COUNTYCARE HEALTH PLAN
PRIOR AUTHORIZATION GUIDELINES

Administered by

October 1, 2026

Reference number(s)
1959-A

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 Indications[1-6]

- 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

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- 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.

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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.

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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:

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    - 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 disease[7]

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.

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- 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 disease[7]

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 toxicity[7]

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 disease[7]

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.

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- 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

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- 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)

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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 Methotrexate[22]

- 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[21]

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

References

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Reference number(s)
1378-A

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

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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:

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- 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

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Reference number(s)
5125-A

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 Indications[1]

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:

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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).

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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 Products[3]

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%

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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%

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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%

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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%

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Reference number(s)
1641-A

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 Indications[1]

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.

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Reference number(s)
1641-A

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.

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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

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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

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Reference number(s)
1646-A

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 Uses[6-7]

- PAH (WHO Group I) in pediatric members.

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

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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 m^2 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.

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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)

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- 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

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Reference number(s)
6410-C

Initial Prior Authorization with Quantity Limit Anorexigenic Agents Supplemental Indications Only

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths except Zepbound vials, which are covered under the LillyDirect manufacturer program and Wegovy HD 7.2 mg injection. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Wegovy	semaglutide
Zepbound	tirzepatide

Indications

FDA-approved Indications

Wegovy

Wegovy injection is indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- To reduce excess body weight and maintain weight reduction long term in:
  - Adults and pediatric patients aged 12 years and older with obesity.
  - Adults with overweight in the presence of at least one weight-related comorbid condition.

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- For the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. This indication is approved under accelerated approval based on improvement of MASH and fibrosis. Continued approval for this indication may be contingent upon the verification and description of clinical benefit in a confirmatory trial.

Wegovy tablets are indicated in combination with a reduced calorie diet and increased physical activity:

- To reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
- To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of Use

- Concomitant use of Wegovy (semaglutide) tablets or Wegovy (semaglutide) injection with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

Zepbound

Zepbound is indicated in combination with a reduced-calorie diet and increased physical activity:

- to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition.
- to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity.

Limitations of Use

Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

Coverage Criteria

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis – Wegovy Injection ONLY

Authorization may be granted when the requested drug is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in an adult when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide) injection
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The requested drug is being prescribed by, or in consultation with, a gastroenterologist or hepatologist.

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- The patient's moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following: non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]) OR historical liver biopsy. [ACTION REQUIRED: Documentation is required for approval.]

Obstructive Sleep Apnea – Zepbound ONLY

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has a current body mass index (BMI) greater than or equal to 30 kg/m^2. [ACTION REQUIRED: Documentation is required for approval.]

Risk Reduction of Major Adverse Cardiovascular Events – Wegovy ONLY

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide)
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following: [ACTION REQUIRED: Documentation is required for approval.]
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient has a baseline body mass index (BMI) greater than or equal to 27 kg/m^2. [NOTE: If the patient is transitioning from another drug therapy for weight loss, please consider their baseline BMI at the start of any drug therapy.] [ACTION REQUIRED: Documentation is required for approval.]
- The patient does NOT have type 2 diabetes. [NOTE: Ozempic is indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established

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cardiovascular disease. Patients with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]

- The patient is currently receiving guideline-directed management and therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) OR the patient has a clinical reason not to be treated with GDMT for cardiovascular disease. [ACTION REQUIRED: Documentation is required for approval.]

Continuation of Therapy

Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis – Wegovy Injection ONLY

Authorization may be granted when the requested drug is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in an adult when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide) injection.
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in Enhanced Liver Fibrosis [ELF] score, improvement in liver stiffness measurement [LSM] by ultrasound-based elastography, magnetic resonance elastography [MRE]). [ACTION REQUIRED: Documentation is required for approval.]
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

Obstructive Sleep Apnea – Zepbound ONLY

Authorization may be granted when the requested drug is being used to treat moderate to severe obstructive sleep apnea (OSA) in an adult with obesity when ALL of the following criteria are met:

- The request is for Zepbound (tirzepatide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has an established diagnosis of moderate to severe OSA with an apnea-hypopnea index (AHI) of at least 15 events per hour on polysomnography (PSG) or home sleep apnea test (HSAT) with a technically adequate device. [ACTION REQUIRED: Documentation is required for approval.]
- The patient has achieved or maintained a positive response to treatment from baseline, evidenced by a decrease in OSA symptoms.
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

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Risk Reduction of Major Adverse Cardiovascular Events – Wegovy ONLY

Authorization may be granted when the requested drug is being used to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction (MI), or non-fatal stroke) in an adult with established cardiovascular disease AND either obesity or overweight when ALL of the following criteria are met:

- The request is for Wegovy (semaglutide).
- The requested drug is being used with a reduced-calorie diet AND increased physical activity.
- The patient has established cardiovascular disease with a history of ONE of the following: [ACTION REQUIRED: Documentation is required for approval.]
    - Previous MI.
    - Previous stroke.
    - Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease.
    - Prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty).
- The patient is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability.

Quantity Limits Apply

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 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	Dosage	1 Month Limit	3 Months Limit
Wegovy (semaglutide) injection	0.25 mg / 0.5 mL, 0.5 mg / 0.5 mL, 1 mg / 0.5 mL	2 mL (1 package of 4 prefilled single-dose syringes or pens each) / 21 days	6 mL (3 packages of 4 prefilled single-dose syringes or pens each) / 63 days
Wegovy (semaglutide) injection	1.7 mg / 0.75 mL, 2.4 mg / 0.75 mL	3 mL (1 package of 4 prefilled single-dose syringes or pens each) / 21 days	9 mL (3 packages of 4 prefilled single-dose syringes or pens each) / 63 days
Wegovy FlexTouch (semaglutide) injection	2.4 mg / 0.75 mL	3 mL (1 single-patient-use FlexTouch pen) / 21 days	9 mL (3 single-patient-use FlexTouch pens) / 63 days

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Drug	Dosage	1 Month Limit	3 Months Limit
Wegovy (semaglutide) tablet	1.5 mg, 4 mg, 9 mg, 25 mg	30 tablets / 25 days	90 tablets / 75 days
Zepbound (tirzepatide) pre-filled single-dose pens	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	2 mL (4 pre-filled single-dose pens) / 21 days	6 mL (12 pre-filled single-dose pens) / 63 days
Zepbound (tirzepatide) single-patient-use KwikPens	2.5 mg / 0.6 mL, 5 mg / 0.6 mL, 7.5 mg / 0.6 mL, 10 mg / 0.6 mL, 12.5 mg / 0.6 mL, 15 mg / 0.6 mL	2.4 mL (1 single-patient-use KwikPen) / 21 days	7.2 mL (3 single-patient-use KwikPens) / 63 days

Duration of Approval (DOA)

- 6410-C:
  - Wegovy (semaglutide) Injection:
    - Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (MASH): DOA: 12 months
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months
  - Wegovy (semaglutide) Tablet:
    - Risk reduction of major adverse cardiovascular events: DOA: 12 months
  - Zepbound: Initial therapy DOA: 6 months; Continuation of therapy DOA: 12 months

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Reference number(s)
5520-A

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).

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- 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).

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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[6]

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%

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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%

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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%

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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%

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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%

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Reference number(s)
5521-A

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).

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- 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.

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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 Products[8]

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%

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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%

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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%

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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%

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Reference number(s)
1743-A

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).

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- 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).

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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 Products[8]

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

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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%

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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%

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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%

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Reference number(s)
6646-A

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).

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- 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).

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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 Products[7]

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%

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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%

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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%

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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%

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1. Ebglyss [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2024.
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Reference number(s)
6762-A

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).

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- 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).

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- 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%

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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%

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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%

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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%

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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

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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.
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Reference number(s)
5522-A

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).

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- 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, Eblgyss, Nemluvio) or a systemic targeted synthetic drug (e.g., Cibinqo) indicated for the treatment of atopic dermatitis.

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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 products[7]

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%

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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%

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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%

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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

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Reference number(s)
1746-A

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 Indications[1]

- 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.

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- 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.

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Reference number(s)
3881-A

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 Indication[1]

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 sclerosis[1]

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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]

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.

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Reference number(s)
1764-A

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 Indications[1]

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

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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.

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- 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.

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Reference number(s)
6220-A

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 Indications[1]

- 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

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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.

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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.

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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)

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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.

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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 Leflunomide[8]

- 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

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Reference number(s)
2247-A

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

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- 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.

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Reference number(s)
2247-A

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

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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

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- 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.

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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.

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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.

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Reference number(s)
865-C

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.

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Limitations of Use

If Chewtadzy 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.

Chewtadzy 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:

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[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

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Reference number(s)
4517-A

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 Indications[1]

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]

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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) Infection[1-3]

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

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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]

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

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:

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- 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.

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- 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.

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

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

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

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.

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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

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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.

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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:

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- 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.

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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

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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

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Reference number(s)
3481-E

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.

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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,

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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

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Drug	1 Month Limit	3 Month Limit
Qulipta 10 mg, 30 mg, 60 mg (atogepant)	30 tablets / 25 days	90 tablets / 75 days
Ubrelvy 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, Ubrelvy, 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

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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

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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

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Reference number(s)
5142-A

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 Indications[1]

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

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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).

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- 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 Products[6]

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%

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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%

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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

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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%

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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%

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Reference number(s)
2005-A

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 Indication[1]

- 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

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Reference number(s)
2005-A

Compendial Use[25]

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.

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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.

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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 hydroxycholorquine or sulfasalazine.
    - Member has a documented contraindication to hydroxychloroquine (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
    - Member has moderateto 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).

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- 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.

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  - 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).

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Immune Checkpoint Inhibitor-Related Toxicity[25]

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

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- 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:

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- 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 Leflunomide[19]

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

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- 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

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Reference number(s)
1624-A

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.

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Reference number(s)
1624-A

Coverage Criteria

Secondary Hyperparathyroidism with CKD on Dialysis[1]

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 Hyperparathyroidism[1]

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 Carcinoma[1]

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 Dialysis[1]

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).

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Appendix[9]

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

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Reference number(s)
1654-A

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 Indications[1]

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:

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Initial requests

- Chart notes or medical record documentation showing pre-treatment 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.

Prescriber Specialties

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

Coverage Criteria[1-5]

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 beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

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- 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.

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Reference number(s)
1114-A

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)

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- 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

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Reference number(s)
2017-A

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 Indications[1]

- 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.

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Reference number(s)
2017-A

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 enthesis-related arthritis: rheumatologist

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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.

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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

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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:

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- 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.

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Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide[14]

- 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

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Reference number(s)
2562-A

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 Indications[1]

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:

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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.

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    - 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).

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Reference number(s)
1836-A

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).

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Reference number(s)
1836-A

Continuation of Therapy[1-3]

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.

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2. Dalfampridine [package insert]. Raleigh, NC: Accord Healthcare, Inc.; October 2023.
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Reference number(s)
1622-A

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 Indications[1-5]

- 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 Uses[9-11]

Hereditary hemochromatosis

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

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Reference number(s)
1622-A

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.

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Hereditary Hemochromatosis[9-11]

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

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Reference number(s)
1888-E

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit Desvenlafaxine, Fetzima

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
desvenlafaxine (brand unavailable)	desvenlafaxine	extended-release tablets
Fetzima	levomilnacipran	all
Pristiq	desvenlafaxine succinate	extended-release tablets

Indications

FDA-approved Indications

Desvenlafaxine ER

Desvenlafaxine is indicated for the treatment of adults with major depressive disorder (MDD).

Fetzima

Fetzima is indicated for the treatment of major depressive disorder (MDD) in adults.

Limitation of Use: Fetzima is not approved for the management of fibromyalgia. The efficacy and safety of Fetzima for the management of fibromyalgia have not been established.

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Pristiq

Pristiq is indicated for the treatment of adults with major depressive disorder (MDD).

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 a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI), mirtazapine, OR bupropion (except generic for Zyban) 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 Quantity

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

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
Desvenlafaxine (all brand/generic products)	30 tablets / 25 days	90 tablets / 75 days
Fetzima	30 capsules / 25 days	90 capsules / 75 days

Coverage Criteria

Major Depressive Disorder (MDD)

Authorization may be granted when the requested drug is being prescribed for the treatment of an adult patient with major depressive disorder (MDD) when the following criteria is met:

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- The patient has experienced an inadequate treatment response, intolerance or the patient has a contraindication to ANY of the following: a serotonin and norepinephrine reuptake inhibitor (SNRI), a selective serotonin reuptake inhibitor (SSRI), mirtazapine, bupropion.

Quantity Limits Apply

Desvenlafaxine (all brand/generic products): 30 tablets per 25 days, 90 tablets per 75 days

Fetzima: 30 capsules per 25 days, 90 capsules 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)

- 1888-E: DOA: 12 months

References

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Reference number(s)
621-C

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.

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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

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Reference number(s)
1845-A

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

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Relapsing Forms of Multiple Sclerosis[1-3]

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 Syndrome[1-3]

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

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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.

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Reference number(s)
3762-C

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

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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

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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

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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.
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Reference number(s)
1690-A

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 Indications[1]

- 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)

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- 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 Uses[25]

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.

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Reference number(s)
1690-A

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.

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- 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

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- 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:

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- 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 beta$_2$-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 beta$_2$-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:

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  - 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 Nodularis[19-22]

Authorization of 6 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nemluvio) 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)

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- 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 (FEV_1)/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 $beta_2$-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:

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- 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 Pemphigoid[36-38]

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

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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 Nodularis[19-22]

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

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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 FEV_1) 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 Toxicities[25]

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 Pemphigoid[36-38]

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

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Appendix A: Relative Potency of Select Topical Corticosteroid Products[7]

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%

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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%

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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%

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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

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Reference number(s)
6634-A

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 Indication[1]

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

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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).

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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 Products[7]

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%

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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%

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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%

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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%

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Reference number(s)
2003-A

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 Indications[1]

- 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 arthritis[26]
- Reactive arthritis[4]

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- Hidradenitis suppurativa, severe, refractory[4]
- Behcet's disease[4,17]
- Graft versus host disease[4,16,22,23]
- Immune checkpoint inhibitor-related toxicity[22]

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

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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

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- 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).

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- 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

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- 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:

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- 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.

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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 toxicity[22]

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

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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)

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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.

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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 Acitretin[25]

- 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

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- 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

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Reference number(s)
1277-A, 1276-A

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

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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/1.73m^2]), the requested drug will NOT be used in combination with Tekturna (aliskiren).

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Duration of Approval (DOA)

- 1277-A: DOA: 36 months
- 1276-A: DOA: 12 months

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Reference number(s)
2609-A

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 Indications[1]

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 Complex[1]

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.

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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).

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Reference number(s)
1619-A

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 Indications[1-3]

- 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

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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 treatment[4]

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 Surgery[1-3]

Authorization of 8 weeks may be granted for reduction of allogenic 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.

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Anemia Due to Zidovudine in HIV-infected Patients[1-3]

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 Transfusions[5]

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.

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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 Surgery[1-3]

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

Anemia Due to Zidovudine in HIV-infected Patients[1-3]

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 Transfusions[5]

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 Cancer[4]

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.

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Reference number(s)
1565-C

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.

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    - 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

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Reference number(s)
2921-A

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 Indications[1]

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

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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 Therapy[3]

- 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)

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- 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[6]

- High FRAX fracture 10–year probability: Major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 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.

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Reference number(s)
2024-A

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

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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.

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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).

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Reference number(s)
1937-A, 1938-A, 1946-A, 1939-A, 1945-A, 2688-A

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]

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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

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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

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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.

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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
- Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

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Reference number(s)
2413-A

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 Indications[1]

- 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

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- 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

Asthma[1-5]

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)

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- 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

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    - 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.

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Reference number(s)
1841-A

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 Indications[1-4]

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.

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Coverage Criteria

Relapsing Forms of Multiple Sclerosis[1-6]

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 Syndrome[1-6]

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).

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Reference number(s)
1801-A

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 Indications[1]

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.

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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.

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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:

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- 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).

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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)

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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.

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Reference number(s)
2538-A

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-asmn

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]

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:

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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).

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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 Acitretin[5]

- 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

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

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Reference number(s)
4378-A

Specialty Guideline Management
Imcivree

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
Imcivree	setmelanotide

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]

Imcivree is indicated to reduce excess body weight and maintain reduction long term in adults and pediatric patients aged:

- 4 years and older with acquired hypothalamic obesity (HO)
- 2 years and older with Bardet-Biedl syndrome (BBS)
- 2 years and older with pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

Limitations of Use:

Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective:

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- Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign.
- Other types of obesity not related to acquired HO, BBS, or POMC, PCSK1, or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity.

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:

- Acquired Hypothalamic Obesity
  - Initial requests:
    - MRI or CT scan records documenting structural damage, lesions, or tumors in the hypothalamus
    - Medical record (e.g., chart notes) and growth chart (in members less than 18 years of age) documentation of pretreatment BMI and weight
  - Continuation requests (where applicable): Medical record (e.g., chart notes) and growth chart documentation of current BMI and current weight
- Obesity due to POMC, PCSK1, or LEPR deficiency
  - Initial requests:
    - Genetic test results documenting homozygous or compound heterozygous variants in POMC, PCSK1, or LEPR genes
    - Medical record (e.g., chart notes) and growth chart (in members less than 18 years of age) documentation of pretreatment BMI and weight
  - Continuation requests (where applicable): Medical record (e.g., chart notes) and growth chart documentation of current BMI and current weight
- Obesity due to Bardet-Biedl Syndrome (BBS)
  - Initial requests:
    - Chart notes, medical record documentation, or genetic testing confirming a variant in both alleles of one of the core genes associated with Bardet-Biedl syndrome (if applicable)
    - Chart notes or medical record documentation supporting clinical diagnosis
    - Medical record (e.g., chart notes) and growth chart (in members less than 18 years of age) documentation of pretreatment BMI and weight
  - Continuation requests (where applicable): Medical record (e.g., chart notes) and growth chart documentation of current BMI and current weight

Prescriber Specialties

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

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- Obesity due to POMC, PCSK1, or LEPR deficiency and BBS: an endocrinologist, a geneticist or a prescriber specialized in the treatment of metabolic disorders
- Acquired Hypothalamic Obesity: an endocrinologist or a prescriber specialized in the treatment of metabolic disorders

Exclusion Criteria

Acquired Hypothalamic Obesity[1]

- Diagnosis of Prader-Willi syndrome (PWS) or Rapid-onset obesity with hypoventilation, hypothalamic, autonomic dysregulation, neuroendocrine tumor syndrome (ROHHADNET).

Coverage Criteria

Acquired Hypothalamic Obesity [1,7]

Authorization of 12 months may be granted to reduce excess body weight and maintain weight reduction long term for members 4 years of age or older with acquired hypothalamic obesity (HO) when all of the following criteria are met:

- Member has documented diagnosis of acquired HO defined as both of the following:
  - The member has experienced a traumatic or disease-related (e.g., oncological) injury to the hypothalamus detectable on MRI or CT scan.
  - Member has had a rapid, clinically significant increase in BMI (more than or equal to 5% BMI increase in adults and more than or equal to 1.0 BMI standard deviation [SDS] increase in pediatric patients) that began within the first 12 months after the onset of hypothalamic damage.
- The member has obesity defined as one of the following:
  - BMI greater than or equal to 30 kg/m^2 in members 18 years of age or older
  - BMI greater than or equal to equal to 95th percentile for age on growth chart assessment in members less than 18 years of age

Obesity due to POMC, PCSK1, or LEPR Deficiency[1,2,4,6]

Authorization of 6 months may be granted to reduce excess body weight and maintain weight reduction long term for members with obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency when all of the following criteria are met:

- Diagnosis is confirmed by genetic testing demonstrating homozygous or compound heterozygous variants in POMC, PCSK1, or LEPR genes

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- POMC, PCSK1, or LEPR gene variants are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
- The member is 2 years of age or older
- The member has obesity defined as one of the following:
    - BMI greater than or equal to 30 kg/m^2 in members 18 years of age or older
    - BMI greater than or equal to 95th percentile for age on growth chart assessment in members less than 18 years of age

Obesity due to Bardet-Biedl Syndrome[1-6]

Authorization of 12 months may be granted to reduce excess body weight and maintain weight reduction long term for members with obesity due to Bardet-Biedl syndrome (BBS) when all of the following criteria are met:

- The member has a diagnosis of BBS defined as one of the following:
    - Member has 4 primary features of the Beales criteria (see Appendix)
    - Member has 3 primary and 2 secondary features of the Beales criteria (see Appendix)
    - Member has had genetic testing confirming a variant in both alleles of one of the core genes associated with Bardet-Biedl syndrome (e.g., BBS1, BBS2, ARL6) and 1 primary feature of the Beales criteria (see Appendix)
- The member is 2 years of age or older
- The member has obesity defined as one of the following:
    - BMI greater than or equal to 30 kg/m^2 in members 18 years of age or older
    - BMI greater than or equal to 95th percentile for age on growth chart assessment in members less than 18 years of age

Continuation of Therapy

Acquired Hypothalamic Obesity

- Authorization of up to 12 months may be granted for continued treatment in members requesting reauthorization when the member has received less than 12 months of therapy.
- Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member has received 12 months of therapy or more and the member has had a reduction in BMI of at least 5% from baseline or has achieved or sustained clinically meaningful weight loss.

Obesity due to POMC, PCSK1, or LEPR Deficiency

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when one of the following is met:

- The member has received less than 12 months of therapy and one of the following is met:

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    - Member has lost at least 5% of baseline body weight
    - Member is less than 18 years of age and has had a reduction in BMI of at least 5% from baseline
- Member has received 12 months of therapy or more and has achieved or sustained clinically meaningful weight loss
- The member is 2 years of age or older.

Obesity due to Bardet-Biedl Syndrome

- Authorization of up to 12 months may be granted for continued treatment in members requesting reauthorization when the member has received less than 12 months of therapy.
- Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when the member has received 12 months of therapy or more and one of the following is met:
    - Member has lost at least 5% of baseline body weight
    - Member is less than 18 years of age and has had a reduction in BMI of at least 5% from baseline
- The member is 2 years of age or older.

Appendix[3]

Beales Diagnostic Criteria

Primary features

- Rod-cone dystrophy
- Polydactyly
- Obesity
- Learning disability
- Hypogonadism in males
- Renal abnormalities

Secondary features

- Speech disorder/delay
- Strabismus/cataracts/astigmatism
- Brachydactyly/syndactyly
- Developmental delay
- Polyuria/polydipsia (nephrogenic diabetes insipidus)
- Ataxia/poor coordination/imbalance
- Mild spasticity (especially lower limbs)
- Diabetes mellitus
- Dental crowding/hypodontia/small roots/high arched palate
- Left ventricular hypertrophy/congenital heart disease

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- Hepatic fibrosis

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Reference number(s)
2182-A

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 Indications[1-6]

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

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- 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 spondyloarthritis[7]
- Behcet's disease[8,32]
- Hidradenitis suppurativa[8]
- Pyoderma gangrenosum[8,33]
- Sarcoidosis[8]
- Takayasu's arteritis[8]
- Uveitis[8]
- Reactive arthritis[31]
- Immune checkpoint inhibitor-related toxicity[27]
- Acute graft versus host disease[27]
- Moderate to severe plaque psoriasis[22]

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.

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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)

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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.

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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.

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    - 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:

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  - 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.

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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]

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Authorization of 12 months may be granted for members who have previous 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]

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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)

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- 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

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- 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

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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.

Other[1-6]

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.

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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 Leflunomide[35]

- 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.

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Reference number(s)
1750-A

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 Indications[1]

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.

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

Coverage Criteria

Tardive dyskinesia[1-3]

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

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Reference number(s)
1177-C

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.

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Reference number(s)
1177-C

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).

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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

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2. Dayvigo [package insert]. Nutley, NJ: Eisai Inc.; December 2023.
3. Quviviq [package insert]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; September 2024.
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5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/26/2024).
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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.

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Reference number(s)
118-A

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.

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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 – severe[8]

Cutaneous T-Cell Lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome)[6]

Keratosis follicularis (Darier Disease) – severe[8]

Keratosis Palmaris et Plantaris - severe[6]

Lamellar ichthyosis – severe skin involvement[6]

Neuroblastoma[8]

Pityriasis rubra pilaris[6]

Rosacea – severe refractory[8]

Squamous Cell Cancers – to reduce the development of precancers and skin cancers in high risk patients[8]

Transient acantholytic dermatosis (Grover's Disease) – severe[8]

Coverage Criteria

Acne Vulgaris, Rosacea

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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

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2. Accutane [package insert]. Scottsdale, AZ: JG Pharma Inc.; September 2022.
3. Amnesteem [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2024.
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5. Zenatane [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; September 2022.
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7. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed July 15, 2025.
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Reference number(s)
280-A

Initial Prior Authorization
Sporanox Oral Capsules

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
Sporanox	itraconazole	oral capsules

Indications

FDA-approved Indications

Sporanox (itraconazole) Capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Specimens for fungal cultures and other relevant laboratory studies (wet mount, histopathology, serology) should be obtained before therapy to isolate and identify causative organisms. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, antiinfective therapy should be adjusted accordingly.

Sporanox Capsules are also indicated for the treatment of the following fungal infections in non-immunocompromised patients:

- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium), and
- Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

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Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.

Compendial Uses

Coccidioidomycosis[2,3]

Coccidioidomycosis prophylaxis in HIV infection[2,3]

Cryptococcosis[2,3]

Histoplasmosis prophylaxis in HIV infection[2,3]

Invasive fungal infection prophylaxis in liver transplant patients[3]

Invasive fungal infection prophylaxis in patients with hematologic malignancies[3]

Invasive fungal infection prophylaxis in patients with chronic granulomatous disease[3]

Microsporidiosis[2]

Talaromycosis (formerly Penicilliosis)[2,3,8]

Pityriasis versicolor/Tinea versicolor[3]

Sporotrichosis[2,3]

Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis[3]

Primary Therapy for Allergic Bronchopulmonary Aspergillosis, in combination with systemic corticosteroids[2,3,4]

Primary Therapy for Chronic Cavitary Pulmonary Aspergillosis[2,3,4]

Coverage Criteria

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The requested drug is NOT being used in a footbath
- The patient meets ONE of the following:
    - The requested drug is being prescribed for ONE of the following:
        - Pityriasis versicolor
        - Tinea versicolor
        - Onychomycosis due to dermatophytes (Tinea unguium) confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
        - Histoplasmosis prophylaxis in HIV infection
        - Coccidioidomycosis prophylaxis in HIV infection
        - Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease
        - Primary therapy for chronic cavitary pulmonary aspergillosis

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- Blastomycosis
- Histoplasmosis
- Primary therapy for allergic bronchopulmonary aspergillosis, in combination with systemic corticosteroids
- Aspergillosis in a patient intolerant of or refractory to amphotericin B therapy
- Coccidioidomycosis
- Cryptococcosis
- Sporotrichosis
- Talaromycosis (formerly Penicilliosis)
- Microsporidiosis
- Invasive fungal infection prophylaxis in a liver transplant patient
- Invasive fungal infection prophylaxis in a patient with a hematologic malignancy

- The requested drug is being prescribed for ONE of the following: Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis and the following criteria is met:
  - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following: fluconazole, griseofulvin, terbinafine

Duration of Approval (DOA)

- 280-A:
  - Pityriasis versicolor, Tinea versicolor, Onychomycosis due to dermatophytes (Tinea unguium), Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis: DOA: 3 months
  - Blastomycosis, Primary therapy for allergic bronchopulmonary aspergillosis, Aspergillosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Talaromycosis (formerly Penicilliosis), Microsporidiosis, Invasive fungal infection prophylaxis in a liver transplant patient, Invasive fungal infection prophylaxis in a patient with a hematologic malignancy: DOA: 6 months
  - Histoplasmosis, Histoplasmosis prophylaxis in HIV infection, Coccidioidomycosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease, Primary therapy for chronic cavitary pulmonary aspergillosis: DOA: 12 months

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Reference number(s)
1286-A

Initial Prior Authorization
Itraconazole (Sporanox Oral Solution)

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
Sporanox	itraconazole	oral solution

Indications

FDA-Approved Indications

Sporanox (itraconazole) Oral Solution is indicated for the treatment of oropharyngeal and esophageal candidiasis.

Compendial Uses

Blastomycosis[3,4]

Histoplasmosis[3,4]

Aspergillosis in a patient intolerant of or refractory to amphotericin B therapy [1,3,4]

Coccidioidomycosis[3,4]

Coccidioidomycosis prophylaxis in HIV infection[3,4]

Cryptococcosis[3,4]

Histoplasmosis prophylaxis in HIV infection[3,4]

Invasive fungal infection prophylaxis in liver transplant patients[4]

Invasive fungal infection prophylaxis in a patient with hematologic malignancies[4]

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Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease[4]

Microsporidiosis[3]

Onychomycosis[3]

Talaromycosis (formerly Penicilliosis)[3,4,10]

Pityriasis versicolor/Tinea versicolor[4]

Sporotrichosis[3,4]

Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis[4]

Primary Therapy for Allergic Bronchopulmonary Aspergillosis, in combination with systemic corticosteroids[3,4,6]

Primary Therapy for Chronic Cavitary Pulmonary Aspergillosis[3,4,6]

Coverage Criteria

Authorization may be granted for the requested drug when NOT being used in a footbath and ONE of the following criteria is met:

- The requested drug is being prescribed for the treatment of oropharyngeal candidiasis or esophageal candidiasis and the following criteria is met:
    - The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to fluconazole
- The patient is unable to take itraconazole capsules due to ONE of the following: inability to swallow itraconazole capsules, inability to achieve therapeutic levels with itraconazole capsules and ONE of the following criteria is met:
    - The requested drug is being prescribed for ONE of the following:
        - Pityriasis versicolor
        - Tinea versicolor
        - Onychomycosis due to dermatophytes (Tinea unguium) confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy)
        - Histoplasmosis prophylaxis in HIV infection
        - Coccidioidomycosis prophylaxis in HIV infection
        - Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease
        - Primary therapy for chronic cavitary pulmonary aspergillosis
        - Blastomycosis
        - Histoplasmosis
        - Primary therapy for allergic bronchopulmonary aspergillosis, in combination with systemic corticosteroids
        - Aspergillosis in a patient intolerant of or refractory to amphotericin B therapy

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- Coccidioidomycosis
- Cryptococcosis
- Sporotrichosis
- Talaromycosis (formerly Penicilliosis)
- Microsporidiosis
- Invasive fungal infection prophylaxis in a liver transplant patient
- Invasive fungal infection prophylaxis in a patient with a hematologic malignancy

- The requested drug is being prescribed for ONE of the following: Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis and the following criteria is met:
  - The patient experienced an inadequate treatment response, intolerance, or has a contraindication to ONE of the following: fluconazole, griseofulvin, terbinafine

Duration of Approval (DOA)

- 1286-A:
  - Pityriasis versicolor, Tinea versicolor, Onychomycosis due to dermatophytes (Tinea unguium), Tinea corporis, Tinea cruris, Tinea capitis, Tinea manuum, Tinea pedis: DOA: 3 months
  - Oropharyngeal candidiasis, Esophageal candidiasis, Blastomycosis, Primary therapy for allergic bronchopulmonary aspergillosis, Aspergillosis, Coccidioidomycosis, Cryptococcosis, Sporotrichosis, Talaromycosis (formerly Penicilliosis), Microsporidiosis, Invasive fungal infection prophylaxis in a liver transplant patient, Invasive fungal infection prophylaxis in a patient with a hematologic malignancy: DOA: 6 months
  - Histoplasmosis, Histoplasmosis prophylaxis in HIV infection, Coccidioidomycosis prophylaxis in HIV infection, Invasive fungal infection prophylaxis in a patient with chronic granulomatous disease, Primary therapy for chronic cavitary pulmonary aspergillosis: DOA: 12 months

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Reference number(s)
2845-A

Initial Prior Authorization
Tolsura

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
Tolsura	itraconazole

Indications

FDA-Approved Indications

Tolsura is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

Specimens for fungal cultures and other relevant laboratory studies (wet mount, histopathology, serology) should be obtained before therapy to isolate and identify causative organisms. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-fungal therapy should be adjusted accordingly.

Limitations of Use:

Tolsura is not indicated for the treatment of onychomycosis.

Tolsura is NOT interchangeable or substitutable with other itraconazole products due to the differences in the dosing between Tolsura and other itraconazole products. Therefore, follow the specific dosage recommendations for Tolsura.

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Reference number(s)
2845-A

Coverage Criteria

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

- The requested drug is being prescribed for the treatment of blastomycosis.
- The requested drug is being prescribed for the treatment of histoplasmosis.
- The requested drug is being prescribed for the treatment of aspergillosis in a patient intolerant of or refractory to amphotericin B therapy.

Duration of Approval (DOA)

- 2845-A: DOA: 6 months

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Reference number(s)
2042-A

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

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- 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

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- 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])

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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)

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- 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

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- 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)

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        - 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.

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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.

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- 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.

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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.

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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

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  - 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 $\geq 200/mm^3$
- Adult members with significant bleeding, platelet count < 20,000/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 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

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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).

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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

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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)

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Reference number(s)
4871-A

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) ≥ 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:

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- 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) ≥ 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

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Reference number(s)
4129-A

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 Indication[1]

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.

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Coverage Criteria

Relapsing forms of multiple sclerosis[1]

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]

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

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Reference number(s)
1957-A

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 Indications[1]

- 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 Uses[13]

- Immune checkpoint inhibitor-related toxicity - inflammatory arthritis
- Giant cell arteritis (GCA)

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

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Reference number(s)
1957-A

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.

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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.

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- 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).

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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 toxicity[13]

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])

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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

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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 Leflunomide[10]

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

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- 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

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Reference number(s)
1802-A

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 Indications[1]

- 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 disease[6]
- Recurrent pericarditis (RP)[16]
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)[17-19]
- Schnitzler syndrome[2,20,21]

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- Gout and pseudogout (calcium pyrophosphate deposition)[2,25-27]
- Chimeric antigen receptor (CAR) T-cell-related toxicities[6]
- Erdheim-Chester Disease[6]
- Immune checkpoint inhibitor-related toxicity—immunotherapy-related hemophagocytic lymphohistiocytosis (HLH)-like syndrome[6]

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.

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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

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- 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,

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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.

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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 Disease[6]

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.

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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 Flares[25-38]

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 Toxicities[6]

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 Disease[6]

Authorization of 12 months may be granted for the treatment of Erdheim-Chester disease.

Immune Checkpoint Inhibitor-Related Toxicity[6]

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.

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- 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])

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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.

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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 Leflunomide[36]

- 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

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Reference number(s)
Policy: 2134-A
Qsets: 5920-A, 6284-A

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

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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[1-5]

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-naive 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).

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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 Ribavirin[1-5]

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

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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

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Reference number(s)
1971-A, 6047-A

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 Indications[1-3]

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 cancer[4]
- Ovarian cancer - Malignant sex cord-stromal tumors (7.5 mg and 22.5 mg)[4]

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- 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 Specialties[9]

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 Cancer[1-4]

Authorization of 12 months may be granted for treatment of prostate cancer.

Gender Dysphoria[5-7]

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.

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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 Cancer[10]

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 Dysphoria[9]

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:

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- 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.

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Reference number(s)
1989-A, 1990-A, 2117-A

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 Indications[1]

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 CPP[3-6]
- Use in combination with growth hormone for children with growth failure and advancing puberty[8-12]
- Prostate cancer[13]
- 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 cycle[16]

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

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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 Failure[8-12]

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).

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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.

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Reference number(s)
3517-C

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.

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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).

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Reference number(s)
1331-C

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

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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).

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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, electrodessication 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

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- 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, electrodessication 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 criteira 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.

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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.

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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.

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Reference number(s)
1330-J

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

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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).

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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, electrodessication 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

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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, electrodessication 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 criteira 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.

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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.

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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.

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Reference number(s)
843-A, 1023-A

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.

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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).

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Reference number(s)
1970-A, 6049-A

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.

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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 cancer[3]
- 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 Sarcoma[3]

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.

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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 Cancer[3]

Authorization of 12 months may be granted for treatment of hormone receptor-positive breast cancer.

Ovarian Cancer[3]

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.

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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 Sarcoma[3]

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:

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- 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 Sarcoma[3]

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.

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Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

References

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Reference number(s)
1972-A, 6051-A

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 Indication[1]

Lupron Depot-PED is indicated for the treatment of pediatric patients with central precocious puberty (CPP).

Compendial Uses[7-9]

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

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releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.

Prescriber Specialties[12]

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 Dysphoria[7-9]

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.

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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 Dysphoria[11]

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.

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- 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.

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Reference number(s)
Policy: 2242-A
Qsets: 5920-A, 6284-A

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 Indications[1]

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).

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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-naive 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-naive 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

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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-naive 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-naive 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

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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 determined[2]

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:

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- 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 Ribavirin[2]

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.

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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.

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Reference number(s)
2973-A

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 Indication[1]

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.

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Reference number(s)
2973-A

Coverage Criteria

Relapsing forms of multiple sclerosis[1]

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]

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.

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Reference number(s)
2160-A

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.

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Reference number(s)
2160-A

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/Disease[1-4]

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/Disease[1-4]

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

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Reference number(s)
4752-A

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.

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Reference number(s)
4752-A

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

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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.

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Reference number(s)
3102-C

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:

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- 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).

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Reference number(s)
6592-A

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:

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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).

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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

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- 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%

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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%

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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%

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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%

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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%

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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

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Reference number(s)
1931-A

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.

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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.

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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.

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- 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.

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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

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- 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)

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- 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

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- 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

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- Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
- Persistent neutropenia

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Reference number(s)
3648-D

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:

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- 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.

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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

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Reference number(s)
1655-A

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 Indications[1]

- 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

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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, 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 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-PDGFRA fusion gene test results.
- Chart notes or medical record showing pretreatment blood eosinophil count.

Continuation requests

- FIP1L1-PDGFRA fusion gene test results.
- Chart notes or medical record documentation supporting improvement in HES control.

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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-PDGFRA kinase-positive HES.

Prescriber Specialties

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

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- 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:

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- 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:

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- 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 (FEV_1)/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:

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  - 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 beta$_2$-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.

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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 FEV_1) 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.

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Reference number(s)
1707-A

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.

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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

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Reference number(s)
1882-A

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 Indications[1]

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):

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- 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).

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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

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Reference number(s)
2597-A

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 Indications[1]

- 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.

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Reference number(s)
2597-A

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.

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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.

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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.

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Reference number(s)
2219-M

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

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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

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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-

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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.

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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).

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- 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.

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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.

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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

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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.

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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.

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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

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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

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	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)

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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

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				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)

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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)

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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)

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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)

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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)

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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

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				(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

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(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

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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)

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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

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3. ConZip [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC.; December 2023.
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Reference number(s)
5556-C

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

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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.

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Reference number(s)
5556-C

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

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Reference number(s)
288-C

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.

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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:

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- 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.
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Reference number(s)
3960-A

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)

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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

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Reference number(s)
3134-A

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.

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Reference number(s)
3134-A

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.
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Reference number(s)
Policy: 2139-A
Qsets: 5920-A, 6284-A

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.

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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:

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- Member is a liver transplant recipient.
- Member has had an inadequate response, intolerance, or contraindication to ribavirin.

Myeloproliferative Neoplasms[2]

Authorization of 12 months may be granted for treatment of myeloproliferative neoplasms (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis).

Systemic Mastocytosis[2]

Authorization of 12 months may be granted for treatment of systemic mastocytosis.

Adult T-Cell Leukemia/Lymphoma[2]

Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.

Mycosis Fungoides/Sezary Syndrome[2]

Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders[2]

Authorization of 12 months may be granted for treatment of primary cutaneous CD30+ T-cell lymphoproliferative disorders.

Hairy Cell Leukemia[2]

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

Erdheim-Chester Disease[2]

Authorization of 12 months may be granted for treatment of Erdheim-Chester disease.

Chronic Myeloid Leukemia[2]

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

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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.

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Reference number(s)
4631-A

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 Indication[1]

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

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Relapsing forms of multiple sclerosis[1]

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]

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

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Reference number(s)
2026-A

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 Indications[1-6]

- 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.

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- 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 Uses[7]

- 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.

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Reference number(s)
2026-A

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)

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- 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 Therapy[1-6]

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)

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- 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[13-15]

- High FRAX fracture probability: 10-year major osteoporosis-related fracture risk ≥ 20% or hip fracture risk ≥ 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

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Reference number(s)
1928-A

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.

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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

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- 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 $30x10^9$/L
  - $30x10^9$/L to $50x10^9$/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.

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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 $50x10^9$/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 $50x10^9$/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 $50x10^9$/L to $200x10^9$/L.
- Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/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 $50x10^9$/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 $50x10^9$/L who are transfusion-independent.
- Authorization of 12 months may be granted to members with current platelet count of $50x10^9$/L to $200x10^9$/L.

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- Authorization of 12 months may be granted to members with current platelet count greater than $200x10^9$/L to less than or equal to $400x10^9$/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

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Reference number(s)
4179-A

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

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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
Otulfi	ustekinumab-aauz
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-aauz (unbranded Otulfi)	ustekinumab-aauz
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,

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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.

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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 of 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).

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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 ≤ 3% body surface area (BSA)
- Member has a ≥ 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.

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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%

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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%

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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%

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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 Acitretin[57]

- 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

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Reference number(s)
2018-A

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 Indications[1]

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.

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Limitations of use

Rasuvo is not indicated for the treatment of neoplastic diseases.

Compendial Use

Microscopic polyangiitis[6]

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 Criteria[2-6]

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.

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Reference number(s)
3373-E

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

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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.]

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- 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

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Reference number(s)
7242-C

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.

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- 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

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Reference number(s)
1987-D

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

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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.

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- 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).

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        - 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

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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 Leflunomide[47]

- 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

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Reference number(s)
3173-A

Specialty Guideline Management
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

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]

- Adults 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
- Adults and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to one or more TNF blockers
- Adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable
- Adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq.
- Adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers

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- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy
- Adults with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers. If TNF blockers are clinically inadvisable, patients should have received at least one approved systemic therapy prior to use of Rinvoq.
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers
- Adults with 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 (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and 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. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Giant cell arteritis (GCA)

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Atopic dermatitis

Initial requests

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

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Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Ulcerative colitis (UC) and Crohn's disease (CD)

Initial requests

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 to therapy or remission.

Prescriber Specialties

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

- Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, polyarticular juvenile idiopathic arthritis, and giant cell arteritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Atopic dermatitis: dermatologist or allergist/immunologist
- Ulcerative colitis and Crohn's disease: gastroenterologist

Coverage Criteria

Rheumatoid arthritis (RA)[1-3,5,6]

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active rheumatoid arthritis (RA) when the member has had an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor.

Psoriatic arthritis (PsA)[1,7,14,16]

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active psoriatic arthritis when the member has had an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor.

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Atopic dermatitis[1,8-9,17,21,24-25]

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:
        - A medium potency to super-high potency topical corticosteroid (see Appendix)
        - A topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)
        - A topical Janus kinase (JAK) inhibitor (e.g., Opzelura)
        - A topical phosphodiesterase-4 (PDE-4) inhibitor (e.g., Eucrisa, Zoryve)
        - A topical aryl hydrocarbon receptor agonist (e.g., Vtama)
    - The use of medium potency to super-high potency topical corticosteroid, topical calcineurin inhibitor, topical JAK inhibitor, topical PDE-4 inhibitor, and topical aryl hydrocarbon receptor agonist are not advisable for the member (e.g., due to contraindications, prior intolerances).
- Member has had an inadequate response, intolerance, or contraindication to treatment with other systemic drug products, including biologics, indicated for the treatment of atopic dermatitis in the past 12 months.

Ulcerative colitis (UC)[1]

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. If TNF inhibitors are clinically inadvisable, the member should have received at least one approved systemic therapy prior to use of the requested medication.

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1,13,15]

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 had an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor.

Crohn's disease (CD)[1]

Authorization of 12 months may be granted for treatment of moderately to severely active CD when the member has had an inadequate response or intolerance to at least one TNF inhibitor. If TNF inhibitors are clinically inadvisable, the member should have received at least one approved systemic therapy prior to use of the requested medication.

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Polyarticular juvenile idiopathic arthritis (pJIA)[1]

Authorization of 12 months may be granted for members 2 years of age or older for treatment of active polyarticular juvenile idiopathic arthritis when the member has had an inadequate response, intolerance, or has a contraindication to at least one TNF inhibitor.

Giant cell arteritis (GCA)[1]

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])

Continuation of Therapy

Rheumatoid arthritis (RA)[1,3,5,6]

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[1,7,16]

Authorization of 12 months may be granted for 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)

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Atopic dermatitis[1,8]

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).

Ulcerative colitis (UC)[1,10-12]

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)

Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)[1,13,15]

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)

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Crohn's disease (CD)[1,18,19]

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)

Polyarticular juvenile idiopathic arthritis (pJIA)[1,20]

Authorization of 12 months may be granted for members 2 years of age or older (including new members) 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

Giant cell arteritis (GCA)[1,23]

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)

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- Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
- Limb claudication
- Acute-phase reactants (i.e., erythrocyte sedimentation rate [ESR] or serum C-reactive protein [CRP])

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 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.

Appendix

Table. Relative Potency of Select Topical Corticosteroid Products[17]

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 Aerosol, Spray Aerosol, Solution (scalp)	0.05%

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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, Solution	0.1%
II. High potency (group 2)	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream	0.1%
III. High potency (group 3)	Betamethasone dipropionate	Cream	0.05%
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%

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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)	Fluticasone propionate	Cream	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, Paste (mouth/throat), Ointment	0.1%
IV. Medium potency (group 4)	Triamcinolone acetonide	Ointment	0.05%

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Potency	Drug	Dosage form	Strength
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	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%

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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, Lotion, Solution	2.5%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Gel, Lotion	2%
VII. Least potent (group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Liquid, Lotion, 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, Ointment	1%

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Reference number(s)
2099-A

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 Indications[1]

- 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)

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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 Uses[2]

- 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.

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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 Lymphoma[2]

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 Lymphoma[2]

Authorization of 12 months may be granted for treatment of CD20 positive Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma.

Hodgkin Lymphoma, Nodular Lymphocyte-Predominant[2]

Authorization of 12 months may be granted for treatment of CD20 positive Hodgkin lymphoma, nodular lymphocyte-predominant.

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Reference number(s)
2099-A

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.

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Reference number(s)
1704-A

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:

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  - 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 Uses[3-8]

- Autoimmune hemolytic anemia[7]
- B-cell acute lymphoblastic leukemia (ALL)[4]
- B-cell lymphomas[4-6]
  - Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas[4]
  - B-cell lymphoblastic lymphoma[5,6]
  - Burkitt lymphoma[4]
  - Castleman's disease[4]
  - Diffuse Large B-Cell lymphoma[4]
  - Follicular lymphoma[4]
  - 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 lymphoma[4]
  - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements[4]
  - Mantle cell lymphoma[4]
  - Marginal zone lymphomas[4]

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    - 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 Lymphomas[4]
  - Primary Mediastinal Large B-Cell Lymphoma[4]
- Central nervous system (CNS) cancers[4]
  - Leptomeningeal metastases from lymphomas
  - Primary CNS lymphomas
- Chronic graft-versus-host disease (GVHD)[4]
- CLL/Small lymphocytic lymphoma (SLL)[4]
- Hairy cell leukemia[4]
- Rosai-Dorfman disease[4]
- Hodgkin's lymphoma, nodular lymphocyte-predominant[4]
- Immune checkpoint inhibitor-related toxicities[4]
- Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients[8]
- Primary cutaneous B-cell lymphoma[4]
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)[7]
- Thrombotic thrombocytopenic purpura[7]
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/ Bing-Neel syndrome[4]
- Allogeneic transplant conditioning[4]
- 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:

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  - 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 Toxicities[4]

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

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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.

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Reference number(s)
1651-A

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 Indications[1-4]

- 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.

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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 m^2 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

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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

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- 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

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Reference number(s)
2015-A

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 Indications[1]

- 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 arthritis[15]
- Immune checkpoint inhibitor-related toxicities - inflammatory arthritis[17]

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

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Reference number(s)
2015-A

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.

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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.

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  - 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).

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    - 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

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Immune Checkpoint Inhibitor-Related Toxicity[17]

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

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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.

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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 Leflunomide[18]

- 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[16]

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

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Reference number(s)
2014-A

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 Indications[1]

- 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 dependance 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 spondyloarthritis[2]
- Immune checkpoint inhibitor-related toxicities - inflammatory arthritis[21]

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

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Reference number(s)
2014-A

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:

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- 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:

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        - 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.

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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 Toxicity[21]

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.

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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

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- 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 Leflunomide[20]

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease

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- 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

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Reference number(s)
4908-A

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 Indications[1]

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

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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) Deficiency[1-6]

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

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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

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- 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

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Reference number(s)
Policy: 2137-A
Qsets: 5920-A, 6284-A

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.

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Coverage Criteria

Hepatitis C Virus Infection, without Ribavirin[1-5]

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.

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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

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- 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

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Reference number(s)
5600-A

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 Indications[1]

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).

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- 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:

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- 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 Acitretin[4]

- 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

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Reference number(s)
Policy: 2141-A
Qsets: 5920-A, 6284-A

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 Indications[1]

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 Uses[2]

Hepatitis C virus genotype 5 or 6 infection (refer to Mavyret SGM)

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

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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 Ribavirin[1]

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 Ribavirin[1]

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

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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) Ineligiblity[2]

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

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- A baseline hemoglobin < 10 g/dL
- History of pre-existing cardiac disease

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Reference number(s)
1539-D

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.

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Reference number(s)
2889-A

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 Indications[1]

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.

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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 behavior[1-4]

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:

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- 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 serotoninergic 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.

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        - 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.

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Reference number(s)
1640-A

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 Indications[1-4]

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 Uses[5]

Secondary Raynaud's phenomenon

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

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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 m^2 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

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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)

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- 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

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Reference number(s)
1808-A

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

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Relapsing Forms of Multiple Sclerosis[1-3]

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 Syndrome[1-3]

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

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Reference number(s)
2028-A

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 Indications[1-5]

- 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.

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Reference number(s)
2028-A

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:

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- 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 Therapy[1-5]

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 Therapy[8]

- 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)

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- 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 ≥ 20% or hip fracture risk ≥ 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

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Reference number(s)
976-A

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.

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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

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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

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Reference number(s)
976-A

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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.
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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.

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Reference number(s)
3060-A

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.

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- 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:

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- 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.
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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.

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Reference number(s)
1368-A

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

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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 a 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)

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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.

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- 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

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"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

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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.
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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.
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Reference number(s)
1370-A

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.

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- 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.

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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

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6. Testosterone Topical Solution [package insert]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; December 2023.
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9. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/03/2025).
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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.

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Reference number(s)
5104-A

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 Indications[1]

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:

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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 Criteria[1-4]

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.

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- 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

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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.

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Reference number(s)
1846-A

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.

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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.

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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).

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Reference number(s)
1846-A

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.

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Reference number(s)
1650-A

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.

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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 m^2 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.

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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)

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- 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

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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
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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

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Reference number(s)
5156-A

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 Indications[1]

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.

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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.

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Reference number(s)
4446-A

Initial Prior Authorization
Verquvo

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
Verquvo	vericiguat

Indications

FDA-approved Indications

Verquvo is indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

Coverage Criteria

Chronic Heart Failure

Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death and heart failure (HF) hospitalization in an adult patient with symptomatic chronic heart failure when ALL of the following criteria are met:

- The patient has a left ventricular ejection fraction (LVEF) less than 45 percent. [ACTION REQUIRED: Documentation is required for approval.]
- The patient is currently receiving optimal therapy for heart failure management (e.g., angiotensin-converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB],

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angiotensin receptor-neprilysin inhibitor [ARNI], beta-blocker, sodium-glucose co-transporter-2 inhibitor [SGLT2I], mineralocorticoid receptor antagonist [MRA]).
- The patient has had ANY of the following:
  - Hospitalization for heart failure within the past 6 months.
  - Use of outpatient intravenous (IV) diuretics for heart failure within the past 3 months.

Continuation of Therapy

Chronic Heart Failure

Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death and heart failure (HF) hospitalization in an adult patient with symptomatic chronic heart failure when ALL of the following criteria are met:

- The patient has a left ventricular ejection fraction (LVEF) less than 45 percent. [ACTION REQUIRED: Documentation is required for approval.]
- The patient is currently receiving optimal therapy for heart failure management (e.g., angiotensin-converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB], angiotensin receptor-neprilysin inhibitor [ARNI], beta-blocker, sodium-glucose co-transporter-2 inhibitor [SGLT2I], mineralocorticoid receptor antagonist [MRA]).

Duration of Approval (DOA)

- 4446-A: DOA: 12 months

References

1. Verquvo [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp.; January 2026.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2026. https://online.lexi.com. Accessed March 31, 2026.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/31/2026).
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.

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Reference number(s)
6249-C

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.

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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.

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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.

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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.
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Reference number(s)
Policy: 2176-A
Qsets: 5920-A, 6284-A

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 Indications[1]

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.

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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).

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Hepatitis C Virus Infection, in combination with Ribavirin[2]

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.

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- 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.

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Reference number(s)
3395-A

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 Indication[1]

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.

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Reference number(s)
3395-A

Coverage Criteria

Relapsing Forms of Multiple Sclerosis[1]

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]

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.

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Reference number(s)
6455-A

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 Indications[1]

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.

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Reference number(s)
6455-A

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.

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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)

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- 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
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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

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Reference number(s)
2011-A

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 Indications[1]

- 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.

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Compendial Uses

- Non-radiographic axial spondyloarthritis[15,16]
- Oligoarticular juvenile idiopathic arthritis[11]
- Immune checkpoint inhibitor-related toxicity[14]

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.

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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.

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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 Toxicity[14]

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.

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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)

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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.

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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.

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Reference number(s)
1656-A

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.

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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 Uses[12]

- 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).

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- 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).

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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.

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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.

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- 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

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    - 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.

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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 Mastocytosis[13]

- 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

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Reference number(s)
Policy: 2145-A
Qsets: 5920-A, 6284-A

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 Indications[1]

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.

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Reference number(s)
Policy: 2145-A
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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.

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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

Appendix[2]

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.

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Reference number(s)
3747-A

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 Indications[1]

- 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:

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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 Sclerosis[1]

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]

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

Ulcerative Colitis[1]

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.

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Ulcerative Colitis[3-4]

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.

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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.

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Reference number(s)
2380-A

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 Uses[9]

- For treatment-related bone loss in patients with prostate cancer receiving androgen deprivation therapy (ADT)

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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 Prevention[1-4]

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

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- 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 Cancer[9]

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 ≥ 20% or hip fracture risk ≥ 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

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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.

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