	Which of the following applies to the patient? ☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions) ☐ Patient has active TB (If checked, no further questions)		
22	What is the diagnosis? ☐ Plaque psoriasis (If checked, go to 26) ☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 23) ☐ Psoriatic arthritis (If checked, go to 41) ☐ Crohn's disease (If checked, go to 56) ☐ Ulcerative colitis (If checked, go to 62) ☐ Other, please specify. _____ (If checked, no further questions)		
23	Is the patient an adult (18 years of age or older)? [If Yes, then go to 24. If No, then no further questions.]	Yes	No

24	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 25. If No, then no further questions.]	Yes	No
25	What is the primary diagnosis being treated? ☐ Psoriatic arthritis (If checked, go to 43) ☐ Plaque psoriasis (If checked, go to 28)		
26	Is the patient an adult (18 years of age or older)? [If Yes, then go to 27. If No, then no further questions.]	Yes	No
27	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 28. If No, then no further questions.]	Yes	No
28	Has the patient been diagnosed with moderate to severe plaque psoriasis? [If Yes, then go to 29. If No, then no further questions.]	Yes	No
29	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 30. If No, then go to 34.]	Yes	No
30	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 34) ☐ No (If checked, go to 31) ☐ Unknown (If checked, go to 34)		
31	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 32. If No, then no further questions.]	Yes	No
32	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 68. If No, then go to 33.]	Yes	No
33	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 68. If No, then no further questions.]	Yes	No
34	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes,	Yes	No

medical record documentation, or claims history supporting previous medications tried. *ACTION REQUIRED: Submit supporting documentation*
[If Yes, then go to 68. If No, then go to 35.]

35	Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? <i>ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of affected areas. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then go to 36.]	Yes	No

36	Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%? [If Yes, then no further questions. If No, then go to 37.]	Yes	No

37	What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? Indicate percentage. <i>ACTION REQUIRED: Please attach chart notes or medical record documentation of body surface area affected.</i>		

☐ Greater than or equal to 3% to less than 10% of BSA
ACTION REQUIRED: Submit supporting documentation (If checked, go to 38)

☐ Greater than or equal to 10% of BSA
ACTION REQUIRED: Submit supporting documentation (If checked, go to 68)

38	Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then go to 39.]	Yes	No

39	Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 40. If No, then no further questions.]	Yes	No

40	Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 68) ☐ Drug interaction (If checked, go to 68) ☐ Risk of treatment-related toxicity (If checked, go to 68) ☐ Pregnancy or currently planning pregnancy (If checked, go to 68) ☐ Breastfeeding (If checked, go to 68)		

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 68)

☐ Hypersensitivity (If checked, go to 68)

☐ History of intolerance or adverse event (If checked, go to 68)

☐ Other, please specify. _____ (If checked, no further questions)

41	Is the patient an adult (18 years of age or older)? [If Yes, then go to 42. If No, then no further questions.]	Yes	No

42	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 43. If No, then no further questions.]	Yes	No

43	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 44. If No, then go to 47.]	Yes	No

44	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 47)

☐ No (If checked, go to 45)

☐ Unknown (If checked, go to 47)

45	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 46. If No, then no further questions.]	Yes	No

46	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of swollen joints **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ Number of tender joints **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ Dactylitis **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ Enthesitis **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ Skin and/or nail involvement **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ Functional status **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 68)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ None of the above (If checked, no further questions)

47	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 48. If No, then no further questions.]	Yes	No
48	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) that is indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then go to 49.]	Yes	No
49	What is the patient's disease severity? ☐ Mild to moderate (If checked, go to 50) ☐ Severe (If checked, go to 68)		
50	Does the patient have enthesitis? [If Yes, then go to 68. If No, then go to 51.]	Yes	No
51	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then go to 52.]	Yes	No
52	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then go to 53.]	Yes	No
53	Does the patient have a contraindication to methotrexate or leflunomide? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 55. If No, then go to 54.]	Yes	No
54	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 68. If No, then no further questions.]	Yes	No
55	Please indicate the contraindication methotrexate or leflunomide.		

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 68)

☐ Drug interaction (If checked, go to 68)

☐ Risk of treatment-related toxicity (If checked, go to 68)

☐ Pregnancy or currently planning pregnancy (If checked, go to 68)

☐ Breastfeeding (If checked, go to 68)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 68)

☐ Hypersensitivity (If checked, go to 68)

☐ History of intolerance or adverse event (If checked, go to 68)

☐ Other, please specify. _____ (If checked, no further questions)

56	Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? [If Yes, then go to 57. If No, then no further questions.]	Yes	No

57	Is the patient an adult (18 years of age or older)? [If Yes, then go to 58. If No, then no further questions.]	Yes	No

58	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 59. If No, then no further questions.]	Yes	No

59 Which of the following applies to this request for the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 68)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 68)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 60)

60 Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 61)

☐ None of the above (If checked, no further questions)

61 Which of the following has the patient experienced improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response.

☐ Abdominal pain or tenderness **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Diarrhea **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Body weight **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Abdominal mass **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Hematocrit **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 68)

☐ None of the above (If checked, no further questions)

62	Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? [If Yes, then go to 63. If No, then no further questions.]	Yes	No

63	Is the patient an adult (18 years of age or older)? [If Yes, then go to 64. If No, then no further questions.]	Yes	No

64	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 65. If No, then no further questions.]	Yes	No

65 Which of the following applies to this request for the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 68)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 68)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 66)

66 Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 67)

☐ None of the above (If checked, no further questions)

67 Which of the following has the patient experienced improvement in from baseline? *ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.*

☐ Stool frequency *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Rectal bleeding *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Urgency of defecation *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Fecal calprotectin (FC) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 68)

☐ None of the above (If checked, no further questions)

68 What is the diagnosis?

☐ Plaque Psoriasis (If checked, go to 69)

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 69)

☐ Psoriatic arthritis (If checked, go to 69)

☐ Crohn's disease (If checked, go to 74)

☐ Ulcerative colitis (If checked, go to 75)

69	Is the patient currently receiving the requested drug? [If Yes, then go to 70. If No, then go to 72.]	Yes	No

70	Does the prescribed dose exceed 150 mg? [If Yes, then no further questions. If No, then go to 71.]	Yes	No

71	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks?	Yes	No

[No further questions]

72	Does the prescribed dose exceed a loading dose of 150 mg at weeks 0 and 4, and a maintenance dose of 150 mg thereafter? [If Yes, then no further questions. If No, then go to 73.]	Yes	No
73	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No
74	Which of the following applies to this request for the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 76) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 80) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 80)		
75	Which of the following applies to this request for the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 78) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 80) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 80)		
76	Does the prescribed dose exceed a loading dose of 600 mg at weeks 0, 4, and 8, and a maintenance dose of 360 mg thereafter? [If Yes, then no further questions. If No, then go to 77.]	Yes	No
77	Is the prescribed frequency starting at week 12 for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
78	Does the prescribed dose exceed a loading dose of 1200 mg at weeks 0, 4, and 8, and a maintenance dose of 360 mg thereafter? [If Yes, then no further questions. If No, then go to 79.]	Yes	No
79	Is the prescribed frequency starting at week 12 for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
80	Does the prescribed dose exceed 360 mg? [If Yes, then no further questions. If No, then go to 81.]	Yes	No
81	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No

Specialty Guideline Management

Skytrofa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Skytrofa	lonapegsomatropin-tcgd

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Skytrofa is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review (where applicable):

Both initial and continuation of therapy requests:

- Growth chart
- Pretreatment insulin-like growth factor-1 (IGF-1) level (laboratory report or medical record)

documentation)

Initial requests:

- Support for the diagnosis of neonatal growth hormone (GH) deficiency (medical documentation, laboratory report, or imaging report)
- Pretreatment growth hormone provocative test result(s) (laboratory report or medical record documentation)

Continuation of therapy requests:

- Total duration of treatment (approximate duration is acceptable)
- Date of last dose administered
- Approving health plan/pharmacy benefit manager
- Date of prior authorization/approval
- Prior authorization approval letter

IGF-1 levels vary based on the laboratory performing the analysis. Laboratory-specific values must be provided to determine whether the value is within the normal range.

Coverage Criteria

Pediatric Growth Hormone (GH) Deficiency¹⁻⁶

Authorization of 12 months may be granted to members with pediatric growth hormone (GH) deficiency 1 year of age and older when EITHER of the following criteria is met:

- Member has a documented diagnosis of GH deficiency as a neonate (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, magnetic resonance imaging [MRI] results).
- Member meets ALL of the following criteria:
 - Member has either of the following:
 - Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL
 - A documented pituitary or central nervous system (CNS) disorder (see Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
 - For members < 2.5 years of age at initiation of treatment, the pretreatment height is > 2 SD below the mean and growth velocity is slow
 - For members ≥ 2.5 years of age at initiation of treatment, member has either of the following:
 - Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean
 - Pretreatment 1-year height velocity is > 2 SD below the mean
 - Epiphyses are open

Continuation of Therapy

Pediatric Growth Hormone (GH) Deficiency

Authorization of 12 months may be granted for continuation of therapy for pediatric growth hormone (GH) deficiency when ALL of the following criteria are met:

- Member is currently receiving the requested medication or another growth hormone product (e.g., Norditropin) indicated for pediatric GH deficiency
- Epiphyses are open^{1,2} (confirmed by X-ray or X-ray is not available)
- Member's growth rate is > 2 cm/year unless there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty)

Appendix

Examples of Hypothalamic/Pituitary/CNS Disorders

- Congenital genetic abnormalities
 - Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
 - Growth hormone releasing hormone (GHRH) receptor gene defects
 - GH secretagogue receptor gene defects
 - GH gene defects
- Congenital structural abnormalities
 - Optic nerve hypoplasia/septo-optic dysplasia
 - Agenesis of corpus callosum
 - Empty sella syndrome
 - Ectopic posterior pituitary
 - Pituitary aplasia/hypoplasia
 - Pituitary stalk defect
 - Holoprosencephaly
 - Encephalocele
 - Hydrocephalus
 - Anencephaly or prosencephaly
 - Arachnoid cyst
 - Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
 - Vascular malformations

- Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
 - CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
 - Cysts (Rathke cleft cyst or arachnoid cleft cyst)
 - Surgery
 - Radiation
 - Chemotherapy
 - CNS infections
 - CNS infarction
 - Inflammatory processes (e.g., autoimmune hypophysitis)
 - Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
 - Head trauma/traumatic brain injury
 - Aneurysmal subarachnoid hemorrhage
 - Perinatal or postnatal trauma
 - Surgery of the pituitary or hypothalamus

References

1. Skytrofa [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; May 2024.
2. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. Endocr Pract. 2003;9(1):64-76.
3. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. <http://www.nice.org.uk/guidance/ta188>. Accessed January 14, 2025.
4. Wilson TA, Rose SR, Cohen P, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatr. 2003;143:415-421.
5. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. Pediatr Clin North Am. 2011;58:1141-1165.
6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397.

Specialty Guideline Management sofosbuvir-velpatasvir, Epclusa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Epclusa	sofosbuvir-velpatasvir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection:

- Without cirrhosis or with compensated cirrhosis
- With decompensated cirrhosis for use in combination with ribavirin

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin¹⁻⁵

Genotype 1, 2, 3, 4, 5, or 6 infection

- Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).
- Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis when either of the following criteria is met:
 - Member has failed prior treatment with an interferon-based regimen with or without RBV and has not received an NS3/4A protease inhibitor or NS5A inhibitor.
 - Member has failed prior treatment with a sofosbuvir-based regimen and has not received an NS3/4A protease inhibitor or NS5A inhibitor.

Unknown genotype/genotype could not be determined

Authorization of up to 12 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis who are treatment-naïve and do not have any of the following characteristics:

- Hepatitis B surface antigen (HBsAG) positive
- Current pregnancy
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Note: Genotype testing is required for members with any of the characteristics listed.

Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)

Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection who have decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Appendix).

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis. Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

Organ recipient from HCV-viremic donor

Authorization of up to 12 weeks total may be granted for members who have received a liver or non-liver organ transplant from an HCV-viremic donor.

Hepatitis C Virus Infection, in combination with Ribavirin^{1,2,5}

Genotype 3 infection

Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis who have the Y93H substitution associated with velpatasvir resistance.

Decompensated cirrhosis (CTP class B or C)

- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir- or NS5A inhibitor-based regimen.

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness

- For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
- Hepatitis B virus screening results
- Metavir/Fibrosis score

Appendix: Ribavirin (RBV) Ineligibility^{3,4}

Ribavirin (RBV) ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

References

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Sofosbuvir and velpatasvir tablet [package insert]. Foster City, CA: Asegua Therapeutics LLC; April 2022.
3. Ribavirin capsule [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.
4. Ribavirin tablet [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
5. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). HCV guidance: Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Guideline Management

Sotyktu

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sotyktu	deucravacitinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Treatment of adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).

Reference number(s)
5600-A

- Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist.

Coverage Criteria

Plaque psoriasis (PsO)¹⁻⁶

Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Otezla) indicated for treatment of moderate to severe plaque psoriasis.

Authorization of 12 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when any of the following criteria is met:

- Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- At least 10% of body surface area (BSA) is affected.
- At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
 - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
 - Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Continuation of Therapy

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

Reference number(s)
5600-A

- Reduction in body surface area (BSA) affected from baseline
- Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Other^{1,7}

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin⁴

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

References

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
2. Armstrong AW, Gooderham M, Warren RB, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial. *J Am Acad Dermatol*. 2023;88(1):29-39. doi:10.1016/j.jaad.2022.07.002.
3. Strober B, Thaçi D, Sofen H, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: Efficacy and safety results from the 52-week, randomized, double-blinded, phase 3 Program fOr Evaluation of TYK2 inhibitor psoriasis second trial. *J Am Acad Dermatol*. 2023;88(1):40-51.
4. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol*. 2020;82(6): 1445-86.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
6. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol*. 2022;18(8):465-479.
7. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on January 21, 2025 from: <https://www.cdc.gov/tb/testing/index.html>.

Specialty Guideline Management

Sovaldi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sovaldi	sofosbuvir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Sovaldi is indicated for the treatment of:

- Adult patients with genotype 1, 2, 3, or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

Compendial Uses²

Hepatitis C virus genotype 5 or 6 infection (refer to Mavyret SGM)

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, in combination with Peginterferon Alfa (PEG-IFN) and Ribavirin¹

Genotype 1 infection

Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

Genotype 4 infection

Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

Hepatitis C Virus Infection, in combination with Ribavirin¹

Genotype 1 infection

Authorization of up to 24 weeks total may be granted for adult members who have documented interferon (IFN) ineligibility (see Appendix).

Genotype 2 infection

Authorization of up to 12 weeks total may be granted for members 3 years of age or older who are treatment-naïve or failed prior treatment with PEG-IFN with or without ribavirin (RBV).

Genotype 3 infection

Authorization of up to 24 weeks total may be granted for members 3 years of age or older who are treatment-naïve or failed prior treatment with PEG-IFN with or without RBV.

Hepatocellular carcinoma awaiting liver transplantation

Authorization of up to 48 weeks total or until liver transplantation, whichever occurs first, may be granted for adult members with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma awaiting liver transplantation.

Hepatitis C Virus Infection, in combination with Mavyret (with ribavirin)³

Authorization of up to 24 weeks total (as applicable) may be granted for members 3 years of age or older who are prescribed Sovaldi in combination with Mavyret (with RBV) who meet the criteria for approval for

the requested regimen. Refer to the Mavyret SGM for the specific criteria for approval and approval durations.

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection^{1,3}

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness
 - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
 - Hepatitis B virus screening results
 - Metavir/Fibrosis score

Appendix: Interferon (IFN) Ineligibility²

Interferon (IFN) ineligible is defined as one or more of the below:

- Intolerance to IFN
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG-IFN or any of its components
- Major uncontrolled depressive illness
- A baseline neutrophil count < 1,500 cells/mcL
- A baseline platelet count < 90,000 cells/mcL

Reference number(s)
Policy: 2141-A
Qsets: 5920-A, 6284-A

- A baseline hemoglobin < 10 g/dL
- History of pre-existing cardiac disease

References

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
2. Pegasys [package insert]. Vienna, Austria: zr pharma& GmbH; December 2023.
3. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Generics First Criteria

Program Summary

The intent of the criteria is to require that members try and fail an A-rated generic equivalent prior to receiving a brand specialty medication. If the member has experienced treatment failure with an A-rated (i.e., AA, AB, AN, AO, AP, AT) generic equivalent medication due to an intolerable adverse reaction attributed to an inactive ingredient of the generic medication, the requested brand medication will be approved upon submission of supporting documentation.

Prior to dispensing, each referral is reviewed based on all programs implemented for the client.

Coverage Criteria

Authorization may be granted for a requested medication when all of the following criteria are met:

- The member has failed treatment with the generic medication due to an intolerable adverse event (e.g., rash, nausea, vomiting).
- The adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication).
- The adverse event is documented in member's chart note(s) or medical record. Submission of one of the following is required for approval:
 - Specific and detailed chart note(s) or medical record documentation including description, date/time, and severity of the adverse event, dosage and duration of generic medication treatment, required intervention (if any), and relevant tests or laboratory data (if any).
 - MedWatch form of this trial and failure including the adverse reaction.

Note

Due to brand and generic products containing identical active ingredients and having proven bioequivalent pharmacokinetics, differences in the FDA labeled indications between brand and generic products are not, by themselves, sufficient reason to allow access to the brand over the generic.

Specialty Guideline Management

Spravato (esketamine)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Spravato	esketamine	nasal spray

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Spravato is indicated for the treatment of:

- Treatment-resistant depression (TRD) in adults as monotherapy or in conjunction with an oral antidepressant
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

Limitations of Use

The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato.

Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

Reference number(s)
2889-A

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For initial requests:

- Pretreatment depression severity score(s) from standardized rating scale(s) that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
- Medical records documenting inadequate response with antidepressant and augmentation agents for the current depressive episode or evidence based psychotherapy (if applicable)

For continuation of therapy:

Current depression severity score(s) from standardized rating scale(s) that reliably measure depressive symptoms (if applicable)

Prescriber Specialties

This medication must be prescribed by or in consultation with a psychiatrist.

Exclusions

Coverage will not be provided for members with moderate or severe substance or alcohol use disorder that is not currently being treated or medically managed.

Coverage Criteria

Treatment-resistant depression (TRD)/Major Depressive Disorder (MDD) with acute suicidal ideation or behavior¹⁻⁴

Authorization of 3 months may be granted for the treatment of TRD or 1 month for the treatment of MDD with acute suicidal ideation or behavior when all of the following criteria are met:

- Member has a confirmed diagnosis of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.).
- Member is 18 years of age or older.
- The requested medication will be administered under the direct supervision of a healthcare provider.
- Member will be monitored by a health care provider for at least 2 hours after administration.
- Member meets either of the following criteria:
 - For treatment-resistant depression (TRD), member must meet both of the following:
 - Member has experienced an inadequate response during the current depressive episode with two antidepressants from at least two different classes with different mechanisms of action at the maximally tolerated labeled dose, each used for at least 8 weeks within the past 5 years. For the purposes of this criteria, the current depressive episode begins with the most recent onset of acute symptoms. Examples of antidepressant classes include, but are not limited to:
 - Aminoketone (Wellbutrin/SR/XL [bupropion])
 - Monoamine oxidase inhibitors (MAOIs) (e.g., Marplan, Nardil, Parnate, phenelzine, tranylcypromine)
 - Noradrenaline and specific serotonergic antidepressants (NASSAs) (e.g., amoxapine, maprotiline, mirtazapine/ODT, Oleptro ER, Remeron/Solutab, trazodone)
 - Selective serotonin reuptake inhibitors (SSRIs) (e.g., Celexa, citalopram, escitalopram, fluoxetine, fluvoxamine, Lexapro, Luvox/CR, paroxetine, Paxil/CR, Pexeva, Prozac/Weekly, sertraline, Zoloft)
 - Serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., Cymbalta, desvenlafaxine/ER, duloxetine, Effexor/XR, Fetzima, Khedezla, Pristiq, venlafaxine/ER)
 - Tricyclic antidepressants (TCAs) (e.g., amitriptyline, desipramine, doxepin, Elavil, imipramine, Norpramin, nortriptyline, Pamelor, Surmontil, Tofranil, trimipramine)
 - Serotonin modulators (e.g., Trintellix, vortioxetine, Viibryd, vilazodone)
 - Member has experienced an inadequate response with an adequate trial of augmentation therapy for at least 8 weeks within the past 5 years OR evidenced based psychotherapy (i.e., cognitive behavioral therapy [CBT], interpersonal therapy [IPT], supportive therapy [ST], or psychoeducational intervention [PEI]) during the current depressive episode. For the purposes of this criteria, the current depressive episode begins with the most recent onset of acute symptoms.

- Augmentation therapy is defined as:
 - Two antidepressants with different mechanisms of action used concomitantly
 - An antidepressant and a second-generation antipsychotic used concomitantly
 - An antidepressant and lithium used concomitantly
 - An antidepressant and thyroid hormone used concomitantly
- For major depressive disorder (MDD) with acute suicidal ideation or behavior, member meets all of the following:
 - Member has major depressive disorder with current suicidal ideation with intent defined as both of the following:
 - Member has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide
 - Member intends to act on thoughts of killing themselves
 - The prescriber represents that, in the absence of the requested drug, within the next 24 to 48 hours the member will require confinement in an acute care psychiatric institution.
 - The requested drug will be used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine).

Continuation of Therapy

Treatment-resistant depression (TRD)

Authorization of 6 months may be granted for the continuation of treatment of TRD when there is improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.).

Major depressive disorder (MDD) with acute suicidal ideation or behavior

The use of Spravato beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in patients with MDD with acute suicidal ideation or behavior. Member must meet all requirements in the coverage criteria section for approval.

References

1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2025.
2. American Psychological Association. Depression Assessment Instruments. Available at: <https://www.apa.org/depression-guideline/assessment>. Accessed October 21, 2024.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Available at: www.micromedexsolutions.com [available with subscription]. Accessed October 21, 2024.
4. Thase, M and Connolly, R (2021) Unipolar depression in adults: Choosing treatment for resistant depression, UpToDate, Available at www.uptodate.com [available with subscription]. Accessed October 21, 2024.

County Care IL Custom Criteria
Stelara (ustekinumab)
Imuldosa (ustekinumab-srlf)
Otulif (ustekinumab-aaaz)
Pyzchiva (ustekinumab-ttwe)
Selarsdi (ustekinumab-aekn)
Steqeyma(ustekinumab-stba)
Wezlana (ustekinumab-auub)
Yesintek (ustekinumab-kfce)
ustekinumab
ustekinumab-auub
ustekinumab-aaaz
ustekinumab-aekn
ustekinumab-kfce
ustekinumab-srlf
ustekinumab-stba
ustekinumab-ttwe

CRITERIA FOR APPROVAL

- 1 What is the diagnosis?
 - ☐ Crohn's disease (If checked, go to 2)
 - ☐ Plaque psoriasis (If checked, go to 4)
 - ☐ Psoriatic arthritis (If checked, go to 7)
 - ☐ Ulcerative colitis (If checked, go to 12)
 - ☐ Immune checkpoint inhibitor-related diarrhea or colitis (If checked, go to 17)
 - ☐ Other, please specify: _____(If checked, go to 17)
- 2 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the preferred products Cimzia or one of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada)?
[If Yes, then go to 17. If No, then go to 3.]

	Yes	No
- 3 Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor?
[If Yes, then go to 17. If No, then no further questions.]

	Yes	No
- 4 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the following

	Yes	No

products Cimzia, Cosentyx, Enbrel or one of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada)?

[If Yes, then go to 17. If No, then go to 5.]

5	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
7	Has the patient tried and failed TWO of the products Cimzia, Cosentyx, Enbrel, or one of the following adalimumab products; (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada) or Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then go to 8.]	Yes	No
8	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then go to 10.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx, Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
10	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, or one of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
12	Has the patient tried and failed BOTH of the preferred products Xeljanz AND one of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada)? [If Yes, then go to 17. If No, then go to 13.]	Yes	No
13	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D)	Yes	No

Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor?

[If Yes, then go to 14. If No, then go to 15.]

14	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
15	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with one of the following adalimumab products (Humira, Cyltezo, adalimumab-adbm, Simlandi or Abrilada)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Will the requested drug or a biosimilar of the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 18.]	Yes	No
18	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 22. If No, then go to 19.]	Yes	No
19	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	What were the results of the tuberculosis (TB) test? ☐ Positive for TB (If checked, go to 21) ☐ Negative for TB (If checked, go to 22) ☐ Unknown (If checked, no further questions)		
21	Which of the following applies to the patient? ☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions)		

☐ Patient has active TB (If checked, no further questions)

22 What is the diagnosis?

☐ Plaque psoriasis (If checked, go to 26)

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 23)

☐ Psoriatic arthritis (If checked, go to 41)

☐ Crohn's disease (If checked, go to 56)

☐ Ulcerative colitis (If checked, go to 63)

☐ Immune checkpoint inhibitor-related diarrhea or colitis (If checked, go to 70)

☐ Other, please specify. _____ (If checked, no further questions)

23	Is the patient 6 years of age or older? [If Yes, then go to 24. If No, then no further questions.]	Yes	No

24	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 25. If No, then no further questions.]	Yes	No

25 What is the primary diagnosis being treated?

☐ Psoriatic arthritis (If checked, go to 43)

☐ Plaque psoriasis (If checked, go to 28)

26	Is the patient 6 years of age or older? [If Yes, then go to 27. If No, then no further questions.]	Yes	No

27	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 28. If No, then no further questions.]	Yes	No

28	Has the patient been diagnosed with moderate to severe plaque psoriasis? [If Yes, then go to 29. If No, then no further questions.]	Yes	No

29	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 30. If No, then go to 34.]	Yes	No

30 Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program?

☐ Yes (If checked, go to 34)

☐ No (If checked, go to 31)

☐ Unknown (If checked, go to 34)

31	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 32. If No, then no further questions.]	Yes	No
32	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 75. If No, then go to 33.]	Yes	No
33	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 75. If No, then no further questions.]	Yes	No
34	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 75. If No, then go to 35.]	Yes	No
35	Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? <i>ACTION REQUIRED:</i> If Yes, please attach chart notes or medical record documentation of affected areas. <i>ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 75. If No, then go to 36.]	Yes	No
36	Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%? [If Yes, then no further questions. If No, then go to 37.]	Yes	No
37	What is the percentage of body surface area (BSA) affected (prior to starting the requested drug or a biosimilar of the requested drug)? Indicate percentage. <i>ACTION REQUIRED:</i> Please attach chart notes or medical record documentation of body surface area affected.		
	☐ Greater than or equal to 3% to less than 10% of BSA <i>ACTION REQUIRED: Submit supporting documentation</i> (If checked, go to 38)		
	☐ Greater than or equal to 10% of BSA <i>ACTION REQUIRED: Submit supporting documentation</i> (If checked, go to 75)		
38	Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic	Yes	No

treatment with methotrexate, cyclosporine, or acitretin? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. **ACTION REQUIRED: Submit supporting documentation**
[If Yes, then go to 75. If No, then go to 39.]

39	Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 40. If No, then no further questions.]	Yes	No
40	Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 75) ☐ Drug interaction (If checked, go to 75) ☐ Risk of treatment-related toxicity (If checked, go to 75) ☐ Pregnancy or currently planning pregnancy (If checked, go to 75) ☐ Breastfeeding (If checked, go to 75) ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 75) ☐ Hypersensitivity (If checked, go to 75) ☐ History of intolerance or adverse event (If checked, go to 75) ☐ Other, please specify _____ (If checked, no further questions)		
41	Is the patient 6 years of age or older? [If Yes, then go to 42. If No, then no further questions.]	Yes	No
42	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 43. If No, then no further questions.]	Yes	No
43	Is this request for continuation of therapy with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 44. If No, then go to 47.]	Yes	No
44	Is the patient currently receiving the requested drug or a biosimilar of the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 47) ☐ No (If checked, go to 45)		

☐ Unknown (If checked, go to 47)

45	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? [If Yes, then go to 46. If No, then no further questions.]	Yes	No

46	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ Number of tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ Dactylitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ Enthesitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ Skin and/or nail involvement ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ Functional status ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ C-reactive protein (CRP) ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)

☐ None of the above (If checked, no further questions)

47	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 48. If No, then no further questions.]	Yes	No

48	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 75. If No, then go to 49.]	Yes	No

49	What is the patient's disease severity?		

☐ Mild to moderate (If checked, go to 50)

☐ Severe (If checked, go to 75)

50	Does the patient have enthesitis? [If Yes, then go to 75. If No, then go to 51.]	Yes	No

51	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g.,	Yes	No

sulfasalazine) administered at an adequate dose and duration?
ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. **ACTION REQUIRED: Submit supporting documentation**
 [If Yes, then go to 75. If No, then go to 52.]

52	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 75. If No, then go to 53.]	Yes	No
53	Does the patient have a contraindication to methotrexate or leflunomide? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 54. If No, then go to 55.]	Yes	No
54	Please indicate the contraindication to methotrexate or leflunomide. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 75) ☐ Drug interaction (If checked, go to 75) ☐ Risk of treatment-related toxicity (If checked, go to 75) ☐ Pregnancy or currently planning pregnancy (If checked, go to 75) ☐ Breastfeeding (If checked, go to 75) ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 75) ☐ Hypersensitivity (If checked, go to 75) ☐ History of intolerance or adverse event (If checked, go to 75) ☐ Other, please specify. _____ (If checked, no further questions)		
55	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 75. If No, then no further questions.]	Yes	No
56	Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? [If Yes, then go to 57. If No, then no further questions.]	Yes	No
57	Is the patient an adult (18 years of age or older)? [If Yes, then go to 58. If No, then no further questions.]	Yes	No

58	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 59. If No, then no further questions.]	Yes	No
59	Which of the following applies to this request for the requested drug or a biosimilar of the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 75) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 75) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 60)		
60	Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission. ☐ Yes, achieved or maintained remission ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Yes, achieved or maintained a positive clinical response (If checked, go to 61) ☐ No or none of the above (If checked, go to 62)		
61	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy. ☐ Abdominal pain or tenderness ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Diarrhea ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Body weight ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Abdominal mass ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Hematocrit ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound ACTION REQUIRED: Submit supporting documentation (If checked, go to 75) ☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) ACTION REQUIRED: Submit supporting documentation (If checked, go to 75)		

☐ None of the above (If checked, go to 62)

62	Is this a request for an increase in dosing frequency due to the patient not achieving an adequate clinical response at the current frequency?	Yes	No

[If Yes, then go to 75. If No, then no further questions.]

63	Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)?	Yes	No

[If Yes, then go to 64. If No, then no further questions.]

64	Is the patient an adult (18 years of age or older)?	Yes	No

[If Yes, then go to 65. If No, then no further questions.]

65	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a gastroenterologist?	Yes	No

[If Yes, then go to 66. If No, then no further questions.]

66	Which of the following applies to this request for the requested drug or a biosimilar of the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 75)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 75)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 67)

67	Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug or a biosimilar of the requested drug? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 68)

☐ No or none of the above (If checked, go to 69)

68	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy.

☐ Stool frequency *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Rectal bleeding *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Urgency of defecation *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Fecal calprotectin (FC) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 75)

☐ None of the above (If checked, go to 69)

69	Is this a request for an increase in dosing frequency due to the patient not achieving an adequate clinical response at the current frequency? [If Yes, then go to 75. If No, then no further questions.]	Yes	No

70	Is the requested drug or a biosimilar of the requested drug being prescribed by or in consultation with a gastroenterologist, hematologist, or oncologist? [If Yes, then go to 71. If No, then no further questions.]	Yes	No

71	Has the patient experienced an inadequate response to infliximab or vedolizumab? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 74. If No, then go to 72.]	Yes	No

72	Has the patient experienced an intolerance to infliximab or vedolizumab? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 74. If No, then go to 73.]	Yes	No

73	Does the patient have a contraindication to infliximab and vedolizumab? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 74. If No, then no further questions.]	Yes	No

74	Is the requested quantity supported by dosing guidelines found in the compendia or current literature (e.g., Micromedex DrugDex, NCCN compendia, current treatment guidelines)? [No further questions]	Yes	No

75	What is the diagnosis?

☐ Plaque psoriasis (If checked, go to 76)

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 76)

☐ Psoriatic arthritis (If checked, go to 88)

☐ Crohn's disease (If checked, go to 94)

☐ Ulcerative colitis (If checked, go to 94)

76 What is the requested formulation?

☐ Subcutaneous injection (If checked, go to 77)

☐ Intravenous infusion (If checked, no further questions)

77	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 78. If No, then go to 83.]	Yes	No

78 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than or equal to 100 kg _____(If checked, go to 79)

☐ Greater than 100 kg _____(If checked, go to 81)

79	Does the prescribed maintenance dose exceed 45 mg? [If Yes, then no further questions. If No, then go to 80.]	Yes	No

80	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No

81	Does the prescribed maintenance dose exceed 90 mg? [If Yes, then no further questions. If No, then go to 82.]	Yes	No

82	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No

83 What is the patient's weight? Indicate in kilograms (kg).

☐ Less than or equal to 100 kg _____(If checked, go to 84)

☐ Greater than 100 kg _____(If checked, go to 86)

84	Does the prescribed dose exceed a loading dose of 45 mg at weeks 0 and 4, and a maintenance dose of 45 mg thereafter? [If Yes, then no further questions. If No, then go to 85.]	Yes	No

85	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No

86	Does the prescribed dose exceed a loading dose of 90 mg at weeks 0 and 4, and a maintenance dose of 90 mg thereafter? [If Yes, then no further questions. If No, then go to 87.]	Yes	No

87	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No
88	What is the requested formulation? ☐ Subcutaneous injection (If checked, go to 89) ☐ Intravenous infusion (If checked, no further questions)		
89	Is the patient currently receiving the requested drug or a biosimilar of the requested drug? [If Yes, then go to 90. If No, then go to 92.]	Yes	No
90	Does the prescribed maintenance dose exceed 45 mg? [If Yes, then no further questions. If No, then go to 91.]	Yes	No
91	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No
92	Does the prescribed dose exceed a loading dose of 45 mg at weeks 0 and 4, and a maintenance dose of 45 mg thereafter? [If Yes, then no further questions. If No, then go to 93.]	Yes	No
93	Is the prescribed frequency for the maintenance dose more frequent than one dose every 12 weeks? [No further questions]	Yes	No
94	Which of the following applies to this request for the requested drug or a biosimilar of the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 102) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 95) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 97)		
95	Does the prescribed maintenance dose exceed 90 mg? [If Yes, then no further questions. If No, then go to 96.]	Yes	No
96	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
97	Does the prescribed maintenance dose exceed 90 mg? [If Yes, then no further questions. If No, then go to 98.]	Yes	No
98	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [If Yes, then go to 99. If No, then no further questions.]	Yes	No
99	Please select the situation that applies to the patient.		

☐ Patient is continuing therapy at current frequency (If checked, go to 101)

☐ Prescriber is increasing frequency (If checked, go to 100)

100	Does the patient require an increase in dosing frequency due to lack of clinical response at the current dose? [If Yes, then go to 101. If No, then no further questions.]	Yes	No
101	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
102	What is the patient's weight? Indicate in kilograms (kg). ☐ Less than or equal to 55 kg _____(If checked, go to 103) ☐ Greater than 55 kg to less than or equal to 85 kg _____(If checked, go to 105) ☐ Greater than 85 kg _____(If checked, go to 107)		
103	Does the prescribed dose exceed a one-time loading dose of 260 mg and a maintenance dose of 90 mg thereafter? [If Yes, then no further questions. If No, then go to 104.]	Yes	No
104	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
105	Does the prescribed dose exceed a one-time loading dose of 390 mg and a maintenance dose of 90 mg thereafter? [If Yes, then no further questions. If No, then go to 106.]	Yes	No
106	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
107	Does the prescribed dose exceed a one-time loading dose of 520 mg and a maintenance dose of 90 mg thereafter? [If Yes, then no further questions. If No, then go to 108.]	Yes	No
108	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No

Specialty Guideline Management

Tadalafil Products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Adcirca	tadalafil
Alyq	tadalafil
Tadliq	tadalafil

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁴

Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Compendial Uses⁵

Secondary Raynaud's phenomenon

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist for the diagnosis of pulmonary arterial hypertension (PAH).

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)^{1-4,6-9}

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by either of the following criteria:
 - Pretreatment right heart catheterization with all of the following results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units. For pediatric members, pulmonary vascular resistance index (PVRI) > 3 Wood units x m² is also acceptable.
 - For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

Secondary Raynaud's Phenomenon^{5,10-12}

Authorization of 12 months may be granted for treatment of secondary Raynaud's phenomenon when the member has had an inadequate response to one of the following medications:

- Calcium channel blockers
- Angiotensin II receptor blockers
- Selective serotonin reuptake inhibitors
- Alpha blockers
- Angiotensin-converting enzyme inhibitors
- Topical nitrates

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving a tadalafil product through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁷

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)

- Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
- Non-malignant tumors (e.g., uterine leiomyoma)
- Arteritis without connective tissue disease
- Congenital pulmonary artery stenoses
- Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2020.
2. Alyq [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2023.
3. Tadliq [package insert]. Farmville, NC: CMP Pharma, Inc.; October 2023.
4. Tadalafil [package insert]. Bridgewater, NJ: Ajanta Pharma USA Inc.; May 2023.
5. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed April 1, 2025.
6. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018
7. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
8. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J*. 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
9. Ivy D, Rosenzweig EB, Abman SH, et al. Embracing the challenges of neonatal and paediatric pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401345. doi: 10.1183/13993003.01345-2024
10. Curtiss P, Svigos K, Schwager Z, Lo Sicco K, Franks AG Jr. Part II: The treatment of primary and secondary Raynaud's phenomenon. *J Am Acad Dermatol*. 2024 Feb;90(2):237-248. doi: 10.1016/j.jaad.2022.05.067
11. Maltez N, Maxwell LJ, Rirash F, et al. Phosphodiesterase 5 inhibitors (PDE5i) for the treatment of Raynaud's phenomenon. *Cochrane Database Syst Rev*. 2023 Nov 6;11(11):CD014089. doi: 10.1002/14651858
12. Del Galdo F, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Annals of the Rheumatic Diseases Published Online First*: 11 October 2024. doi: 10.1136/ard-2024-226430

Reference number(s)
C29124-A

County Care IL Custom Criteria Taltz

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

_____*Ashley M Robinson PharmD*_____10/21/25
Signature Date

_____*CountyCare*_____
Client Name

CRITERIA FOR APPROVAL

- 1 What is the diagnosis?
 - ☐ Ankylosing spondylitis (If checked, go to 2)
 - ☐ Non-radiographic axial spondyloarthritis (If checked, go to 7)
 - ☐ Plaque psoriasis (If checked, go to 10)
 - ☐ Psoriatic arthritis (If checked, go to 13)
 - ☐ Other, please specify: _____ (If checked, go to 18)
- 2 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel, an adalimumab product, or Xeljanz/Xeljanz XR? Yes No

[If Yes, then go to 18. If No, then go to 3.]
- 3 Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? Yes No

[If Yes, then go to 4. If No, then go to 5.]
- 4 Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx or Xeljanz/Xeljanz XR? Yes No

[If Yes, then go to 18. If No, then no further questions.]
- 5 Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of

	major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 6. If No, then no further questions.]		
6	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel or an adalimumab product? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
7	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the preferred products Cimzia or Cosentyx? [If Yes, then go to 18. If No, then go to 8.]	Yes	No
8	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
10	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel or an adalimumab product? [If Yes, then go to 18. If No, then go to 11.]	Yes	No
11	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
13	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel, Humira or Xeljanz/Xeljanz XR? [If Yes, then go to 18. If No, then go to 14.]	Yes	No
14	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 15. If No, then go to 16.]	Yes	No

15	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx or Xeljanz/Xeljanz XR? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
16	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
18	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 19.]	Yes	No
19	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 23. If No, then go to 20.]	Yes	No
20	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 6 months of initiating therapy? [If Yes, then go to 21. If No, then no further questions.]	Yes	No
21	What were the results of the tuberculosis (TB) test? ☐ Positive for TB (If checked, go to 22) ☐ Negative for TB (If checked, go to 23) ☐ Unknown (If checked, no further questions)		
22	Which of the following applies to the patient? ☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 23) ☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 23) ☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions) ☐ Patient has active TB (If checked, no further questions)		
23	What is the diagnosis? ☐ Plaque psoriasis (If checked, go to 26)		

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 24)

☐ Psoriatic arthritis (If checked, go to 41)

☐ Ankylosing spondylitis (If checked, go to 56)

☐ Non-radiographic axial spondyloarthritis (If checked, go to 56)

☐ Other, please specify. _____ (If checked, no further questions)

24	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 25. If No, then no further questions.]	Yes	No

25 What is the primary diagnosis being treated?

☐ Psoriatic arthritis (If checked, go to 42)

☐ Plaque psoriasis (If checked, go to 27)

26	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 27. If No, then no further questions.]	Yes	No

27	Has the patient been diagnosed with moderate to severe plaque psoriasis? [If Yes, then go to 28. If No, then no further questions.]	Yes	No

28	Is the patient 6 years of age or older? [If Yes, then go to 29. If No, then no further questions.]	Yes	No

29	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 30. If No, then go to 34.]	Yes	No

30 Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?

☐ Yes (If checked, go to 34)

☐ No (If checked, go to 31)

☐ Unknown (If checked, go to 34)

31	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 32. If No, then no further questions.]	Yes	No

32	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 33.]	Yes	No

33	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then no further questions.]	Yes	No
34	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 35.]	Yes	No
35	Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of affected areas. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 36.]	Yes	No
36	Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%? [If Yes, then no further questions. If No, then go to 37.]	Yes	No
37	What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? Indicate percentage. ACTION REQUIRED: Please attach chart notes or medical record documentation of body surface area affected. ☐ Greater than or equal to 3% to less than 10% of BSA ACTION REQUIRED: Submit supporting documentation (If checked, go to 38) ☐ Greater than or equal to 10% of BSA ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)		
38	Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 39.]	Yes	No
39	Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 40. If No, then no further questions.]	Yes	No

- 40 Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin.
- ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 65)
- ☐ Drug interaction (If checked, go to 65)
- ☐ Risk of treatment-related toxicity (If checked, go to 65)
- ☐ Pregnancy or currently planning pregnancy (If checked, go to 65)
- ☐ Breastfeeding (If checked, go to 65)
- ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 65)
- ☐ Hypersensitivity (If checked, go to 65)
- ☐ History of intolerance or adverse event (If checked, go to 65)
- ☐ Other, please specify. _____ (If checked, no further questions)
- 41 Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? Yes No
[If Yes, then go to 42. If No, then no further questions.]
- 42 Is the patient an adult (18 years of age or older)? Yes No
[If Yes, then go to 43. If No, then no further questions.]
- 43 Is this request for continuation of therapy with the requested drug? Yes No
[If Yes, then go to 44. If No, then go to 47.]
- 44 Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?
- ☐ Yes (If checked, go to 47)
- ☐ No (If checked, go to 45)
- ☐ Unknown (If checked, go to 47)
- 45 Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? Yes No
[If Yes, then go to 46. If No, then no further questions.]
- 46 Which of the following has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response.
- ☐ Number of swollen joints **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)

- ☐ Number of tender joints *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ Dactylitis *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ Enthesitis *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ Axial disease *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ Skin and/or nail involvement *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ Functional status *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)
- ☐ None of the above (If checked, no further questions)

47	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 48. If No, then no further questions.]	Yes	No
48	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 49.]	Yes	No
49	What is the patient's disease severity?		
	☐ Mild to moderate (If checked, go to 50)		
	☐ Severe (If checked, go to 65)		
50	Does the patient have enthesitis or predominantly axial disease? [If Yes, then go to 65. If No, then go to 51.]	Yes	No
51	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 52.]	Yes	No
52	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit</i>	Yes	No

supporting documentation

[If Yes, then go to 65. If No, then go to 53.]

53	Does the patient have a contraindication to methotrexate or leflunomide? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 55. If No, then go to 54.]	Yes	No
54	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then no further questions.]	Yes	No
55	Please indicate the contraindication to methotrexate or leflunomide. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 65) ☐ Drug interaction (If checked, go to 65) ☐ Risk of treatment-related toxicity (If checked, go to 65) ☐ Pregnancy or currently planning pregnancy (If checked, go to 65) ☐ Breastfeeding (If checked, go to 65) ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 65) ☐ Hypersensitivity (If checked, go to 65) ☐ History of intolerance or adverse event (If checked, go to 65) ☐ Other, please specify. _____ (If checked, no further questions)		
56	Is the patient an adult (18 years of age or older)? [If Yes, then go to 57. If No, then no further questions.]	Yes	No
57	Is the requested drug being prescribed by or in consultation with a rheumatologist? [If Yes, then go to 58. If No, then no further questions.]	Yes	No
58	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 59. If No, then go to 62.]	Yes	No
59	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 62) ☐ No (If checked, go to 60) ☐ Unknown (If checked, go to 62)		

60	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 61. If No, then no further questions.]	Yes	No
61	Which of the following has the patient experienced an improvement in from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response. ☐ Functional status ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ Total spinal pain ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ Inflammation (e.g., morning stiffness) ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ Swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ Tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ C-reactive protein (CRP) ACTION REQUIRED: Submit supporting documentation (If checked, go to 65) ☐ None of the above (If checked, no further questions)		
62	Has the patient been diagnosed with active ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA)? ☐ Yes - Active ankylosing spondylitis (If checked, go to 63) ☐ Yes - Active non-radiographic axial spondyloarthritis (If checked, go to 63) ☐ No (If checked, no further questions)		
63	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 64.]	Yes	No
64	Has the patient experienced an inadequate response with at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs), or has an intolerance or contraindication to at least TWO NSAIDs? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation	Yes	No

[If Yes, then go to 65. If No, then no further questions.]

65 What is the diagnosis?

☐ Plaque psoriasis (If checked, go to 73)

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 66)

☐ Psoriatic arthritis (If checked, go to 81)

☐ Ankylosing spondylitis (If checked, go to 86)

☐ Non-radiographic axial spondyloarthritis (If checked, go to 91)

66	Is the patient currently receiving Taltz?	Yes	No
	[If Yes, then go to 67. If No, then go to 70.]		

67 What is the patient's age?

☐ 6 years of age to less than 18 years of age (If checked, go to 73)

☐ 18 years of age or older (If checked, go to 68)

68	Does the prescribed maintenance dose exceed 80 mg?	Yes	No
	[If Yes, then no further questions. If No, then go to 69.]		

69	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?	Yes	No
	[No further questions]		

70 What is the patient's age?

☐ 6 years of age to less than 18 years of age (If checked, go to 73)

☐ 18 years of age or older (If checked, go to 71)

71	Does the prescribed dose exceed a loading dose of 160 mg at week 0, 80 mg at weeks 2, 4, 6, 8, 10, and 12, and a maintenance dose of 80 mg thereafter?	Yes	No
	[If Yes, then no further questions. If No, then go to 72.]		

72	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?	Yes	No
	[No further questions]		

73	Is the patient currently receiving Taltz?	Yes	No
	[If Yes, then go to 74. If No, then go to 76.]		

74	Does the prescribed maintenance dose exceed 80 mg?	Yes	No
	[If Yes, then no further questions. If No, then go to 75.]		

75	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks?	Yes	No
	[No further questions]		

76 What is the patient's age?

☐ 6 years of age to less than 18 years of age (If checked, go to 77)

☐ 18 years of age or older (If checked, go to 79)

77	Does the prescribed dose exceed a loading dose of 160 mg at week 0, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 78.]	Yes	No
78	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
79	Does the prescribed dose exceed a loading dose of 160 mg at week 0, 80 mg at weeks 2, 4, 6, 8, 10, and 12, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 80.]	Yes	No
80	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
81	Is the patient currently receiving Taltz? [If Yes, then go to 82. If No, then go to 84.]	Yes	No
82	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 83.]	Yes	No
83	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
84	Does the prescribed dose exceed a loading dose of 160 mg at week 0, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 85.]	Yes	No
85	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
86	Is the patient currently receiving Taltz? [If Yes, then go to 87. If No, then go to 89.]	Yes	No
87	Does the prescribed maintenance dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 88.]	Yes	No
88	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
89	Does the prescribed dose exceed a loading dose of 160 mg at week 0, and a maintenance dose of 80 mg thereafter? [If Yes, then no further questions. If No, then go to 90.]	Yes	No
90	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No

91	Does the prescribed dose exceed 80 mg? [If Yes, then no further questions. If No, then go to 92.]	Yes	No
92	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No

Mapping Instructions		
	Yes	No
1.	1=2 ;2=7 ;3=10 ;4=13 ;5=18	
2.	Go to 18	Go to 3
3.	Go to 4	Go to 5
4.	Go to 18	Deny OR Pend and Continue to 18
5.	Go to 6	Deny OR Pend and Continue to 6
6.	Go to 18	Deny OR Pend and Continue to 18
7.	Go to 18	Go to 8
8.	Go to 9	Deny OR Pend and Continue to 9
9.	Go to 18	Deny OR Pend and Continue to 18
10.	Go to 18	Go to 11
11.	Go to 12	Deny OR Pend and Continue to 12
12.	Go to 18	Deny OR Pend and Continue to 18
13.	Go to 18	Go to 14
14.	Go to 15	Go to 16
15.	Go to 18	Deny OR Pend and Continue to 18
16.	Go to 17	Deny OR Pend and Continue to 17
17.	Go to 18	Deny OR Pend and Continue to 18
18.	Deny OR Pend and Continue to 19	Go to 19
19.	Go to 23	Go to 20
20.	Go to 21	Deny OR Pend and Continue to 21
21.	1=22 ;2=23 ;3=Deny	
22.	1=23 ;2=23 ;3=Deny OR Pend and Continue to 23 ;4=Deny OR Pend and Continue to 23	

23.	1=26 ;2=24 ;3=41 ;4=56 ;5=56 ;6=Deny	
24.	Go to 25	Deny OR Pend and Continue to 25
25.	1=42 ;2=27	
26.	Go to 27	Deny OR Pend and Continue to 27
27.	Go to 28	Deny OR Pend and Continue to 28
28.	Go to 29	Deny OR Pend and Continue to 29
29.	Go to 30	Go to 34
30.	1=34 ;2=31 ;3=34	
31.	Go to 32	Deny OR Pend and Continue to 32
32.	Go to 65	Go to 33
33.	Go to 65	Deny OR Pend and Continue to 65
34.	Go to 65	Go to 35
35.	Go to 65	Go to 36
36.	Deny OR Pend and Continue to 37	Go to 37
37.	1=38 ;2=65	
38.	Go to 65	Go to 39
39.	Go to 40	Deny OR Pend and Continue to 40
40.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=65 ;9=Deny OR Pend and Continue to 65	
41.	Go to 42	Deny OR Pend and Continue to 42
42.	Go to 43	Deny OR Pend and Continue to 43
43.	Go to 44	Go to 47
44.	1=47 ;2=45 ;3=47	
45.	Go to 46	Deny OR Pend and Continue to 46
46.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=65 ;9=Deny OR Pend and Continue to 65	
47.	Go to 48	Deny OR Pend and Continue to 48
48.	Go to 65	Go to 49
49.	1=50 ;2=65	

50.	Go to 65	Go to 51
51.	Go to 65	Go to 52
52.	Go to 65	Go to 53
53.	Go to 55	Go to 54
54.	Go to 65	Deny OR Pend and Continue to 65
55.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=65 ;9=Deny OR Pend and Continue to 65	
56.	Go to 57	Deny OR Pend and Continue to 57
57.	Go to 58	Deny OR Pend and Continue to 58
58.	Go to 59	Go to 62
59.	1=62 ;2=60 ;3=62	
60.	Go to 61	Deny OR Pend and Continue to 61
61.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=Deny OR Pend and Continue to 65	
62.	1=63 ;2=63 ;3=Deny OR Pend and Continue to 63	
63.	Go to 65	Go to 64
64.	Go to 65	Deny OR Pend and Continue to 65
65.	1=73 ;2=66 ;3=81 ;4=86 ;5=91	
66.	Go to 67	Go to 70
67.	1=73 ;2=68	
68.	Deny OR Pend and Continue to 69	Go to 69
69.	Deny	Approve, 12 Months
70.	1=73 ;2=71	
71.	Deny OR Pend and Continue to 72	Go to 72
72.	Deny	Approve, 12 Months
73.	Go to 74	Go to 76
74.	Deny OR Pend and Continue to 75	Go to 75
75.	Deny	Approve, 12 Months
76.	1=77 ;2=79	

Reference number(s)
C29124-A

77.	Deny OR Pend and Continue to 78	Go to 78
78.	Deny	Approve, 12 Months
79.	Deny OR Pend and Continue to 80	Go to 80
80.	Deny	Approve, 12 Months
81.	Go to 82	Go to 84
82.	Deny OR Pend and Continue to 83	Go to 83
83.	Deny	Approve, 12 Months
84.	Deny OR Pend and Continue to 85	Go to 85
85.	Deny	Approve, 12 Months
86.	Go to 87	Go to 89
87.	Deny OR Pend and Continue to 88	Go to 88
88.	Deny	Approve, 12 Months
89.	Deny OR Pend and Continue to 90	Go to 90
90.	Deny	Approve, 12 Months
91.	Deny OR Pend and Continue to 92	Go to 92
92.	Deny	Approve, 12 Months

Specialty Guideline Management teriflunomide-Aubagio

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Aubagio	teriflunomide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis¹⁻³

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹⁻³

Authorization of 12 months may be granted to members for treatment of clinically isolated syndrome of multiple sclerosis.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted to members who are experiencing disease stability or improvement while receiving the requested medication.

Other

- Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).
- Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

References

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. Teriflunomide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; October 2024.
3. Rae-Grant A, Day G, Marrie R, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. *Neurology*. 2018;90(17):777-788.

Specialty Guideline Management teriparatide-Forteo-Bonsity

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Forteo	teriparatide	560 mcg/2.24 ml prefilled pen
Bonsity	teriparatide	560 mcg/2.24 ml prefilled pen
Teriparatide (branded generic)	teriparatide	620 mcg/2.48 ml prefilled pen

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹⁻⁵

- Treatment of postmenopausal women with osteoporosis at high risk for fracture (defined herein as having a history of osteoporotic fracture or multiple risk factors for fracture) or who have failed or are intolerant to other available osteoporosis therapy.
- Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of men and women with osteoporosis associated with sustained glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) fracture probability as applicable to the coverage criteria section.

Coverage Criteria

Postmenopausal Osteoporosis^{1-10,14}

Authorization of an initial total of 12 months may be granted to postmenopausal members with osteoporosis when EITHER of the following criteria is met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position)
- Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B) and meets ANY of the following criteria:
 - Member has indicators of very high fracture risk (e.g., advanced age, frailty, glucocorticoid use, very low T-scores [less than or equal to -3], or increased fall risk)
 - Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], a denosumab product [Prolia, Jubbonti, Ospomyv, Stoboclo], denosumab-bbdz [Jubbonti], abaloparatide [Tymlos])
 - Member has had an oral bisphosphonate trial of at least 1-year duration or there is a clinical reason to avoid treatment with an oral bisphosphonate (see Appendix A)

Primary or Hypogonadal Osteoporosis in Men^{1-5,10,11}

Authorization of an initial total of 12 months may be granted to male members with primary or hypogonadal osteoporosis when EITHER of the following criteria is met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member meets BOTH of the following criteria:
 - Member has a pre-treatment T-score less than or equal to -2.5 OR member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B)
 - Member has had an oral or injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (see Appendix A)

Glucocorticoid-Induced Osteoporosis^{1-5,10,12}

Authorization of an initial total of 12 months may be granted to members with glucocorticoid-induced osteoporosis when ALL of the following criteria are met:

- Member has had an oral or injectable bisphosphonate trial of at least 1-year duration OR there is a clinical reason to avoid treatment with a bisphosphonate (See Appendix A)
- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of ≥ 2.5 mg/day for ≥ 3 months
- Member meets ANY of the following criteria:
 - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position).
 - Member has a pre-treatment T-score less than or equal to -2.5
 - Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix B)

Continuation of Therapy¹⁻⁵

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet one of the following:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets both of the following:
 - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
 - Member has not experienced any adverse effects

Other

The cumulative duration of parathyroid hormone analogs (e.g., teriparatide and abaloparatide) will not exceed a total of 24 months in the member's lifetime unless the member remains at or has returned to having a high risk for fracture.

Appendix

Appendix A. Clinical Reasons to Avoid Oral Bisphosphonate Therapy⁸

- Presence of anatomic or functional esophageal abnormalities that might delay transit of the tablet (e.g., achalasia, stricture, or dysmotility)
- Active upper gastrointestinal problem (e.g., dysphagia, gastritis, duodenitis, erosive esophagitis, ulcers)

- Presence of documented or potential gastrointestinal malabsorption (e.g., gastric bypass procedures, celiac disease, Crohn's disease, infiltrative disorders)
- Inability to stand or sit upright for at least 30 to 60 minutes
- Inability to take oral bisphosphonate at least 30 to 60 minutes before first food, drink, or medication of the day
- Renal insufficiency (creatinine clearance < 35 mL/min)
- History of intolerance to an oral bisphosphonate

Appendix B: FRAX Fracture Risk Assessment Tool^{12,13}

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk $\geq$ 20% or hip fracture risk $\geq$ 3%
- 10-year probability; calculation tool available at: <https://frax.shef.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2 for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day

References

1. Forteo [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2024.
2. Bonsity [package insert]. Morristown, NJ: Alvogen, Inc.; December 2024.
3. Teriparatide [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2024.
4. Teriparatide [package insert]. Morristown, NJ: Alvogen, Inc.; December 2024.
5. Teriparatide [package insert]. Weston, FL: Apotex Corp.; January 2023.
6. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25(10): 2359-2381.
7. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
8. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 update. *Endocr Pract*. 2020;26 (Suppl 1):1-46.
9. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2020;105(3):587-594.
10. Carey JJ. What is a 'failure' of bisphosphonate therapy for osteoporosis? *Cleve Clin J of Med*. 2005;72(11):1033-1039.
11. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocr Metab*. 2012;97(6):1802-1822.
12. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2012.

Reference number(s)
2028-A

13. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: <https://frax.shef.ac.uk/FRAX>. Accessed October 12, 2024.
14. Ensrud KE, Crandall CJ. Osteoporosis. Ann Intern. Med 2017;167(03):ITC17–ITC32.

Initial Prior Authorization

Testosterone – Azmiro, Depo-Testosterone

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Azmiro	testosterone cypionate	injection
Depo-Testosterone	testosterone cypionate	injection

Indications

FDA-approved Indications

Azmiro

Azmiro is indicated for testosterone replacement therapy in males in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy, Klinefelter's syndrome, or toxic damage from alcohol or heavy metals, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use:

- Safety and efficacy of Azmiro in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
- Safety and efficacy of Azmiro in pediatric patients below the age of 12 years have not been established.

Depo-Testosterone

Depo-Testosterone Injection is indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy.
- Hypogonadotropic hypogonadism (congenital or acquired)-gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.

Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Compendial Uses

Azmiro, Depo-Testosterone

Gender dysphoria^{4,6-8} (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, then ALL of the following criteria are met:
 - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or

Reference number(s)
976-A

internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.

- The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 976-A: DOA: 12 months

References

1. Azmiro [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; May 2024.
2. Depo-Testosterone [package insert]. New York, NY: Pharmacia & Upjohn Co; August 2018.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 4, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/04/2025).
5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
6. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
8. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

Initial Prior Authorization

Testosterone – Oral Testosterone Undecanoate

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Jatenzo	testosterone undecanoate	oral
Kyzatrex	testosterone undecanoate	oral
Tlando	testosterone undecanoate	oral
Undecatrex	testosterone undecanoate	oral

Indications

FDA-approved Indications

Jatenzo, Kyzatrex, Tlando, Undecatrex

Testosterone undecanoate is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle- stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.

Reference number(s)
3060-A

- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use:

- Safety and efficacy of testosterone undecanoate in males less than 18 years old have not been established.

Compendial Uses

Jatenzo, Kyzatrex, Tlando, Undecatrex

Gender dysphoria^{7,9-11} (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, then ALL of the following criteria are met:
 - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.
 - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

Reference number(s)
3060-A

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 3060-A: DOA: 12 months

References

1. Jatenzo [package insert]. Fort Collins, CO: Tolmar, Inc.; August 2023.
2. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals LLC; September 2022.
3. Tlando [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; February 2024.
4. Undecatrex [package insert]. San Antonio, TX: Trifluent Pharma, LLC; September 2022.
5. Testopel (testosterone pellets) [package insert]. Malvern, PA: Endo USA; March 2024.

Reference number(s)
3060-A

6. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 4, 2025.
7. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/04/2025).
8. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
9. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
10. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
11. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

Initial Prior Authorization

Testosterone – Testosterone Enanthate

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
testosterone enanthate (generic Delatestry – brand unavailable)	testosterone enanthate	injection
Xyosted	testosterone enanthate	injection

Indications

FDA-approved Indications

Testosterone Enanthate Injection

Males

Testosterone enanthate injection (generic Delatestryl) is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will

be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of testosterone enanthate injection (generic Delatestryl) in men with age-related hypogonadism have not been established.

Delayed puberty - Testosterone enanthate injection (generic Delatestryl) may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Females

Metastatic mammary cancer - Testosterone enanthate injection (generic Delatestryl) may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Xyosted

Xyosted (testosterone enanthate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the low or normal range.

Limitations of Use:

- Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Compendial Uses

Testosterone Enanthate Injection, Xyosted

Gender dysphoria^{5,7-9} (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Breast Cancer (Hormone-Responsive Tumor)

Authorization may be granted when the requested drug is being prescribed for a premenopausal patient with breast cancer who has benefited from oophorectomy AND is considered to have a hormone-responsive tumor when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl).

Delayed Puberty

Authorization may be granted when the requested drug is being prescribed for delayed puberty when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl).

Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, then ALL of the following criteria are met:
 - The requested drug is prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.

- The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Inoperable Metastatic Breast Cancer

Authorization may be granted when the requested drug is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal AND had an incomplete response to other therapy for metastatic breast cancer when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl).

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Breast Cancer (Hormone-Responsive Tumor), Delayed Puberty, Inoperable Metastatic Breast Cancer

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with

“age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]

- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 1368-A: DOA: 12 months

References

1. Testosterone Enanthate [package insert]. E. Windsor, NJ: Eugia US LLC; February 2024.
2. Xyosted [package insert]. Ewing, NJ: Antares Pharma, Inc; August 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 3, 2025.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 3, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/03/2025).
6. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
7. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
8. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
9. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

Initial Prior Authorization

Testosterone – Topical and Nasal

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Androgel	testosterone	topical gel
Fortesta	testosterone	topical gel
Natesto	testosterone	nasal gel
Testim	testosterone	topical gel
testosterone (all brands)	testosterone	topical solution
Vogelxo	testosterone	topical gel

Indications

FDA-approved Indications

Androgel, Fortesta, Natesto, Testim, Testosterone Topical Gel, Testosterone Topical Solution, Vogelxo

Topical and nasal testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.

- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use:

- Safety and efficacy of topical and nasal testosterone products in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.
- Safety and efficacy of topical and nasal testosterone products in males less than 18 years old have not been established.
- Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Compendial Uses

Androgel, Fortesta, Natesto, Testim, Testosterone Topical Gel, Testosterone Topical Solution, Vogelxo

Gender dysphoria^{9,11-13} (also known as transgender and gender diverse (TGD) persons)

Coverage Criteria

Gender Dysphoria

Authorization may be granted when the requested drug is being prescribed for gender dysphoria in a patient who is able to make an informed decision to engage in hormone therapy when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- The patient’s comorbid conditions are reasonably controlled.
- The patient has been educated on ANY contraindications AND side effects to therapy.
- Before the start of therapy, the patient has been informed of fertility preservation options.
- If the patient is less than 18 years of age, then ALL of the following criteria are met:
 - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.
 - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Gender Dysphoria

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 1370-A: DOA: 12 months

References

1. Androgel 1.62% [package insert]. Morristown, NJ: Ascend Therapeutics US, LLC; November 2020.

Reference number(s)
1370-A

2. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; January 2022.
3. Natesto Nasal Gel [package insert]. Mississauga, ON: Acerus Pharmaceutical Corporation; December 2021.
4. Testim [package insert]. Malvern, PA: Endo USA,; August 2021.
5. Testosterone Gel 1% [package insert]. Durham, NC: Encube Ethicals, Inc.; July 2024.
6. Testosterone Topical Solution [package insert]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; December 2023.
7. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.
8. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 3, 2025.
9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/03/2025).
10. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
11. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
12. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
13. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

Specialty Guideline Management

Tezspire

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tezspire	tezepelumab-ekko

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Tezspire is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of use

Not for relief of acute bronchospasm or status asthmaticus.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

Prescriber Specialties

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Coverage Criteria¹⁻⁴

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - High-dose inhaled corticosteroid
 - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Continuation of Therapy

Authorization of 12 months may be granted for continuation of treatment of severe asthma when all of the following criteria are met:

- Member is 12 years of age or older.

- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations
 - A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

References

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
3. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22):2301-2317.
4. Wechsler ME, Colice G, Griffiths JM, et al. SOURCE: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of tezepelumab in reducing oral corticosteroid used in adults with oral corticosteroid dependent asthma. Respir Res. 2020;21(1):264.

Reference number(s)
C29093-A

CountyCare IL Custom Criteria TREMFA (guselkumab)

CLIENT SIGNATURE

By signing below, Client hereby directs the custom criteria in this document to be used for prior authorization reviews. Client acknowledges that Client is solely responsible for the criteria, including updating and maintaining the criteria and ensuring any applicable regulatory compliance.

Ashley M Robinson PharmD _____ 10/21/25 _____
Signature Date

CountyCare
Client Name

CRITERIA FOR APPROVAL

- 1 What is the diagnosis?
 - ☐ Plaque Psoriasis (If checked, go to 2)
 - ☐ Psoriatic Arthritis (If checked, go to 5)
 - ☐ Crohn's Disease (If checked, go to 10)
 - ☐ Ulcerative colitis (If checked, go to 12)
 - ☐ Other, Please specify (If checked, go to 17)
- 2 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 17. If No, then go to 3.]

	Yes	No
- 3 Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 4. If No, then no further questions.]

	Yes	No
- 4 Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx? [If Yes, then go to 17. If No, then no further questions.]

	Yes	No
- 5 Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with TWO of the preferred products Cimzia, Cosentyx, Enbrel, Humira or Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then go to 6.]

	Yes	No
- 6 Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of

	Yes	No

	congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 7. If No, then go to 8.]		
7	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cosentyx and Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
8	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D) History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Cimzia, Cosentyx, Enbrel, or an adalimumab product? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
10	Has the patient had a documented inadequate response, intolerable adverse event, or contraindication with ONE of the following products: A) Cimzia OR B) An adalimumab product? [If Yes, then go to 17. If No, then go to 11.]	Yes	No
11	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
12	Has the patient tried and failed BOTH of the following products: A) An adalimumab product AND B) Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then go to 13.]	Yes	No
13	Does the patient have one of the following clinical reasons to avoid TNF inhibitors: A) History of demyelinating disorder, B) History of congestive heart failure, C) History of hepatitis B virus infection, D) Autoantibody formation/lupus-like syndrome, E) History or risk of lymphoma or other malignancy, F) History of being a primary non-responder to a TNF inhibitor? [If Yes, then go to 14. If No, then go to 15.]	Yes	No
14	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with Xeljanz/Xeljanz XR? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
15	Does the patient have one of the following clinical reasons to avoid JAK inhibitors: A) History or risk of lymphoma, lung cancer, non-melanoma skin cancer, or other malignancy, B) History or risk of major adverse cardiovascular events (MI, stroke, etc.), C) History or risk of thrombotic events (PE, DVT, arterial thrombosis, etc.), D)	Yes	No

History of hepatitis B or hepatitis C virus infection, E) History of being a primary non-responder to a JAK inhibitor?
[If Yes, then go to 16. If No, then no further questions.]

16	Has the patient had a documented inadequate response, intolerable adverse event or contraindication with an adalimumab product? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Will the requested drug be used in combination with any other biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Otezla, Xeljanz) for the same indication? [If Yes, then no further questions. If No, then go to 18.]	Yes	No
18	Has the patient ever received (including current utilizers) a biologic (e.g., Humira) or targeted synthetic drug (e.g., Olumiant, Xeljanz) associated with an increased risk of tuberculosis? [If Yes, then go to 22. If No, then go to 19.]	Yes	No
19	Has the patient had a tuberculosis (TB) test (e.g., tuberculosis skin test [TST], interferon-release assay [IGRA]) within 12 months of initiating therapy? [If Yes, then go to 20. If No, then no further questions.]	Yes	No
20	What were the results of the tuberculosis (TB) test? ☐ Positive for TB (If checked, go to 21) ☐ Negative for TB (If checked, go to 22) ☐ Unknown (If checked, no further questions)		
21	Which of the following applies to the patient? ☐ Patient has latent TB and treatment for latent TB has been initiated (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has been completed (If checked, go to 22) ☐ Patient has latent TB and treatment for latent TB has not been initiated (If checked, no further questions) ☐ Patient has active TB (If checked, no further questions)		
22	What is the diagnosis? ☐ Crohn's disease (If checked, go to 60) ☐ Plaque psoriasis (If checked, go to 25) ☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 23) ☐ Psoriatic arthritis (If checked, go to 40) ☐ Ulcerative colitis (If checked, go to 55)		

☐ Other, please specify. _____ (If checked, no further questions)		
23	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 24. If No, then no further questions.]	Yes No
24	What is the primary diagnosis being treated? ☐ Psoriatic arthritis (If checked, go to 41) ☐ Plaque psoriasis (If checked, go to 26)	
25	Is the requested drug being prescribed by or in consultation with a dermatologist? [If Yes, then go to 26. If No, then no further questions.]	Yes No
26	Has the patient been diagnosed with moderate to severe plaque psoriasis? [If Yes, then go to 27. If No, then no further questions.]	Yes No
27	Is the patient 6 years of age or older and weighs at least 40 kg [If Yes, then go to 28. If No, then no further questions.]	Yes No
28	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 29. If No, then go to 33.]	Yes No
29	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program? ☐ Yes (If checked, go to 33) ☐ No (If checked, go to 30) ☐ Unknown (If checked, go to 33)	
30	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 31. If No, then no further questions.]	Yes No
31	Has the patient experienced a reduction in body surface area (BSA) affected from baseline? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of decreased body surface area affected. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then go to 32.]	Yes No
32	Has the patient experienced an improvement in signs and symptoms of the condition from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of improvement in signs and symptoms. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then no further questions.]	Yes No
33	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated	Yes No

for the treatment of moderate to severe plaque psoriasis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? **ACTION REQUIRED:** If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. **ACTION REQUIRED:** *Submit supporting documentation*
[If Yes, then go to 65. If No, then go to 34.]

34	Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of affected areas. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 35.]	Yes	No

35	Is the percentage of body surface area (BSA) affected (prior to starting the requested medication) less than 3%? [If Yes, then no further questions. If No, then go to 36.]	Yes	No

36	What is the percentage of body surface area (BSA) affected (prior to starting the requested medication)? Indicate percentage. ACTION REQUIRED: Please attach chart notes or medical record documentation of body surface area affected.		

☐ Greater than or equal to 3% to less than 10% of BSA
_____ **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 37)

☐ Greater than or equal to 10% of BSA
_____ **ACTION REQUIRED:** *Submit supporting documentation* (If checked, go to 65)

37	Has the patient experienced an inadequate response, or has an intolerance to phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin? ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 38.]	Yes	No

38	Does the patient have a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid each therapy. ACTION REQUIRED: <i>Submit supporting documentation</i> [If Yes, then go to 39. If No, then no further questions.]	Yes	No

39	Please indicate the clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin.		

☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 65)

☐ Drug interaction (If checked, go to 65)

☐ Risk of treatment-related toxicity (If checked, go to 65)

☐ Pregnancy or currently planning pregnancy (If checked, go to 65)

☐ Breastfeeding (If checked, go to 65)

☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 65)

☐ Hypersensitivity (If checked, go to 65)

☐ History of intolerance or adverse event (If checked, go to 65)

☐ Other, please specify _____ (If checked, no further questions)

40	Is the requested drug being prescribed by or in consultation with a rheumatologist or dermatologist? [If Yes, then go to 41. If No, then no further questions.]	Yes	No

41	Is the patient 6 years of age or older and weighs at least 40 kg [If Yes, then go to 42. If No, then no further questions.]	Yes	No

42	Is this request for continuation of therapy with the requested drug? [If Yes, then go to 43. If No, then go to 46.]	Yes	No

43	Is the patient currently receiving the requested drug through samples or a manufacturer's patient assistance program?		

☐ Yes (If checked, go to 46)

☐ No (If checked, go to 44)

☐ Unknown (If checked, go to 46)

44	Has the patient achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? [If Yes, then go to 45. If No, then no further questions.]	Yes	No

45	Has the patient experienced improvement in any of the following from baseline? ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response.		

☐ Number of swollen joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)

☐ Number of tender joints ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)

☐ Dactylitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)

☐ Enthesitis ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)

☐ Skin and/or nail involvement ACTION REQUIRED: Submit supporting documentation (If checked, go to 65)

☐ Functional status *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ C-reactive protein (CRP) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ None of the above (If checked, no further questions)

46	Has the patient been diagnosed with active psoriatic arthritis (PsA)? [If Yes, then go to 47. If No, then no further questions.]	Yes	No

47	Has the patient ever received or is currently receiving a biologic (e.g., Humira) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for the treatment of active psoriatic arthritis (excluding receiving the drug via samples or a manufacturer's patient assistance program)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 48.]	Yes	No

48	What is the patient's disease severity? ☐ Mild to moderate (If checked, go to 49) ☐ Severe (If checked, go to 65)		

49	Does the patient have enthesitis? [If Yes, then go to 65. If No, then go to 50.]	Yes	No

50	Has the patient had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 51.]	Yes	No

51	Has the patient had an intolerance to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine)? <i>ACTION REQUIRED: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 65. If No, then go to 52.]	Yes	No

52	Does the patient have a contraindication to methotrexate or leflunomide? <i>ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation</i> [If Yes, then go to 53. If No, then go to 54.]	Yes	No

53	Please indicate the contraindication to methotrexate or leflunomide. ☐ Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease (If checked, go to 65)		

- ☐ Drug interaction (If checked, go to 65)
- ☐ Risk of treatment-related toxicity (If checked, go to 65)
- ☐ Pregnancy or currently planning pregnancy (If checked, go to 65)
- ☐ Breastfeeding (If checked, go to 65)
- ☐ Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension) (If checked, go to 65)
- ☐ Hypersensitivity (If checked, go to 65)
- ☐ History of intolerance or adverse event (If checked, go to 65)
- ☐ Other, please specify. _____ (If checked, no further questions)

54	Does the patient have a contraindication to another conventional synthetic drug (e.g., sulfasalazine)? ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation [If Yes, then go to 65. If No, then no further questions.]	Yes	No

55	Has the patient been diagnosed with moderately to severely active ulcerative colitis (UC)? [If Yes, then go to 56. If No, then no further questions.]	Yes	No

56	Is the requested drug being prescribed by or in consultation with a gastroenterologist? [If Yes, then go to 57. If No, then no further questions.]	Yes	No

57 Which of the following applies to this request for the requested drug?

☐ Initiation of the intravenous (IV) loading dose (If checked, go to 65)

☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 65)

☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 58)

58 Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response to treatment as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission **ACTION REQUIRED: Submit supporting documentation** (If checked, go to 65)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 59)

☐ No or none of the above (If checked, no further questions)

- 59 Which of the following has the patient experienced an improvement in from baseline? **ACTION REQUIRED:** Please attach chart notes or medical record documentation supporting positive clinical response to therapy.
- ☐ Stool frequency **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ Rectal bleeding **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ Urgency of defecation **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ C-reactive protein (CRP) **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ Fecal calprotectin (FC) **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo Score) **ACTION REQUIRED:** Submit supporting documentation (If checked, go to 65)
- ☐ None of the above (If checked, no further questions)
- 60 Has the patient been diagnosed with moderately to severely active Crohn's disease (CD)? Yes No
[If Yes, then go to 61. If No, then no further questions.]
- 61 Is the requested drug being prescribed by or in consultation with a gastroenterologist? Yes No
[If Yes, then go to 62. If No, then no further questions.]
- 62 Which of the following applies to this request for the requested drug?
- ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 65)
- ☐ Initiation of the subcutaneous (SQ) loading dose (If checked, go to 65)
- ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 65)
- ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 63)
- 63 Has the patient achieved or maintained remission OR achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition since starting treatment with the requested drug? **ACTION REQUIRED:** If Yes, please attach chart notes or medical record documentation of remission.

☐ Yes, achieved or maintained remission *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Yes, achieved or maintained a positive clinical response (If checked, go to 64)

☐ No or none of the above (If checked, no further questions)

64 Which of the following has the patient experienced an improvement in from baseline? *ACTION REQUIRED: Please attach chart notes or medical record documentation supporting positive clinical response to therapy.*

☐ Abdominal pain or tenderness *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Diarrhea *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Body weight *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Abdominal mass *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Hematocrit *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score) *ACTION REQUIRED: Submit supporting documentation* (If checked, go to 65)

☐ None of the above (If checked, no further questions)

65 What is the diagnosis?

☐ Crohn's disease (If checked, go to 71)

☐ Plaque psoriasis (If checked, go to 66)

☐ Psoriatic arthritis WITH co-existent plaque psoriasis (If checked, go to 66)

☐ Psoriatic arthritis (If checked, go to 66)

☐ Ulcerative colitis (If checked, go to 71)

66	Is the patient currently receiving Tremfya?	Yes	No
	[If Yes, then go to 69. If No, then go to 67.]		

67	Does the prescribed dose exceed a loading dose of 100 mg at weeks 0 and 4, and a maintenance dose of 100 mg thereafter?	Yes	No
	[If Yes, then no further questions. If No, then go to 68.]		

Reference number(s)
C29093-A

68	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
69	Does the prescribed dose exceed 100 mg? [If Yes, then no further questions. If No, then go to 70.]	Yes	No
70	Is the prescribed frequency for the maintenance dose more frequent than one dose every 8 weeks? [No further questions]	Yes	No
71	Which of the following applies to this request for the requested drug? ☐ Initiation of the intravenous (IV) loading dose (If checked, go to 72) ☐ Initiation of the subcutaneous (SQ) loading dose (If checked, go to 74) ☐ Initiation of the subcutaneous (SQ) maintenance dose (If checked, go to 76) ☐ Continuation of the subcutaneous (SQ) maintenance dose (If checked, go to 76)		
72	Does the prescribed dose exceed a loading dose of 200 mg at weeks 0, 4, and 8, and a maintenance dose of 200 mg thereafter? [If Yes, then no further questions. If No, then go to 73.]	Yes	No
73	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No
74	Does the prescribed dose exceed a loading dose of 400 mg at weeks 0, 4, and 8, and a maintenance dose of 200 mg thereafter? [If Yes, then no further questions. If No, then go to 75.]	Yes	No
75	Is the prescribed frequency for the maintenance more frequent than one dose every 4 weeks? [No further questions]	Yes	No
76	Does the prescribed dose exceed 200 mg? [If Yes, then no further questions. If No, then go to 77.]	Yes	No
77	Is the prescribed frequency for the maintenance dose more frequent than one dose every 4 weeks? [No further questions]	Yes	No

Mapping Instructions		
	Yes	No
1.	1=2 ;2=5 ;3=10 ;4=12 ;5=17	
2.	Go to 17	Go to 3
3.	Go to 4	Deny OR Pend and Continue to 4

Reference number(s)
C29093-A

4.	Go to 17	Deny OR Pend and Continue to 17
5.	Go to 17	Go to 6
6.	Go to 7	Go to 8
7.	Go to 17	Deny OR Pend and Continue to 17
8.	Go to 9	Deny OR Pend and Continue to 9
9.	Go to 17	Deny OR Pend and Continue to 17
10.	Go to 17	Go to 11
11.	Go to 17	Deny OR Pend and Continue to 17
12.	Go to 17	Go to 13
13.	Go to 14	Go to 15
14.	Go to 17	Deny OR Pend and Continue to 17
15.	Go to 16	Deny OR Pend and Continue to 16
16.	Go to 17	Deny OR Pend and Continue to 17
17.	Deny OR Pend and Continue to 18	Go to 18
18.	Go to 22	Go to 19
19.	Go to 20	Deny OR Pend and Continue to 20
20.	1=21 ;2=22 ;3=Deny	
21.	1=22 ;2=22 ;3=Deny OR Pend and Continue to 22 ;4=Deny OR Pend and Continue to 22	
22.	1=60 ;2=25 ;3=23 ;4=40 ;5=55 ;6=Deny	
23.	Go to 24	Deny OR Pend and Continue to 24
24.	1=41 ;2=26	
25.	Go to 26	Deny OR Pend and Continue to 26
26.	Go to 27	Deny OR Pend and Continue to 27
27.	Go to 28	Deny OR Pend and Continue to 28
28.	Go to 29	Go to 33
29.	1=33 ;2=30 ;3=33	
30.	Go to 31	Deny OR Pend and Continue to 31
31.	Go to 65	Go to 32

32.	Go to 65	Deny OR Pend and Continue to 65
33.	Go to 65	Go to 34
34.	Go to 65	Go to 35
35.	Deny OR Pend and Continue to 36	Go to 36
36.	1=37 ;2=65	
37.	Go to 65	Go to 38
38.	Go to 39	Deny OR Pend and Continue to 39
39.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=65 ;9=Deny OR Pend and Continue to 65	
40.	Go to 41	Deny OR Pend and Continue to 41
41.	Go to 42	Deny OR Pend and Continue to 42
42.	Go to 43	Go to 46
43.	1=46 ;2=44 ;3=46	
44.	Go to 45	Deny OR Pend and Continue to 45
45.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=Deny OR Pend and Continue to 65	
46.	Go to 47	Deny OR Pend and Continue to 47
47.	Go to 65	Go to 48
48.	1=49 ;2=65	
49.	Go to 65	Go to 50
50.	Go to 65	Go to 51
51.	Go to 65	Go to 52
52.	Go to 53	Go to 54
53.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=65 ;9=Deny OR Pend and Continue to 65	
54.	Go to 65	Deny OR Pend and Continue to 65
55.	Go to 56	Deny OR Pend and Continue to 56
56.	Go to 57	Deny OR Pend and Continue to 57
57.	1=65 ;2=65 ;3=58	
58.	1=65 ;2=59 ;3=Deny OR Pend and Continue to 59	

Reference number(s)
C29093-A

59.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=Deny OR Pend and Continue to 65	
60.	Go to 61	Deny OR Pend and Continue to 61
61.	Go to 62	Deny OR Pend and Continue to 62
62.	1=65 ;2=65 ;3=65 ;4=63	
63.	1=65 ;2=64 ;3=Deny OR Pend and Continue to 64	
64.	1=65 ;2=65 ;3=65 ;4=65 ;5=65 ;6=65 ;7=65 ;8=Deny OR Pend and Continue to 65	
65.	1=71 ;2=66 ;3=66 ;4=66 ;5=71	
66.	Go to 69	Go to 67
67.	Deny OR Pend and Continue to 68	Go to 68
68.	Deny	[Allow 2 PFS/PENS of 100mg/ml every 28 days for first 28 days (daily dose: 0.036) AND 1 PFS/PENS of 100mg/ml every 56 days (daily dose: 0.018); GPI 9025054200D520 & 9025054200E520]. Approve, 12 Months
69.	Deny OR Pend and Continue to 70	Go to 70
70.	Deny	[Allow 1 PFS/PENS of 100mg/ml every 56 days (Daily dose: 0.018), GPI 9025054200D520 & 9025054200E520]. Approve, 12 Months
71.	1=72 ;2=74 ;3=76 ;4=76	
72.	Deny OR Pend and Continue to 73	Go to 73
73.	Deny	[Allow 3 vials of IV SOLN 200 MG/20ML for first 56 days (daily dose: 0.715) GPI 90250542002030 AND 1 PFS/PEN of 200mg/2ml every 28 days (daily dose: 0.072) GPIs 9025054200D540 & 9025054200E540 plus 1 PFS/PENS of 100mg/ml every 56 days (daily dose: 0.018); GPI 9025054200D520 & 9025054200E520]. Approve, 12 Months
74.	Deny OR Pend and Continue to 75	Go to 75
75.	Deny	[Allow 6 PFS/PENS of 200mg/2ml for first 56 days (daily dose: 0.143) AND 1 PFS/PEN of 200mg/2ml every 28 days (daily dose: 0.072) GPIs 9025054200D540 & 9025054200E540 plus 1 PFS/PENS of 100mg/ml every 56 days (daily dose: 0.018) GPI 9025054200D520 & 9025054200E520]. Approve, 12 Months
76.	Deny OR Pend and Continue to 77	Go to 77

Reference number(s)
C29093-A

77.	Deny	[Allow 6 PFS/PENS of 200mg/2ml for first 56 days (daily dose: 0.143) AND 1 PFS/PEN of 200mg/2ml every 28 days (daily dose: 0.072) GPIs 9025054200D540 & 9025054200E540 plus 1 PFS/PENS of 100mg/ml every 56 days (daily dose: 0.018) GPI 9025054200D520 & 9025054200E520]. Approve, 12 Months

Specialty Guideline Management

Tysabri-Tyruko

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tysabri	natalizumab
Tyruko	natalizumab-sztn

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

- Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of tumor necrosis factor alpha (TNF- α). Tysabri and Tyruko should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF- α .
- Indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri and Tyruko increase the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri or Tyruko, physicians should consider whether the expected benefit of Tysabri or Tyruko is sufficient to offset this risk.

Reference number(s)
1846-A

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Crohn's Disease (CD)

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Crohn's disease: gastroenterologist
- Multiple sclerosis: neurologist

Coverage Criteria

Crohn's Disease (CD)¹⁻⁵

Authorization of 12 months may be granted for adult members who have received any other biologic indicated for the treatment of moderately to severely active Crohn's disease and who have been tested for anti-JCV antibodies.

Relapsing Forms of Multiple Sclerosis (MS)^{1,2}

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) and those who have been tested for anti-JCV antibodies.

Clinically Isolated Syndrome (CIS)^{1,2}

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis and those who have been tested for anti-JCV antibodies.

Continuation of Therapy

Crohn's Disease (CD)^{1-3,5}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Relapsing Forms of Multiple Sclerosis (MS) or Clinically Isolated Syndrome (CIS)^{1,2}

Authorization of 12 months may be granted for all members (including new members) who achieve or maintain a positive clinical response with the requested drug as evidenced by experiencing disease stability or improvement.

Other

For all indications: Members cannot use the requested drug concomitantly with any other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying), immunosuppressants, or TNF inhibitors (e.g., adalimumab, infliximab).

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Tysabri [package insert]. Cambridge, MA: Biogen Inc.; October 2023.
2. Tyruko [package insert]. Princeton, NJ: Sandoz Inc.; August 2023.
3. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
4. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113:481-517.
5. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160:2496- 2508.

Specialty Guideline Management

Tyvaso

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tyvaso	treprostinil
Tyvaso DPI	treprostinil

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

- Treatment of pulmonary arterial hypertension (PAH; World Health Organization [WHO] Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with New York Heart Association (NYHA) Functional Class III symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.
- Treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE), and WHO Group 3 connective tissue disease.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Hypertension (PH)¹⁻⁷

Authorization of 12 months may be granted for treatment of PH when ALL of the following criteria are met:

- Member has either of the following criteria:
 - WHO Group 1 class of pulmonary hypertension (refer to Appendix)
 - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3)
- PH was confirmed by either of the following:
 - Pretreatment right heart catheterization with all of the following results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units. For pediatric members, pulmonary vascular resistance index (PVRI) > 3 Wood units x m² is also acceptable.
 - For infants less than one year of age, PH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁴

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)

- Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
- Non-malignant tumors (e.g., uterine leiomyoma)
- Arteritis without connective tissue disease
- Congenital pulmonary artery stenoses
- Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Tyvaso [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; May 2022.
2. Tyvaso DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corp.; October 2024.
3. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018
4. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
5. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J*. 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
6. Ivy D, Rosenzweig EB, Abman SH, et al. Embracing the challenges of neonatal and paediatric pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401345. doi: 10.1183/13993003.01345-2024
7. Shlobin OA, Adir Y, Barbera JA, et al. Pulmonary hypertension associated with lung diseases. *Eur Respir J*. 2024;64(4):2401200. doi: 10.1183/13993003.01200-2024

Specialty Guideline Management

Vabysmo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vabysmo	faricimab-svoa

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Vabysmo is indicated for the treatment of:

- Diabetic macular edema
- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Diabetic Macular Edema^{1,2}

Authorization of 6 months may be granted for treatment of diabetic macular edema.

Reference number(s)
5156-A

Neovascular (Wet) Age-Related Macular Degeneration^{1,3}

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

Macular Edema Following Retinal Vein Occlusion^{1,4}

Authorization of 6 months may be granted for treatment of macular edema following retinal vein occlusion

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

References

1. Vabysmo [package insert]. South San Francisco, CA: Genentech, Inc.; July 2024.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.

Initial Prior Authorization with Quantity Limit Voquezna

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Voquezna	vonoprazan	tablets

Indications

FDA-approved Indications

Voquezna is indicated

- for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
- in combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (H. pylori) infection in adults.
- in combination with amoxicillin for the treatment of H. pylori infection in adults.

Coverage Criteria

Maintenance of Healing of Erosive Esophagitis (EE)

Authorization may be granted when the requested drug is being prescribed for maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI).
 - The patient has experienced an intolerance to a PPI.
 - The patient has a contraindication that would prohibit a trial of a PPI.
- The request is for Voquezna 10 mg tablets.

Relief of Heartburn Associated with Non-erosive Gastroesophageal Reflux (NERD)

Authorization may be granted when the requested drug is being prescribed for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to on-demand or intermittent proton pump inhibitor (PPI) therapy.
 - The patient has experienced an intolerance to a PPI.
 - The patient has a contraindication that would prohibit a trial of a PPI.
- The request is for Voquezna 10 mg tablets.

Treatment of Healing of Erosive Esophagitis (EE)

Authorization may be granted when the requested drug is being prescribed for the treatment of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI).
 - The patient has experienced an intolerance to a PPI.
 - The patient has a contraindication that would prohibit a trial of a PPI.

Treatment of Helicobacter Pylori (H. pylori)

Authorization may be granted when the requested drug is being prescribed for the treatment of Helicobacter pylori (H. pylori) infection in an adult in combination with amoxicillin as dual therapy OR amoxicillin and clarithromycin as triple therapy when the following criteria is met:

- The request is for Voquezna 20 mg tablets.

Quantity Limits Apply

Quantity Limit

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Use of this drug for H. pylori, NERD, and treatment of healing of EE is for short term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time. There should be no 3-month supplies filled.

Drug	1 Month Limit	3 Month Limit
Maintenance of healing of EE	30 tablets / 25 days	90 tablets / 75 days
Relief of heartburn associated with NERD	28 tablets / 28 days	Does Not Apply
Treatment of healing of EE	30 tablets / 25 days	Does Not Apply
Treatment of H. Pylori	28 tablets / 14 days	Does Not Apply

Duration of Approval (DOA)

- 6249-C:
 - Treatment of H. pylori: DOA: 14 days
 - Relief of heartburn associated with non-erosive gastroesophageal reflux: DOA: 4 weeks
 - Treatment of healing of erosive esophagitis: DOA: 8 weeks
 - Maintenance of healing of erosive esophagitis: DOA: 6 months

References

1. Voquezna [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc.; July 2024.

Reference number(s)
6249-C

2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 14, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/14/2025).
4. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022;117(1):27-56.
5. Chey WD, Howden CW, Moss SF et al. ACG Clinical Guideline: Treatment of *Helicobacter pylori* Infection. *Am J Gastroenterol*. 2024;119:1730–1753.

Specialty Guideline Management

Vosevi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vosevi	sofosbuvir-velpatasvir-voxilaprevir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Vosevi is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:

- Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor.
- Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.
 - Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C).

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin^{1,2}

Genotype 1, 2, 4, 5, or 6 infection

Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen, including glecaprevir/pibrentasvir [Mavyret]).

Genotype 3 infection

- Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen, including glecaprevir/pibrentasvir [Mavyret]).
- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who are treatment-naïve and have the Y93H substitution associated with velpatasvir resistance.

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

Hepatitis C Virus Infection, in combination with Ribavirin²

Genotype 3 infection

Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen, including glecaprevir/pibrentasvir [Mavyret]).

Direct-acting antiviral treatment failure

Genotype 1, 2, 3, 4, 5, or 6 infection

- Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with glecaprevir/pibrentasvir (Mavyret).
- Authorization of up to 24 weeks total may be granted for members with or without compensated cirrhosis who failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5, or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 2, 3, 4, 5, or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- This medication will be approved for use in adult members only.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.

- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness
 - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
 - Hepatitis B virus screening results
 - Metavir/Fibrosis score

References

1. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
2. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). HCV guidance: Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Guideline Management

Vumerity

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vumerity	diroximel fumarate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

Vumerity is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist.

Coverage Criteria

Relapsing Forms of Multiple Sclerosis¹

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome.

Continuation of Therapy

For all indications: Authorization of 12 months may be granted to members who are experiencing disease stability or improvement while receiving Vumerity.

Other Criteria

Members will not use Vumerity concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Reference

1. Vumerity [package insert]. Cambridge, MA: Biogen; March 2024.

Specialty Guideline Management

Winrevair

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Winrevair	sotatercept-csrk

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Winrevair is indicated for the treatment of adults with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests: Chart notes, medical record documentation, or claims history supporting current pulmonary arterial hypertension (PAH) therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)¹⁻⁷

Authorization of 12 months may be granted for treatment of PAH in members 18 years of age and older when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by right heart catheterization with all of the following pretreatment (before any PAH therapy) results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units
- The requested medication will be used as add-on therapy.
- Member is currently receiving PAH therapy with medications from at least two of the following drug classes:
 - Endothelin receptor antagonist (e.g., Letairis, Opsumit, Tracleer)
 - Phosphodiesterase-5 inhibitor (e.g., Adcirca, Revatio)
 - Soluble guanylate cyclase stimulator (e.g., Adempas)
 - Prostacyclin analog (e.g., Flolan, Orenitram, Remodulin, Tyvaso, Veletri, Ventavis)
 - Prostacyclin receptor agonist (e.g., Uptravi)

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁶

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease
 - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)
 - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)

Reference number(s)
6455-A

- Non-malignant tumors (e.g., uterine leiomyoma)
- Arteritis without connective tissue disease
- Congenital pulmonary artery stenoses
- Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

References

1. Winrevair [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.
2. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 trial of sotatercept for treatment of pulmonary arterial hypertension. *N Engl J Med*. 2023;388(16):1478-1490. doi: 10.1056/NEJMoa2213558
3. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 trial of sotatercept for treatment of pulmonary arterial hypertension. Supplementary appendix. *N Engl J Med*. 2023;Suppl Appendix.
4. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018
5. Acceleron Pharma, Inc. A Study of Sotatercept for the Treatment of Pulmonary Arterial Hypertension (MK-7962-003/A011-11)(STELLAR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [4/25/2024]. Available from: <https://clinicaltrials.gov/study/NCT04576988>. NLM Identifier: NCT04576988.
6. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J*. 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
7. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J*. 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024

Specialty Guideline Management

Xeljanz-Xeljanz XR

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xeljanz	tofacitinib
Xeljanz XR	tofacitinib extended-release

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

- Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- Adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adult patients with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
- Adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
- Active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.

Reference number(s)
2011-A

Compendial Uses

- Non-radiographic axial spondyloarthritis^{15,16}
- Oligoarticular juvenile idiopathic arthritis¹¹
- Immune checkpoint inhibitor-related toxicity¹⁴

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid Arthritis (RA)

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Non-Radiographic Axial Spondyloarthritis (nr-axSpA), and Articular Juvenile Idiopathic Arthritis (JIA)

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response.

Ulcerative Colitis (UC)

Initial Requests

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.

Reference number(s)
2011-A

Continuation Requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Immune Checkpoint Inhibitor-Related Toxicity

Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and articular juvenile idiopathic arthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Ulcerative colitis: gastroenterologist
- Immune checkpoint inhibitor-related toxicity: gastroenterologist, hematologist, or oncologist

Coverage Criteria

Rheumatoid Arthritis (RA)^{1-3,12-13}

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has experienced an inadequate response, intolerance, or has a contraindication to at least one tumor necrosis factor (TNF) inhibitor.

Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Olumiant) indicated for moderately to severely active RA.

Psoriatic Arthritis (PsA)^{1,7,16,19}

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when both of the following criteria are met:

- The requested drug will be used in combination with a conventional synthetic drug (e.g., methotrexate, leflunomide, sulfasalazine).
- Member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when both of the following criteria are met:

- The requested drug will be used in combination with a conventional synthetic drug (e.g., methotrexate, leflunomide, sulfasalazine).
- Member has previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,15,17}

Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active non-radiographic axial spondyloarthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

Ulcerative Colitis (UC)^{1,6,8,10}

Authorization of 12 months may be granted for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.

Authorization of 12 months may be granted for members who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug (e.g., Rinvoq) indicated for moderately to severely active ulcerative colitis.

Articular Juvenile Idiopathic Arthritis (JIA)^{1,11,18}

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active articular juvenile idiopathic arthritis when the member has experienced an inadequate response or intolerance to at least one TNF inhibitor.

Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic (other than a TNF inhibitor) or targeted synthetic drug indicated for active articular juvenile idiopathic arthritis.

Immune Checkpoint Inhibitor-Related Toxicity¹⁴

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has experienced an inadequate response, intolerance, or contraindication to infliximab or vedolizumab.

Continuation of Therapy

Rheumatoid Arthritis (RA)^{1-3,12}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderately to severely active RA and who achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Psoriatic Arthritis (PsA)^{1,7,19}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of swollen joints
- Number of tender joints
- Dactylitis
- Enthesitis
- Axial disease
- Skin and/or nail involvement
- Functional status
- C-reactive protein (CRP)

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA)^{1,15}

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Functional status
- Total spinal pain
- Inflammation (e.g., morning stiffness)
- Swollen joints
- Tender joints
- C-reactive protein (CRP)

Ulcerative Colitis (UC)^{1,6,8,10}

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Articular Juvenile Idiopathic Arthritis (JIA)^{1,11}

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
- Number of joints with limitation of movement
- Functional ability

Immune Checkpoint Inhibitor-Related Toxicity

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other^{1,9}

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

Reference number(s)
2011-A

If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested drug to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested drug.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Xeljanz/Xeljanz XR [package insert]. New York, NY: Pfizer, Inc.; May 2024.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
3. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79:685-699.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
5. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
6. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32.
8. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114:384-413.
9. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 11, 2024 from: <https://www.cdc.gov/tb/testing/>.
10. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020;158:1450.
11. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care Res (Hoboken)*. 2019; 71(6):717-734.

Reference number(s)
2011-A

12. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum.* 2010;62(9):2569-81.
13. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res.* 2021.
14. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 14, 2024.
15. 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.
16. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531.
17. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis.* 2017;0:1-14.
18. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
19. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.

Specialty Guideline Management

Xolair-Omlyclo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xolair	omalizumab
Omlyclo	omalizumab-igec

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications^{1,2}

Allergic asthma

Indicated for adult and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Limitations of use

Not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

IgE-mediated food allergy

Indicated for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

Is to be used in conjunction with food allergen avoidance.

Limitations of use

Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Chronic spontaneous urticaria (CSU)

Indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.

Limitations of use

Not indicated for treatment of other forms of urticaria.

Compendial Uses¹²

- Immune checkpoint inhibitor-related toxicities
- Systemic mastocytosis

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Asthma

Initial requests

- Chart notes or medical record documentation showing pre-treatment IgE level (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

CRSwNP

Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), Meltzer Clinical Score, or endoscopic nasal polyp score (NPS) (where applicable).

- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

IgE-Mediated Food Allergy

Initial requests

Chart notes, medical record documentation, or laboratory tests showing the following (where applicable):

- Pre-treatment allergen-specific IgE level.
- Skin-prick test wheal diameter.
- Pre-treatment serum IgE level.
- Positive result of a physician controlled oral food challenge.
- History of a systemic reaction to a food.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy (e.g., reduction or absence of hypersensitivity to food allergen).

CSU

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

Immune Checkpoint Inhibitor-Related Toxicity

Initial requests

Chart notes or medical record documentation showing pre-treatment IgE level.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

Systemic Mastocytosis

Initial requests

- Chart notes or medical record documentation supporting diagnosis of systemic mastocytosis.
- Chart notes, medical record documentation, or claims history supporting previous medications tried (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Asthma: allergist/immunologist or pulmonologist
- CRSwNP: allergist/immunologist or otolaryngologist
- IgE-mediated food allergy: allergist/immunologist
- Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist, or oncologist

Coverage Criteria

Asthma^{1-6,14}

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma in the past year.

Authorization of 6 months may be granted for treatment of moderate-to-severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
- Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
 - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - Medium-to-high-dose inhaled corticosteroid
 - Additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)^{1,2,10,11,15-17}

Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for chronic rhinosinusitis with nasal polyps (CRSwNP) in the past year.

Authorization of 6 months may be granted for treatment of CRSwNP when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has bilateral nasal polyps and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- Member has one of the following:
 - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
 - Meltzer Clinical Score of 2 or higher in both nostrils.
 - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - Rhinorrhea (anterior/posterior).
 - Reduction or loss of smell.
 - Facial pain or pressure.
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

IgE-Mediated Food Allergy^{1,2,19,20}

Authorization of 6 months may be granted for reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

- Member is 1 year of age or older.
- IgE-mediated food allergy has been confirmed by either of the following:
 - Pre-treatment food allergen-specific IgE level greater than or equal to 6 IU/mL.
 - Skin-prick test (SPC) with wheal diameter greater than or equal to 4 mm.
- Member has either of the following:
 - A positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms).
 - History of a systemic reaction to a food.
- Member has a pre-treatment serum IgE level greater than or equal to 30 IU/mL.
- Member will continue to follow a food-allergen avoidance diet.

Chronic Spontaneous Urticaria^{1,2,7,8}

Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for chronic spontaneous urticaria in the past year.

Authorization of 6 months may be granted for treatment of chronic spontaneous urticaria when all of the following criteria are met:

- Member is 12 years of age or older.

- Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
- Member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
- Member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks.

Immune Checkpoint Inhibitor-Related Toxicity^{12,21}

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when both of the following criteria are met:

- The member has a refractory case of immune-therapy related severe (G3) pruritus with no response to gabapentinoids in one month.
- The member has elevated IgE levels.

Systemic Mastocytosis^{12,13}

Authorization of 12 months may be granted for treatment of systemic mastocytosis when both of the following criteria are met:

- The major and at least one minor diagnostic criterion for systemic mastocytosis are present or three or more minor diagnostic criteria are present (see Appendix).
- The requested medication will be used in any of the following treatment settings:
 - Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when the member has tried both of the following:
 - H1 blockers and H2 blockers
 - Corticosteroids
 - Used for prevention of recurrent unprovoked anaphylaxis.
 - Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test.
 - Used to improve tolerability of venom immunotherapy.

Continuation of Therapy

Asthma^{1,2}

Authorization of 12 months may be granted for continuation of treatment of moderate-to-severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations

- A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)^{1,2,10,11,15}

Authorization of 12 months may be granted for continuation of treatment of CRSwNP when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has experienced a positive response as evidenced by improvement in signs and symptoms (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

IgE-Mediated Food Allergy^{1,2,20}

Authorization of 12 months may be granted for reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

- Member is 1 year of age or older.
- Member has achieved or maintained a positive clinical response to therapy as evidenced by a reduction or absence of hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen.
- Member will continue to maintain a food-allergen avoidance diet.

Chronic Spontaneous Urticaria^{1,2,7}

Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

Immune Checkpoint Inhibitor-Related Toxicity and Systemic Mastocytosis^{12,21}

Authorization of 12 months may be granted for continuation of treatment of refractory immune checkpoint inhibitor-related severe (G3) pruritus or systemic mastocytosis when the member achieves or maintains a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Appendix

2024 WHO Diagnostic Criteria for Systemic Mastocytosis¹³

- Major Criteria: multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs
- Minor Criteria
 - Atypical mast cell morphology, including spindle shape or immature morphology, present in greater than 25% of all mast cells on bone marrow smears or in other extracutaneous organ(s)
 - KIT p.D816V mutation or other activating KIT mutation(s) detected in peripheral blood, bone marrow, or other extracutaneous organ(s)
 - Mast cells aberrantly express one or more of the following antigens: CD2, CD25, CD30
 - Baseline serum tryptase concentration of greater than 20 ng/mL in the absence of an associated myeloid neoplasm; in the case of a known HαT, the tryptase level could be adjusted

References

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. Omlyclo [package insert]. Jersey City, NJ: Celltrion USA, Inc.; March 2025.
3. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Asthma Management Guidelines: Focused Updates 2020. Bethesda, MD: National Heart Lung and Blood Institute; December 2020. Available at <https://www.nhlbi.nih.gov/sites/default/files/publications/AsthmaManagementGuidelinesReport-2-4-21.pdf>. Accessed March 1, 2025.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
5. Strunk RC, Bloomberg GR. Omalizumab for asthma. N Engl J Med. 2006;354(25):2689-2695.
6. Kew KM, Karner C, Mindus SM. Combination formoterol and budesonide as maintenance and reliever therapy versus combination inhaler maintenance for chronic asthma in adults and children (review). Cochrane Database Syst Rev. 2013;12:CD009019.

7. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022 Mar;77(3):734-766.
8. Bernstein DI, Blessing-Moore J, Cox L, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. American Academy of Allergy, Asthma & Immunology Practice Parameter. <http://www.aaaai.org/practice-resources/statements-and-practice-parameters/practice-parameter-guidelines.aspx>. Accessed March 1, 2025.
9. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368(10):924-935.
10. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03280550, A Clinical Trial of Omalizumab in Participants with Chronic Rhinosinusitis with Nasal Polyps (POLYP 1) 2017 Sep 12. Available from: <https://clinicaltrials.gov/ct2/show/NCT03280550>.
11. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03280537, A Clinical Trial of Omalizumab in Participants with Chronic Rhinosinusitis with Nasal Polyps (POLYP 2) 2017 Sep 12. Available from: <https://clinicaltrials.gov/ct2/show/NCT03280537>.
12. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 1, 2025.
13. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed March 1, 2025.
14. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22):2301-2317.
15. Bachert C, Han JK, Wagenmann M, et al. EUFOREA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRSwNP) and biologics: Definitions and management. *J Allergy Clin Immunol*. 2021;147(1):29-36.
16. Fokkens WJ, Lund VJ, Hopkins C, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. *Rhinology*. 2020;58(Suppl S29):1-464.
17. Hopkins C. Chronic Rhinosinusitis with Nasal Polyps. *N Engl J Med*. 2019;381(1):55-63.
18. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023 Feb;151(2):386-398.
19. NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol*. 2010;126(6 Suppl):S1-58.
20. Wood RA, Togias A, Sicherer SH, et al. Omalizumab for the Treatment of Multiple Food Allergies. *N Engl J Med*. 2024;390(10):889-899.
21. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®). Management of Immune Checkpoint-Related Toxicities. Version 1.2025. Available at: www.nccn.org. Accessed March 1, 2025.

Specialty Guideline Management

Zepatier

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zepatier	elbasvir-grazoprevir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Zepatier is indicated for the treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kilograms (kg).

Zepatier is indicated for use with ribavirin in certain patient populations.

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh class B or C). Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin^{1,2}

Genotype 1a infection

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix) who are treatment-naïve or who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV) without an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir).

Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir).

Genotype 4 infection

Authorization of up to 12 weeks total may be granted for members who are treatment-naïve.

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix) who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

Hepatitis C Virus Infection, in combination with Ribavirin^{1,2}

Genotype 1a infection

Authorization of up to 16 weeks total may be granted for members with baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix) who are treatment-naïve or who failed prior treatment with PEG-IFN and RBV with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Appendix) who failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir, or telaprevir).

Genotype 1b infection

Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

Genotype 4 infection

Authorization of up to 16 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV.

Hepatitis C Virus and Human Immunodeficiency Virus (HIV) Coinfection^{1,2}

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 12 years of age or older or weigh at least 30 kg.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
 - Treatment status (i.e., treatment-naïve or retreatment)
 - For initial treatment: confirmation of member readiness
 - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
 - Hepatitis B virus screening results
 - Metavir/Fibrosis score

Appendix²

NS5A Resistance-Associated Substitutions (Polymorphisms)

NS5A resistance-associated substitutions (polymorphisms) at amino acid positions M28, Q30, L31 or Y93. Examples include M28A/T, Q30H/R, L31M/V, and Y93C/H/N.

References

1. Zepatier [package insert]. Rahway, NJ: Merck & Co., Inc.; May 2022.
2. American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA). Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last updated December 19, 2023. Accessed August 9, 2025.

Specialty Guideline Management

Zeposia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zeposia	ozanimod

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Treatment of moderately to severely active ulcerative colitis (UC) in adults.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Ulcerative colitis (UC)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Ulcerative colitis: gastroenterologist
- Multiple sclerosis: neurologist

Coverage Criteria

Relapsing Forms of Multiple Sclerosis¹

Authorization of 12 months may be granted to members who have been diagnosed with a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse).

Clinically Isolated Syndrome¹

Authorization of 12 months may be granted to members for the treatment of clinically isolated syndrome of multiple sclerosis.

Ulcerative Colitis¹

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Continuation of Therapy

Relapsing Forms of Multiple Sclerosis and Clinically Isolated Syndrome

Authorization of 12 months may be granted when the member is experiencing disease stability or improvement while receiving Zeposia.

Ulcerative Colitis³⁻⁴

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency
- Rectal bleeding
- Urgency of defecation
- C-reactive protein (CRP)
- Fecal calprotectin (FC)
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Other

For all indications: Member cannot use the requested medication concomitantly with immunomodulators, biologic drugs, targeted synthetic drugs, or disease modifying multiple sclerosis agents for the same indication (Note: Ampyra and Nuedexta are not disease modifying).

For multiple sclerosis: authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

References

1. Zeposia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.
2. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106 Suppl 1:S2-S26.

Reference number(s)
3747-A

3. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114:384-413.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158:1450-1461.

Specialty Guideline Management

zoledronic acid-Reclast

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Reclast	zoledronic acid

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment to increase bone mass in men with osteoporosis
- Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
- Treatment of Paget's disease of bone in men and women

Limitations of Use

Optimal duration of use has not been determined. For patients of low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.

Compendial Uses⁹

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Chart notes or medical record documentation indicating a history of fractures, T-score, and Fracture Risk Assessment Tool (FRAX) fracture probability (where applicable)
- Chart notes, medical record documentation, or claims history supporting use of androgen deprivation therapy.

Coverage Criteria

Postmenopausal Osteoporosis, Treatment and Prevention¹⁻⁴

Authorization of 12 months may be granted to postmenopausal members for treatment or prevention of osteoporosis when ANY of the following criteria are met:

- Member has a history of fragility fractures (e.g., low trauma fracture from force similar to a fall from standing position)
- Member has a pre-treatment T-score less than or equal to -2.5
- Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1)

Osteoporosis in Men^{1-3,5}

Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met:

- Member has a history of an osteoporotic vertebral or hip fracture
- Member has a pre-treatment T-score less than or equal to -2.5
- Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)

Glucocorticoid-Induced Osteoporosis^{1,2,6}

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when BOTH of the following criteria are met:

- Member is currently receiving or will be initiating glucocorticoid therapy at an equivalent prednisone dose of greater than or equal to 2.5 mg/day for at least 3 months
- Member meets ANY of the following criteria:
 - Member has a history of a fragility fracture (e.g., low trauma fracture from force similar to a fall from standing position)
 - Member has a pre-treatment T-score of less than or equal to -2.5

- Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (see Appendix)

Paget's Disease of Bone^{1,2,7}

Authorization of 1 month (one dose [5 mg]) may be granted for treatment of Paget's disease of bone.

Prostate Cancer⁹

Authorization of 12 months may be granted for members with prostate cancer for treatment-related bone loss when receiving androgen deprivation therapy (ADT) (e.g., gosarelin, leuprolide, triptorelin).

Continuation of Therapy

Paget's Disease of Bone

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All Other Indications

Authorization of 12 months may be granted for all members (including new members) who are currently receiving the requested medication through a previously authorized pharmacy or medical benefit, who meet either of the following criteria:

- Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
- Member has received 24 months of therapy or more and meets both of the following criteria:
 - Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
 - Member has not experienced any adverse effects

Appendix

Fracture Risk Assessment Tool (FRAX)^{6,8}

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk $\geq$ 20% or hip fracture risk $\geq$ 3%
- 10-year probability; calculation tool available at: <https://frax.shef.ac.uk/FRAX/>
- The estimated risk score generated with FRAX should be multiplied by 1.15 for major osteoporotic fracture (including fractures of the spine [clinical], hip, wrist, or humerus) and 1.2

Reference number(s)
2380-A

for hip fracture if glucocorticoid treatment is greater than 7.5 mg (prednisone equivalent) per day.

References

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
2. Zoledronic acid injection [package insert]. Princeton, NJ: Fosun Pharma USA Inc.; February 2023.
3. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2022;33(10):2049-2102.
4. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2020 update. *Endocr Pract*. 2020;26(Suppl 1):1-46.
5. Watts NB, Adler RA, Bilezikian JP, et al. Osteoporosis in men: an Endocrine Society clinical practice guideline. *J Clin Endocr Metab*. 2012;97(6):1802-1822.
6. Humphrey MB, Russell L, Danila MI, et al. 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis Rheumatol*. 2023;75(12):2088-2102.
7. Singer FR, Bone HG, Hosking DJ, et al. Paget's disease of bone: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99(12):4408-22.
8. FRAX® Fracture Risk Assessment Tool. © Centre for Metabolic Bone Diseases, University of Sheffield, UK. Available at: <https://frax.shef.ac.uk/FRAX/>. Accessed October 8, 2024.
9. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed October 8, 2024.