COUNTYCARE HEALTH PLAN
PRIOR AUTHORIZATION GUIDELINES

Administered by

January 1, 2025

Reference number
1959-A

SPECIALTY GUIDELINE MANAGEMENT

ACTEMRA (tocilizumab)
TOFIDENCE (tocilizumab-bavi)
TYENNE (tocilizumab-aazg)

POLICY

I. 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.

A. FDA-Approved Indications
1. 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).
2. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA).
3. Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA).
4. Adult patients with giant cell arteritis (GCA).
5. Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function.
6. 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).
7. 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).

B. Compendial Uses
1. Unicentric Castleman disease
2. Multicentric Castleman disease
3. Oligoarticular juvenile idiopathic arthritis
4. Immune checkpoint inhibitor-related toxicities - inflammatory arthritis
5. Acute graft versus host disease
6. Cytokine release syndrome (other than severe or life-threatening CAR T cell-induced CRS)
7. Polymyalgia rheumatica
8. 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.

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
1. Initial requests:

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

2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Articular juvenile idiopathic arthritis
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Systemic juvenile idiopathic arthritis (sJIA)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

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

E. Giant cell arteritis (GCA): For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

F. Systemic sclerosis-associated interstitial lung disease (SSc-ILD): For initial requests: Result of a chest high-resolution computed tomography (HRCT) study.

G. Polymyalgia rheumatica
1. 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.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis, and polymyalgia rheumatica: rheumatologist
B. Systemic sclerosis-associated interstitial lung disease: rheumatologist or pulmonologist
C. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist
D. Cytokine release syndrome, unicentric Castleman disease, multicentric Castleman disease, and acute graft versus host disease: oncologist or hematologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. 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:
   i. Member has been tested for either of the following biomarkers and the test was positive:
      a. Rheumatoid factor (RF)
      b. Anti-cyclic citrullinated peptide (anti-CCP)
   ii. Member has been tested for ALL of the following biomarkers:
      a. RF
      b. Anti-CCP
      c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

B. Articular juvenile idiopathic arthritis

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. 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:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
      b. High disease activity.
      c. Is judged to be at high risk for disabling joint disease.

C. Systemic juvenile idiopathic arthritis (sJIA)

1. 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.

2. 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).

D. Giant cell arteritis (GCA)

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:

1. Temporal artery biopsy or cross-sectional imaging

2. Acute-phase reactant elevation (i.e., high erythrocyte sedimentation rate [ESR] and/or high serum C-reactive protein [CRP]).

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

F. Cytokine release syndrome
1. Authorization of 1 month may be granted for members 2 years of age or older for treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS).
2. Authorization of 1 month may be granted for treatment of cytokine release syndrome in members with refractory CRS related to blinatumomab therapy.

G. Unicentric Castleman disease
Authorization of 12 months may be granted for treatment of unicentric Castleman disease when all of the following are met:
1. The member is human immunodeficiency virus (HIV)-negative.
2. The member is human herpesvirus-8-negative.
3. The requested medication will be used as a single agent.
4. The disease has progressed following treatment of relapsed/refractory disease.

H. Multicentric Castleman disease
Authorization of 12 months may be granted for treatment of multicentric Castleman disease when both of the following are met:
1. The requested medication will be used as a single agent.
2. The disease has progressed following treatment of relapsed/refractory or progressive disease.

I. Immune checkpoint inhibitor-related toxicity
Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when then member has severe immunotherapy-related inflammatory arthritis and either of the following is met:
1. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
2. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

J. Acute graft versus host disease
Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:
1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

K. Polymyalgia rheumatica (PMR)
Authorization of 12 months may be granted for treatment of polymyalgia rheumatica (PMR) when any of the following criteria is met:
1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has experienced a disease flare during a taper with systemic corticosteroids.
3. Member has experienced an inadequate response to methotrexate.
4. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Articular juvenile idiopathic arthritis

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:

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

C. Systemic juvenile idiopathic arthritis (sJIA)

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:

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

D. Giant cell arteritis (GCA)

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:

1. Headaches
2. Scalp tenderness
3. Tenderness and/or thickening of superficial temporal arteries
4. Constitutional symptoms (e.g., weight loss, fever, fatigue, night sweats)
5. Jaw and/or tongue claudication
6. Acute visual symptoms (e.g., amaurosis fugax, acute visual loss, diplopia)
7. Symptoms of polymyalgia rheumatica (e.g., shoulder and/or hip girdle pain)
8. Limb claudication

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

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.

F. 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.

G. Cytokine release syndrome and acute graft versus host disease
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

H. 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.

I. 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:
1. Morning stiffness
2. Hip or shoulder pain
3. Hip or shoulder range of motion
4. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

Appendix A: Examples of clinical reasons to avoid pharmacologic treatment with methotrexate
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding

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

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

IX. REFERENCES

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Reference number(s)
5125-A

SPECIALTY GUIDELINE MANAGEMENT

ADBRY (tralokinumab-ldrm)

POLICY

I. 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
Indicated for the 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests:
   1. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
   2. Member's chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapy is not advisable for the member.
B. For continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

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

B. Authorization of 4 months may be granted for members 12 years of age or older for treatment of moderate-to-severe atopic dermatitis when both of the following criteria are met:
   1. 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.

2. Member meets one of the following:
   i. Member has had an inadequate treatment response with one of the following in the past year:
      a. A medium potency to super-high potency topical corticosteroid (see Appendix)
      b. A topical calcineurin inhibitor
   ii. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).

V. 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).

VI. OTHER

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

VII. 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%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%

Potency	Drug	Dosage form	Strength
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%
		Cream	1%

VIII. REFERENCES

Reference number(s)
5125-A

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Reference number(s)
1641-A

SPECIALTY GUIDELINE MANAGEMENT

ADEMPAS (riociguat)

POLICY

I. 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

A. 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.

B. 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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Pulmonary arterial hypertension (PAH)
Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:
1. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
2. PAH was confirmed by right heart catheterization with all of the following pretreatment results:
   i. Mean pulmonary arterial pressure (mPAP) > 20 mmHg
   ii. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
   iii. Pulmonary vascular resistance (PVR) ≥ 3 Wood units

B. Chronic thromboembolic pulmonary hypertension (CTEPH)
Authorization of 12 months may be granted for treatment of CTEPH when ALL of the following criteria are met:
1. Member has CTEPH defined as WHO Group 4 class of pulmonary hypertension (refer to Appendix).
2. Member meets either criterion (i) or criterion (ii) below:

i. Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA)
ii. Inoperable CTEPH with diagnosis confirmed by BOTH of the following (a. and b.):
   a. Computed tomography (CT)/magnetic resonance imaging (MRI) angiography or pulmonary angiography
   b. Pretreatment right heart catheterization with all of the following results:
      1. mPAP > 20 mmHg
      2. PCWP ≤ 15 mmHg
      3. PVR ≥ 3 Wood units

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in Section III 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.

V. APPENDIX

WHO Classification of Pulmonary Hypertension (PH)
1 Pulmonary arterial hypertension (PAH)
1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4. PAH associated with:
   1.4.1 Connective tissue disease
   1.4.2 Human immunodeficiency virus (HIV) infection
   1.4.3 Portal hypertension
   1.4.4 Congenital heart disease
   1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
1.7 Persistent PH of the newborn syndrome

2 PH due to left heart disease
2.1 PH due to heart failure with preserved left ventricular ejection fraction (LVEF)
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH

3 PH due to lung diseases and/or hypoxia
3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders

4 PH due to pulmonary artery obstructions
4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
   4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
   4.2.2 Other malignant tumors
      Renal carcinoma

Uterine carcinoma
Germ cell tumors of the testis
Other tumors
4.2.3 Non-malignant tumors
Uterine leiomyoma
4.2.4 Arteritis without connective tissue disease
4.2.5 Congenital pulmonary artery stenosis
4.2.6 Parasites
Hydatidosis

5 PH with unclear and/or multifactorial mechanisms

5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
5.3 Others: Chronic renal failure with or without hemodialysis, fibrosing mediastinitis
5.4 Complex congenital heart disease

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PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**GLUCAGON-LIKE PEPTIDE 1 (GLP-1) RECEPTOR AGONIST**
BRAND NAME* **(generic)**	**ADLYXIN (lixisenatide)** **BYDUREON BCISE (exenatide extended-release)** **BYETTA (exenatide)** **OZEMPIC (semaglutide)** **RYBELSUS (semaglutide)** **TRULICITY (dulaglutide)** **VICTOZA (liraglutide)**
Status: CVS Caremark® Criteria	***REG***
Type: Initial Prior Authorization with Quantity Limit	***Ref # 5496-C***

POLICY

FDA-APPROVED INDICATIONS

Adlyxin

Adlyxin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Adlyxin should not be used in patients with type 1 diabetes mellitus.
- Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.

Bydureon BCise

Bydureon BCise is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.

Limitations of Use:

- Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans.
- Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus.
- Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide.
- Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Byetta
Byetta is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Byetta is not indicated for use in patients with type 1 diabetes.
- Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Ozempic
Ozempic is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use:

- Ozempic has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Rybelsus
Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus.

Trulicity
Trulicity is indicated:

- as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

Limitations of Use

- Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Trulicity should not be used in patients with type 1 diabetes mellitus.
- Trulicity has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Victoza
Victoza is indicated:
- as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus.
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Limitations of Use
- Victoza should not be used in patients with type 1 diabetes mellitus.
- Victoza contains liraglutide and should not be coadministered with other liraglutide-containing products.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The patient has a diagnosis of type 2 diabetes mellitus
  AND
  - The patient has NOT been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza]

  OR
  - The patient has been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza]

    AND
    - The patient has demonstrated a reduction in A1C since starting GLP-1 Agonist therapy

    OR
    - The request is for Trulicity (dulaglutide)

      AND
      - The patient has established cardiovascular disease or multiple cardiovascular risk factors

    OR
    - The request is for Ozempic (semaglutide) or Victoza (liraglutide)

      AND
      - The patient has established cardiovascular disease

Quantity Limits apply.

QUANTITY LIMIT
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.

Drug	Maximum Dosing	Package Size(s)	1 Month Limit* 3 Months Limit*

Adlyxin	20mcg daily	Starter pack - 2 pens (1 pen of 10mcg, 1 pen of 20mcg), 14 doses per pen, 3mL each Maintenance pack - 2 pens of 20mcg, 14 doses per pen, 3mL each	2 prefilled pens (6mL) / 21 days 6 prefilled pens (18mL) / 63 days
Bydureon BCISE	2mg once weekly	Carton of 4 single-dose autoinjectors (2mg/0.85mL each)	4 auto-injectors (3.4mL) / 21 days 12 auto-injectors (10.2mL) / 63 days
Byetta	10mcg twice daily	5mcg dose, 60 doses, 1.2mL prefilled pen	1 prefilled pen (1.2mL) / 25 days 3 prefilled pens (3.6mL) / 75 days
		10mcg dose, 60 doses, 2.4mL prefilled pen	1 prefilled pen (2.4mL) / 25 days 3 prefilled pens (7.2mL) / 75 days
Ozempic	2mg once weekly	Carton of 1 pen (2mg/1.5mL)	1 prefilled pen (1.5mL) / 21 days 3 prefilled pens (4.5mL) / 63 days
		Carton of 1 pen (2mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
		Carton of 1 pen (4mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
		Carton of 1 pen (8mg/3mL)	1 prefilled pen (3mL) / 21 days 3 prefilled pens (9mL) / 63 days
Rybelsus	14mg once daily	3mg, 7mg, 14mg in bottles of 30 tablets	30 tablets / 25 days 90 tablets / 75 days
Trulicity	4.5mg once weekly	0.75mg/0.5mL, 1.5mg/0.5mL, 3mg/0.5mL, 4.5mg/0.5mL in cartons of 4 single-dose pens (0.5mL each)	4 pens (2mL) / 21 days 12 pens (6mL) / 63 days
Victoza	1.8mg once daily	Package of 2 or 3 pens (18mg/3mL each)	3 prefilled pens (9mL) / 25 days 9 prefilled pens (27mL) / 75 days
**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 OR 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.*			

Duration of Approval (DOA):

- 5496-C: DOA: 36 months

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Reference number(s)
1891-A

SPECIALTY GUIDELINE MANAGEMENT

AVASTIN (bevacizumab)
ALYMSYS (bevacizumab-maly)
AVZIVI (bevacizumab-tnjn)
MVASI (bevacizumab-awwb)
VEGZELMA (bevacizumab-adcd)
ZIRABEV (bevacizumab-bvzr)

POLICY

I. 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.

A. FDA-Approved Indications

1. Metastatic Colorectal Cancer (mCRC)
   a. Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer.
   b. Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen.
2. First-Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC)
   Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer.
3. Recurrent Glioblastoma (RGM)
   Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, is indicated for the treatment of recurrent glioblastoma in adults.
4. Metastatic Renal Cell Carcinoma (mRCC)
   Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with interferon alfa, is indicated for the treatment of metastatic renal cell carcinoma.
5. Persistent, Recurrent, or Metastatic Cervical Cancer
   Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer.
6. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
   a. Avastin, Mvasi, Vegzelma or Zirabev, in combination with carboplatin and paclitaxel, followed by Avastin, Mvasi, Vegzelma or Zirabev as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection.
   b. Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.
   c. Avastin, Mvasi, Vegzelma or Zirabev, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Avastin, Mvasi, Vegzelma or Zirabev as a single agent,

is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

7. Hepatocellular Carcinoma
   Avastin, in combination with atezolizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

B. Compendial Uses

1. Breast Cancer
2. Central Nervous System (CNS) Cancers
   a. Circumscribed glioma
   b. Diffuse high grade gliomas
   c. Glioblastoma
   d. IDH mutant astrocytoma (WHO Grade 2, 3, or 4)
   e. Oligodendroglioma (WHO Grade 2 or 3)
   f. Intracranial and Spinal Ependymoma (excluding subependymoma)
   g. Medulloblastoma
   h. Primary Central Nervous System Lymphoma
   i. Meningiomas
   j. Limited and Extensive Brain Metastases
   k. Metastatic Spine Tumors
   l. Neurofibromatosis type 2 vestibular schwannomas
3. Pleural Mesothelioma, Peritoneal Mesothelioma, Pericardial Mesothelioma, Tunica Vaginalis Testis Mesothelioma
4. Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer
5. Soft Tissue Sarcoma
   a. Angiosarcoma
   b. Solitary Fibrous Tumor/Hemangiopericytoma
6. Uterine Neoplasms/Endometrial Carcinoma
7. Vulvar Carcinoma
8. Small Bowel Adenocarcinoma
9. Ampullary Adenocarcinoma
10. Appendiceal Adenocarcinoma
11. Anal Adenocarcinoma
12. Renal Cell Carcinoma
13. Hepatocellular Carcinoma
14. Ophthalmic Disorders
    a. Diabetic Macular Edema
    b. Neovascular (wet) Age-Related Macular Degeneration
    c. Macular Edema following Retinal Vein Occlusion
    d. Proliferative Diabetic Retinopathy
    e. Choroidal Neovascularization
    f. Neovascular Glaucoma
    g. Retinopathy of Prematurity
    h. Polypoidal Choroidal Vasculopathy

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

II. CRITERIA FOR INITIAL APPROVAL

A. Ophthalmic Disorders

Authorization of 6 months may be granted for treatment of the following retinal disorders:

1. Diabetic Macular Edema

2. Neovascular (wet) Age-Related Macular Degeneration
3. Macular Edema following Retinal Vein Occlusion
4. Proliferative Diabetic Retinopathy
5. Choroidal Neovascularization (including myopic choroidal neovascularization, angioid streaks, choroiditis [including choroiditis secondary to ocular histoplasmosis], idiopathic degenerative myopia, retinal dystrophies, rubeosis iridis, pseudoxanthoma elasticum, and trauma)
6. Neovascular Glaucoma
7. Retinopathy of Prematurity
8. Polypoidal Choroidal Vasculopathy

B. Colorectal Cancer (CRC)
Authorization of 12 months may be granted for treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma.

C. Small Bowel Adenocarcinoma
Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma.

D. Ampullary Adenocarcinoma
Authorization of 12 months may be granted for treatment of intestinal-type ampullary adenocarcinoma that is progressive, unresectable, or metastatic.

E. Non-Small Cell Lung Cancer (NSCLC)
Authorization of 12 months may be granted for treatment of recurrent, unresectable, advanced, or metastatic non-squamous NSCLC.

F. CNS Cancer
Authorization of 12 months may be granted for treatment of the following types of CNS cancer:
1. Circumscribed glioma
2. Diffuse high grade gliomas
3. Glioblastoma
4. IDH mutant astrocytoma (WHO Grade 2, 3 or 4)
5. Oligodendroglioma (WHO Grade 2 or 3)
6. Intracranial and Spinal Ependymoma (excludes subependymoma)
7. Medulloblastoma
8. Primary Central Nervous System Lymphoma
9. Meningiomas
10. Limited and Extensive Brain Metastases
11. Metastatic Spine Tumors
12. Neurofibromatosis type 2 vestibular schwannomas

G. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Authorization of 12 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and malignant sex cord stromal tumors.

H. Uterine Neoplasms/Endometrial Carcinoma
Authorization of 12 months may be granted for treatment of progressive, recurrent, or metastatic uterine neoplasms or endometrial carcinoma.

I. Cervical/Vaginal Cancer
Authorization of 12 months may be granted for treatment of persistent, recurrent, or metastatic cervical or vaginal cancer.

J. Breast Cancer

Authorization of 12 months may be granted for treatment of metastatic breast cancer.

K. Renal Cell Carcinoma
Authorization of 12 months may be granted for treatment of relapsed or stage IV renal cell carcinoma.

L. Soft Tissue Sarcoma
1. Authorization of 12 months may be granted for treatment of angiosarcoma, as single agent therapy.
2. Authorization of 12 months may be granted for treatment of solitary fibrous tumor or hemangiopericytoma, in combination with temozolomide.

M. Mesothelioma
1. Authorization of 12 months may be granted for treatment of pleural mesothelioma, peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when any of the following criteria are met:
   a. As first-line therapy in combination with pemetrexed and either cisplatin or carboplatin, followed by single-agent maintenance bevacizumab
   b. As subsequent therapy in combination with pemetrexed and either cisplatin or carboplatin if immunotherapy was administered as first-line treatment
2. Authorization of 12 months may be granted for treatment of peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when used in combination with atezolizumab as subsequent therapy.

N. Vulvar Carcinoma
Authorization of 12 months may be granted for treatment of advanced, recurrent, or metastatic vulvar carcinoma, including squamous cell carcinoma and adenocarcinoma.

O. Hepatocellular Carcinoma
1. Authorization of 12 months may be granted for treatment of unresectable, inoperable, or metastatic hepatocellular carcinoma, when the requested medication will be used as initial treatment in combination with atezolizumab.
2. Authorization of 12 months may be granted for adjuvant treatment of operable hepatocellular carcinoma, when the member is at a high risk of recurrence and the requested medication will be used in combination with atezolizumab.

III. CONTINUATION OF THERAPY

A. Ophthalmic Disorders
For ophthalmic disorders, authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II 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).

B. All Other Indications
For all other indications, authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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Reference number(s)
3881-A

SPECIALTY GUIDELINE MANAGEMENT

BAFIERTAM (monomethyl fumarate)

POLICY

I. 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
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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER CRITERIA

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

VI. REFERENCES

1. Bafiertam [package insert]. High Point, NC: Banner Life Sciences LLC; January 2023.

Reference number(s)
4517-A

SPECIALTY GUIDELINE MANAGEMENT

CABENUVA (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension)

POLICY

I. 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
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 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.

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

Human immunodeficiency virus type 1 (HIV-1) infection
Authorization of 12 months may be granted for treatment of human immunodeficiency virus type 1 (HIV-1) infection when all of the following criteria are met:
A. Member is currently receiving a stable antiretroviral regimen.
B. Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA level (viral load) less than 50 copies per mL.
C. Member has no history of treatment failure.
D. Member has no known or suspected resistance to either cabotegravir or rilpivirine.

IV. 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 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.

V. REFERENCES

1. Cabenuva [package insert]. Durham, NC: ViiV Healthcare; February 2023.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed November 7, 2023.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS INJECTABLE, INTRAVENOUS INFUSION**
BRAND NAME* (generic)	**AIMOVIG (erenumab-aooe injection)** **AJOVY (fremanezumab-vfrm injection)** **EMGALITY (galcanezumab-gnlm injection)** **VYEPTI (eptinezumab-jjmr injection, for intravenous use)**
Status: CVS Caremark® Criteria	***Ref # 2581-C***
Type: Initial Prior Authorization with Quantity Limit	***Ref # REG 3160-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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

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

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)

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

QUANTITY LIMITS APPLY

QUANTITY LIMIT **Migraine:**		
Drug	**1 Month Limit***	**3 Month Limit***
Aimovig 70 mg, 140 mg (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy 225 mg (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
MAINTENANCE DOSE	1 mL (1 syringe or pen x 1 mL each) / 25 days	3 mL (3 syringes or pens x 1 mL each) / 75 days

Maintenance dose applies to those not new to therapy (i.e., patient has filled a prescription for Emgality in the past 180 days).		
Vyepti 100 mg (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:		
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
**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)

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

- 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

REFERENCES

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; May 2023.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc: October 2022.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; October 2022.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed April 11, 2024.
6. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *04/11/2024*).
7. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2012;78;1337-1345.
8. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2013;80;871
9. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: https://www.aan.com/Guidelines/Home/GetGuidelineContent/545. Accessed April 2024.
10. Ailani J, Burch RC, Robbins MS et al. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021; 61:1021-1039.
11. Charles A, Digre K, Goadsby P, et al. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024; 00:1-9.
12. American Headache Society. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache 2019; 59:1-18.
13. Robbins M, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. Headache 2016;56:1093-1106.
14. Francis G, et al. Acute and preventive pharmacologic treatment of cluster headache. American Academy of Neurology. Neurology 2010; 463-473.

Written by:	UM Development (TM/JK)
Date written:	05/2018
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Reviewed:	Medical Affairs (EPA) 05/2018, (EPA) 09/2018, (EPA) 10/2018, 10/2018, (GD) 03/2019, (CHART) 08/29/2019, (CHART) 03/12/20, (CHART) 04/30/20, (CHART) 06/25/20, (CHART) 10/8/2020, 07/01/2021, 06/30/2022, 06/01/2023, 05/30/2024, 08/29/2024
External Review:	05/2018, 10/2018, 04/2019 (FYI), 10/2019, 03/2020, 06/2020 (FYI), 10/2020, 10/2021, 10/2022, 10/2023, 10/2024, 10/2024 (FYI)

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the preventive treatment of migraine in an adult patient? [If Yes, then go to 2. If No, then go to 10.]	Yes	No
2	Has the patient received at least 3 months of treatment with the requested drug? [If Yes, then go to 3. If No, then go to 6.]	Yes	No
3	Is this request for any of the following: A) Aimovig, B) Ajovy, C) Emgality 120 mg, D) Vyepti? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient had a reduction in migraine days per month from baseline? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient require MORE than the plan allowance of any of the following: A) 1 injection (70 mg or 140 mg) per month of Aimovig, B) 3 injections (225 mg each) per 3 months of Ajovy, C) 1 injection (120 mg) per month of Emgality, D) 3 single dose vials (100 mg each) for intravenous infusion per 3 months of Vyepti? [No further questions] RPH Note: If yes, then deny and enter a partial approval per Quantity Limit Chart.	Yes	No
6	Is this request for any of the following: A) Aimovig, B) Ajovy, C) Vyepti? [If Yes, then go to 7. If No, then go to 8.]	Yes	No
7	Does the patient require MORE than the plan allowance of any of the following: A) 1 injection (70 mg or 140 mg) per month of Aimovig, B) 3 injections (225 mg each) per 3 months of Ajovy, C) 3 single dose vials (100 mg each) for intravenous infusion per 3 months of Vyepti? [No further questions] RPH Note: If yes, then deny and enter a partial approval per Quantity Limit Chart	Yes	No
8	Is this request for Emgality 120 mg? [If Yes, then go to 9. If No, then no further questions.]	Yes	No

9	Does the patient require MORE than the plan allowance of 4 injections (120 mg each) per first 3 months of Emgality (i.e., loading dose of 2 injections followed by 1 injection per month)? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 120 mg: 4 mL (4 syringes or pens x 1 mL each) per 75 days*.	Yes	No
10	Is this request for Emgality 100 mg for the treatment of episodic cluster headache in an adult patient? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Has the patient received at least 3 weeks of treatment with the requested drug? [If Yes, then go to 12. If No, then go to 14.]	Yes	No
12	Has the patient had a reduction in weekly cluster headache attack frequency from baseline? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Does the patient require MORE than the plan allowance of 3 injections (100 mg each) per month of Emgality? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days* OR 9 mL (9 syringes x 1 mL each) per 75 days*	Yes	No
14	Has the patient experienced an inadequate treatment response to ANY of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)? [If Yes, then go to 16. If No, then go to 15.]	Yes	No
15	Has the patient experienced an intolerance to or does the patient have a contraindication to ANY of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Does the patient require MORE than the plan allowance of 3 injections (100 mg each) per month of Emgality? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days*	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 10	
2.	Go to 3	Go to 6	
3.	Go to 4	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use for Aimovig, Ajovy, Emgality 120 mg and Vyepti is for preventative treatment of migraine in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed

			the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - Aimovig, Ajovy, Emgality 120 mg, Vyepti]
4.	Go to 5	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
5.	[Please select the appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	[PA Approved for 12 months. See Quantity Limit Chart]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers A) 1 autoinjector per month of Aimovig 70 mg, 140 mg, B) 3 autoinjectors or syringes per 3 months of Ajovy 225 mg, C) 1 syringe or pen per month of Emgality 120 mg, or D) 3 single dose vials per 3 months of Vyepti 100 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Continuation, Migraine]
6.	Go to 7	Go to 8	
7.	[Please select the appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	[PA Approved for 3 months. See Quantity Limit Chart]. Approve, 3 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers A) 1 autoinjector per month of Aimovig 70 mg, 140 mg, B) 3 autoinjectors or syringes per 3 months of Ajovy 225 mg, C) 3 single dose vials per 3 months of Vyepti 100 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review [Short Description: Quantity, Exceeds max limit, Partial denial – Initial, Migraine - Aimovig, Ajovy, Vyepti]
8.	Go to 9	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use for Aimovig, Ajovy, Vyepti and Emgality 120 mg is for

			preventative treatment of migraine in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - Aimovig, Ajovy, Vyepti, Emgality 120 mg]
9.	Deny	[PA Approved for 3 months. Approve Emgality 120 mg: 4 mL (4 syringes or pens x 1 mL each) per 75 days]. Approve, 3 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (4 syringes or pens per first 3 months then 1 injection per month of Emgality 120 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Initial, Migraine - Emgality]
10.	Go to 11	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for preventive treatment of migraine and treatment of cluster headaches in an adult. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis - all]
11.	Go to 12	Go to 14	
12.	Go to 13	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
13.	Deny	[PA Approved for 12 months. Approve Emgality 100 mg: 3 mL (3 syringes x 1mL each)	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (3 syringes per month of Emgality 100 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also

		per 25 days* OR 9 mL (9 syringes x 1 mL each) per 75 days*]. Approve, 12 Months	request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - Cluster]
14.	Go to 16	Go to 15	
15.	Go to 16	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried sumatriptan (nasal or subcutaneous) or zolmitriptan (nasal or oral), and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy – Cluster]
16.	Deny	[PA Approved for 1 month. Approve Emgality 100 mg: 3 mL (3 syringes x 1 mL each) per 25 days*]. Approve, 1 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (3 syringes per month of Emgality 100 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - Cluster]

STEP THERAPY CRITERIA

DRUG CLASS **CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS INJECTABLE, INTRAVENOUS INFUSION**

BRAND NAME (generic)

AIMOVIG
(erenumab-aooe injection)

AJOVY
(fremanezumab-vfrm injection)

EMGALITY
(galcanezumab-gnlm injection)

VYEPTI
(eptinezumab-jjmr injection, for intravenous use)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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

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

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* 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* with QUANTITY LIMIT For EMGALITY 100 mg
**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 1 day supply of sumatriptan (nasal or subcutaneous) or zolmitriptan (nasal or oral) within the past 730 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.** If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

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

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

Migraine:

Drug	**1 Month Limit***	**3 Month Limit***
Aimovig 70 mg, 140 mg (erenumab-aooe injection)	1 mL (1 autoinjector x 1 mL each) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy 225 mg (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
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 100 mg (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:		
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

**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.*

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)

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

QUANTITY LIMITS APPLY

POST LIMIT QUANTITY

Migraine:

Drug	1 Month Limit*	3 Month Limit*
Aimovig 70 mg, 140 mg (erenumab-aooe injection)	1 mL (1 autoinjector) / 25 days	3 mL (3 autoinjectors x 1 mL each) / 75 days
Ajovy 225 mg (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	2 mL (2 syringes or pens x 1 mL each) / 25 days	4 mL (4 syringes or pens x 1 mL each) / 75 days

has not filled a prescription for Emgality in the past 180 days).		
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 100 mg (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:		
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
**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)

- 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
- 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

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STEP THERAPY CRITERIA

DRUG CLASS	**ORAL, NASAL CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS**
BRAND NAME* (generic)	**NURTEC ODT (rimegepant)** **QULIPTA (atogepant)** **UBRELVY (ubrogepant)** **ZAVZPRET (zavegepant)**

Status: CVS Caremark® Criteria
Type: Initial Step Therapy with Quantity Limit;
Post Step Therapy Prior Authorization with Quantity Limit ***Ref # 3481-E***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

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.
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, 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.

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

**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.*

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

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
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

**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.*

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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Written by: UM Development (TM)
Date Written: 12/2019

Revised:	(TM) 02/2020 (added Nurtec ODT); (MAC) 06/2020 (updated document name/title), 06/2021 (Nurtec ODT label update), 06/2021 (no changes); (TM) 09/2021 (added Qulipta, initial doa 3mos), (change Nurtec initial doa to 3 mos), 06/2022 (no clinical changes), 02/2023 (added DDE to PL RPh note and mapping), 03/2023 (added Zavzpret, UDR); (KMB) 04/2023 (update Qulipta indication), 06/2023 (no clinical changes), 05/2024 (removed preventive step & added candesartan to initial step as a prereq), 08/2024 (removed concurrent CGRP exclusion & added valproic acid to initial step for Nurtec and Qulipta)
Reviewed:	Medical Affairs (CHART) 01/16/20, 03/12/20, 06/25/20, 10/8/2020, 10/07/2021, 10/14/2021, 06/30/2022, 03/23/2023, 04/27/2023, 06/01/2023, 05/30/2024, 08/29/2024
External Review:	01/2020, 03/2020, 08/2020, 08/2021, 10/2021, 12/2021 (FYI), 10/2022, 04/2023, 06/2023 (FYI), 10/2023, 10/2024, 10/2024 (FYI)

CRITERIA FOR APPROVAL

1	Is the request for Nurtec ODT, Ubrelvy, or Zavzpret being prescribed for the acute treatment of migraine in an adult patient? [If Yes, then go to 2. If No, then go to 5.]	Yes	No
2	Has the patient experienced an inadequate treatment response or an intolerance to two triptan 5-HT1 receptor agonists? [If Yes, then go to 4. If No, then go to 3.]	Yes	No
3	Does the patient have a contraindication that would prohibit a trial of triptan 5-HT1 receptor agonists? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Does the patient require MORE than the plan allowance of any of the following: A) Nurtec ODT or Ubrelvy 16 tablets per month, B) Zavzpret 6 nasal spray units per 3 weeks or 24 nasal spray units per 3 months? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Nurtec ODT or Ubrelvy: 0.64 tablets per day AND 16 tablets per 25 days or 48 tablets per 75 days, or Zavzpret 0.34 nasal spray units per day AND 6 nasal spray units per 18 days or 24 nasal spray units per 75 days.	Yes	No
5	Is the request for Nurtec ODT being prescribed for the preventive treatment of episodic migraine in an adult patient? [If Yes, then go to 7. If No, then go to 6.]	Yes	No
6	Is the request for Qulipta being prescribed for the preventive treatment of migraine in an adult patient? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has the patient received at least 3 months of treatment with the requested drug? [If Yes, then go to 8. If No, then go to 10.]	Yes	No
8	Has the patient had a reduction in migraine days per month from baseline? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Does the patient require MORE than the plan allowance of any of the following: A) Nurtec ODT 16 tablets per month, B) Qulipta 30 tablets per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Nurtec ODT 0.64 tablets per day AND 16 tablets per 25 days or 48 tablets per 75 days, or Qulipta 1.2 tablets per day AND 30 tablets per 25 days or 90 tablets per 75 days.	Yes	No

10	Does the patient require MORE than the plan allowance of any of the following: A) Nurtec ODT 16 tablets per month, B) Qulipta 30 tablets per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for Nurtec ODT 0.64 tablets per day AND 16 tablets per 25 days or 48 tablets per 75 days, or Qulipta 1.2 tablets per day AND 30 tablets per 25 days or 90 tablets per 75 days.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 5	
2.	Go to 4	Go to 3	
3.	Go to 4	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because A) You have not tried two triptan 5-HT1 receptor agonists, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy two triptan 5-HT1 receptor agonists]
4.	[Please select appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	[PA Approved for 12 months. Approve Nurtec ODT or Ubrelvy: 0.64 tablets per day AND 16 tabs per 25 days* or 48 tabs per 75 days* OR Zavzpret: 0.34 nasal spray units per day AND 6 nasal spray units per 18 days* or 24 nasal spray units per 75 days*]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers A) 16 tablets per month of Nurtec ODT 75 mg, B) 16 tablets per month of Ubrelvy 50 mg, C) 16 tablets per month of Ubrelvy100 mg, or D) 6 nasal spray units per 3 weeks or 24 nasal spray units per 3 months of Zavzpret. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial, acute treatment]
5.	Go to 7	Go to 6	

6.	Go to 7	[Please select appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) Nurtec ODT, Ubrelvy, or Zavzpret for the acute treatment of migraine in an adult patient, B) Nurtec ODT for the preventive treatment of episodic migraine in an adult patient, or C) Qulipta for the preventive treatment of migraine in an adult patient. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
7.	Go to 8	Go to 10	
8.	Go to 9	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
9.	[Please select appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage]. Deny	[PA Approved for 12 months. Approve Nurtec ODT: 0.64 tablets per day AND 16 tabs per 25 days* or 48 tabs per 75 days*, OR Qulipta: 1.2 tablets per day AND 30 tabs per 25 days* or 90 tabs per 75 days*]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers: A) 16 tablets per month of Nurtec ODT 75 mg, B) 30 tablets per month of Qulipta 10 mg, C) 30 tablets per month of Qulipta 30 mg, or D) 30 tablets per month of Qulipta 60 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial, Prevention]
10.	[Please select appropriate denial close option. RPh Note: For the denial verbiage, only include the	[PA Approved for 3 months. Approve Nurtec ODT: 0.64 tablets per day AND 16 tabs per 25 days* or 48	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers: A) 16 tablets per month of Nurtec ODT 75 mg, B) 30 tablets per month of Qulipta 10 mg, C) 30 tablets per month of Qulipta 30 mg, or D) 30 tablets per month of Qulipta 60 mg. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request

	requested drug. Remove all the other drugs from the verbiage]. Deny	tabs per 75 days* OR Qulipta: 1.2 tablets per day AND 30 tabs per 25 days* or 90 tabs per 75 days*]. Approve, 3 Months	the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial, Prevention]

Reference number(s)
5142-A

SPECIALTY GUIDELINE MANAGEMENT

CIBINQO (abrocitinib)

POLICY

I. 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
Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests:
   1. Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).
   2. Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
B. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Atopic dermatitis
A. 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 experienced an inadequate response or intolerance to at least one biologic (e.g., Dupixent, Adbry) or a targeted synthetic drug (e.g., Rinvoq) in the past year.

B. 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. 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.
2. Member meets one of the following:
   i. Member has had an inadequate treatment response with one of the following in the past year:
      a. A medium potency to super-high potency topical corticosteroid (see Appendix)
      b. A topical calcineurin inhibitor
   ii. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
3. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.

V. 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).

VI. 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 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.

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

VII. 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%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%

Potency	Drug	Dosage form	Strength
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%

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

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Reference number(s)
2005-A

SPECIALTY GUIDELINE MANAGEMENT

CIMZIA (certolizumab pegol)

POLICY

I. 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.

A. FDA-Approved Indications
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.
2. Treatment of adults with moderately to severely active rheumatoid arthritis.
3. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
4. Treatment of adult patients with active psoriatic arthritis.
5. Treatment of adults with active ankylosing spondylitis.
6. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
7. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

B. Compendial Use
Immune checkpoint inhibitor-related toxicity - inflammatory arthritis

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
1. For initial requests:
   i. 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.
   ii. 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).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Polyarticular juvenile idiopathic arthritis (pJIA)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), and immune checkpoint inhibitor-related toxicity
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Crohn's disease (CD)
   Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E. Plaque psoriasis (PsO)
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Crohn's disease: gastroenterologist
D. Plaque psoriasis: dermatologist
E. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid Factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP

3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

ii. Member meets either of the following criteria:
   a. Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
   b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Polyarticular juvenile idiopathic arthritis (pJIA)

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and member also meets one of the following:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
      b. High disease activity.
      c. Is judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:
   i. Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

E. Crohn's disease (CD)
Authorization of 12 months may be granted for adult members for treatment of moderately to severely active Crohn's disease.

F. Plaque psoriasis (PsO)
1. 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 the treatment of moderate to severe plaque psoriasis.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

G. Immune checkpoint inhibitor-related toxicity
Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has severe immunotherapy-related inflammatory arthritis and meets either of the following:
1. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
2. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)
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.

B. Polyarticular juvenile idiopathic arthritis (pJIA)
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:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)

2. Number of joints with limitation of movement
3. Functional ability

C. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

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:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Crohn's disease (CD)

1. 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.

2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

F. Plaque psoriasis (PsO)

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:

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

G. 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.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Appendix B: Risk factors for articular juvenile idiopathic arthritis
1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

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Reference number(s)
1624-A

SPECIALTY GUIDELINE MANAGEMENT

SENSIPAR (cinacalcet)
cinacalcet

POLICY

I. 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.

A. FDA-Approved Indications
1. Secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis
2. Hypercalcemia in adult patients with parathyroid carcinoma
3. 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

B. Compendial Use
Tertiary hyperparathyroidism in post-kidney transplant patients not receiving dialysis

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

II. CRITERIA FOR INITIAL APPROVAL

A. Secondary Hyperparathyroidism with CKD on Dialysis
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).

B. Primary Hyperparathyroidism
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).

C. Tertiary Hyperparathyroidism in Post-Kidney Transplant Patients Not Receiving Dialysis
Authorization of 12 months may be granted for treatment of tertiary hyperparathyroidism in a member who has had a kidney transplant, is not receiving dialysis, and has a serum calcium level (corrected for albumin) greater than or equal to 8.4 mg/dL (see Appendix).

D. Parathyroid Carcinoma
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).

III. CONTINUATION OF THERAPY

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

A. Secondary Hyperparathyroidism with CKD on Dialysis
Member is experiencing benefit from therapy as evidenced by a decrease in intact parathyroid hormone (iPTH) levels from pretreatment baseline.

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

IV. APPENDIX

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

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Reference number(s)
1654-A

SPECIALTY GUIDELINE MANAGEMENT

CINQAIR (reslizumab)

POLICY

I. 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
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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. For initial requests:
   1. Chart notes or medical record documentation showing baseline blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
   2. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
B. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   1. Member is 18 years of age or older.
   2. Member meets either of the following criteria:

   a. Member has a baseline blood eosinophil count of at least 400 cells per microliter.
   b. Member is dependent on systemic corticosteroids.
3. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
   a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
   b. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
   c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
4. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
   a. High-dose inhaled corticosteroid
   b. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
5. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

V. CONTINUATION OF THERAPY

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

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

VI. 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.

VII. REFERENCES

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5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22): 2301-2317.

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)

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

Duration of Approval (DOA)

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

References

1. 21 USC 353a: Pharmacy compounding From Title 21-FOOD AND DRUGS CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER V-DRUGS AND DEVICES Part A-Drugs and Devices. Available at: https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section353a&num=0&saved=%7CKGNvbXBvdW5kIGRydWdzKQ%3D%3D%7CdHJlZXNvcnQ%3D%7CdHJ1ZQ%3D%3D%7C15%7Ctrue%7Cprelim. Accessed July 2024.
2. Compounding Quality Act. U.S. Food and Drug Administration. Pharmacy Compounding. Available at: https://www.govinfo.gov/app/details/BILLS-113hr3204enr. Accessed July 2024.
3. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pharmacy-compounding-human-drug-products-under-section-503a-federal-food-drug-and-cosmetic-act. Accessed July 2024.
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5. Compounding and the FDA: Questions and Answers. Available at: https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers. Accessed July 2024.
6. USP Compounding Standards. Available at: https://www.usp.org/compounding. Accessed July 2024.
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9. Is it Really FDA Approved? Available at: https://www.fda.gov/forconsumers/consumerupdates/ucm047470.htm. Accessed July 2024.
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11. Menopause. Available at: https://www.fda.gov/consumers/womens-health-topics/menopause. Accessed July 2024.
12. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on the Clinical Utility of Treating Patients with Compounded Bioidentical Hormone Replacement Therapy, Jackson L.M., Parker R.M., & Mattison D.R. (Eds.). (2020) *The clinical utility of compounded bioidentical hormone therapy: A review of safety, effectiveness, and use*. National Academies Press (US).
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PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **CONTINUOUS GLUCOSE MONITORS**

**BRAND NAME*
(generic)**

DEXCOM (ALL PRODUCTS)

ENLITE (ALL PRODUCTS)

EVERSENSE (ALL PRODUCTS)

FREESTYLE LIBRE (ALL PRODUCTS)

GUARDIAN (ALL PRODUCTS)

MINILINK (ALL PRODUCTS)

MINIMED (ALL PRODUCTS)

PARADIGM (ALL PRODUCTS)

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C28339-C***

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of diabetes mellitus? [If Yes, then go to 2. If No, then go to 8.]	Yes	No
2	Is the patient using an intensive insulin regimen? [NOTE: An intensive insulin regimen is defined as multiple daily injections of insulin (i.e., 3 or more injections per day) or insulin pump therapy.] [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is this a request for continuation of therapy with a continuous glucose monitor (CGM)? [If Yes, then go to 4. If No, then go to 6.]	Yes	No
4	Has the patient experienced improved glycemic control OR decreased hypoglycemia episodes while using a continuous glucose monitor (CGM)? [If Yes, then skip to question 9. If No, then go to 5.]	Yes	No
5	Is the patient being assessed every six months by the prescriber for adherence to their continuous glucose monitor (CGM) regimen and diabetes treatment plan? [If yes, then skip to question 9. If no, then no further questions]	Yes	No
6	Is the patient 18 years of age or older? [If Yes, then go to 7. If No, then skip to question 9.]	Yes	No
7	Is the patient currently not meeting glycemic targets OR is the patient experiencing hypoglycemia (including hypoglycemia unawareness)? [If yes then skip to question 9. No further questions]	Yes	No

8	Does the patient have a diagnosis of glycogen storage disease? [If no, then no further questions]	Yes	No
9	Is this request for a replacement continuous glucose monitor (CGM) receiver, transmitter, or sensor due to incompatibility? [If no, then skip to question 11.]	Yes	No
10	Does the patient use an insulin pump that requires use of a specific continuous glucose monitor (CGM) or has the insulin regimen changed such that the new regimen is not compatible with the patient's current continuous glucose monitor (CGM)? [No further questions.]	Yes	No
11	Is this request for replacement of the continuous glucose monitor (CGM) receiver, transmitter, or sensors due to loss or dysfunction of current device or components?	Yes	No

QUANTITY LIMIT

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

Drug	1 Month Limit
Dexcom G6	3 sensors / 30 days
Dexcom G7	3 sensors / 30 days
Enlite	5 sensors / 30 days

Drug	4 Week Limit
Freestyle Libre 2	2 sensors / 28 days
Freestyle Libre 3	2 sensors / 28 days
Freestyle Libre 14-Day	2 sensors / 28 days
Guardian 3	5 sensors / 28 days
Guardian 4	5 sensors / 28 days

Drug	Limit
Eversense	1 sensor / 90 days
Eversense E3 (XL)	1 sensor / 180 days

Drug	Limit
Dexcom G6 and G7 Receivers	1 receiver / 365 days
Freestyle Libre Receivers	1 receiver / 365 days
Guardian Receivers	1 receiver / 365 days

Drug	Limit
Dexcom transmitters	1 transmitter / 90 days
Eversense	1 transmitter / 90 days

Guardian	1 transmitter / 90 days
Minilink	1 transmitter / 90 days
Minimed	1 transmitter / 90 days
Paradigm	1 transmitter / 90 days

REFERENCES

1. CountyCare Prior Authorization Approval Policy: Continuous Glucose Monitors. August 2024

DOCUMENT HISTORY
Created: VLS 08/2024
Revised:
Reviewed: APN 10/2024

Reference number
2017-A

SPECIALTY GUIDELINE MANAGEMENT

COSENTYX (secukinumab)

POLICY

I. 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

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

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

II. DOCUMENTATION

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

A. Plaque psoriasis (PsO)
    1. Initial requests
        i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
        ii. 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.
    2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and enthesitis-related arthritis (ERA), hidradenitis suppurativa
    1. 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.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Plaque psoriasis: dermatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Ankylosing spondylitis, non-radiographic axial spondyloarthritis, and enthesis-related arthritis: rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis (PsO)

1. 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.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

B. Psoriatic arthritis (PsA)

1. 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.

2. 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:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:
   i. Member has had an inadequate response to at least two nonsteroidal anti-inflammatory drugs (NSAIDs).

ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Enthesitis-related arthritis (ERA)

1. 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.

2. 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:
   i. 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.
   ii. Member meets either of the following:
      a. Member has had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs), sulfasalazine, or methotrexate.
      b. Member has an intolerance or contraindication to NSAIDs, sulfasalazine (e.g., porphyria, intestinal or urinary obstruction), and methotrexate (see Appendix).

E. Hidradenitis suppurativa

1. 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.

2. 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:
   i. 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).
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

V. CONTINUATION OF THERAPY

A. Plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members 6 years of age or older (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

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

B. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement

7. Functional status
8. C-reactive protein (CRP)

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
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:
1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Enthesitis-related arthritis (ERA)
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:
1. Number of flares
2. Number of joints with active arthritis (e.g., swelling, pain)
3. Number of joints with limited movement
4. Dactylitis
5. Enthesitis

E. Hidradenitis suppurativa
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:
1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

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

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

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13. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
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Reference number(s)
1845-A

SPECIALTY GUIDELINE MANAGEMENT

TECFIDERA (dimethyl fumarate)
dimethyl fumarate

POLICY

I. 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
Tecfidera 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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

VI. REFERENCES

1. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; March 2024.
2. dimethyl fumarate [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2024.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ELIQUIS
(apixaban)

PRADAXA
(dabigatran)

SAVAYSA
(edoxaban)

XARELTO ORAL SUSPENSION
(rivaroxaban oral suspension)

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C25427-A***

CRITERIA FOR APPROVAL

1	Is this request for continuation of therapy? [If no, then skip to question 8.]	Yes	No
2	Does the patient demonstrate the need for continued anticoagulation for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
3	Does the patient demonstrate the need for continued anticoagulation for ONE of the following FDA-approved labeled indications: A) Treatment of deep vein thrombosis (DVT), B) Treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
4	Is this request for Eliquis (apixaban), Xarelto (rivaroxaban), or Pradaxa (dabigatran) in a patient who demonstrates a need for continued anticoagulation for reduction in the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
5	Is this request for Xarelto (rivaroxaban) in a patient who demonstrates a need for continued anticoagulation for ONE of the following FDA approved indications: A) Reduction of the risk of major cardiovascular (CV) events in coronary artery disease (CAD), B) Reduction of the risk of major thrombotic events in peripheral arterial disease (PAD), C) Thromboprophylaxis in pediatric patients 2 years of age and older with congenital heart disease after the Fontan procedure? [If yes, then no further questions.]	Yes	No
6	Is this request for Xarelto (rivaroxaban) in a pediatric patients less than 18 years of age who demonstrates a need for continued anticoagulation for treatment of venous thromboembolism (VTE) and reduction in risk of recurrent VTE?	Yes	No

	[If yes, then no further questions.]		
7	Does the patient demonstrate the need for continued anticoagulation for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, or D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [No further questions.]	Yes	No
8	Is this request for Xarelto (rivaroxaban) Oral Suspension? [If no, then go to question 13.]	Yes	No
9	Is this request for the treatment of venous thromboembolism (VTE) and reduction in risk of recurrent VTE in patients less than 18 years of age? [If no, then skip to question 12.]	Yes	No
10	Is the patient less than 6 months of age? [If no, then no further questions.]	Yes	No
11	Does the patient meet ALL of the following criteria: A) Greater than or equal to 37 weeks of gestation, B) Greater than or equal to 10 days of oral feeding, C) Greater than or equal to 2.6kg at time of dosing? [No further questions.]	Yes	No
12	Is this request for thromboprophylaxis in pediatric patients greater than or equal to 2 years of age with congenital heart disease after the Fontan procedure? [If yes, then no further questions.] [If no, then skip to questions 26.]	Yes	No
13	Is this request for Eliquis (apixaban)? [If no, then skip to question 20.]	Yes	No
14	Does the patient have documented clinically significant treatment failure, intolerance, or contraindication to Xarelto (rivaroxaban)? [If no, then no further questions.]	Yes	No
15	Is this request for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
16	Is this request for treatment of deep vein thrombosis (DVT) or treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
17	Is this request for deep vein thromboembolism (DVT) prophylaxis after hip replacement surgery? [If yes, then no further questions.]	Yes	No

18	Is this request for deep vein thromboembolism (DVT) prophylaxis after knee replacement surgery? [If yes, then no further questions.]	Yes	No
19	Is this request for the reduction in risk of recurrence of deep vein thromboembolism (DVT) or pulmonary embolism (PE)? [If yes, then no further questions.] [If no, then skip to questions 26.]	Yes	No
20	Is this request for Pradaxa (dabigatran) or Savaysa (edoxaban)? [If no, then no further questions.]	Yes	No
21	Does the patient have documented clinically significant treatment failure, intolerance, or contraindication to PREFERRED direct oral anticoagulants? [If no, then no further questions.]	Yes	No
22	Is this request for reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation? [If yes, then no further questions.]	Yes	No
23	Is the requested drug being used for treatment of deep vein thrombosis (DVT) or treatment of pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
24	Is this request for Pradaxa (dabigatran) for deep vein thromboembolism (DVT) prophylaxis after hip surgery? [If yes, then no further questions.]	Yes	No
25	Is this request for Pradaxa (dabigatran) for the reduction in risk of recurrence of deep vein thromboembolism (DVT) or pulmonary embolism (PE)? [If yes, then no further questions.]	Yes	No
26	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, or D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [No further questions.]	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

Written by: UM Development (VLS)
Date Written: 06/2023
Revised:
Reviewed: Medical Affairs: (APN) 08/2023

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

than 70 mg/dL), wide fluctuations in blood glucose before mealtime, “dawn” phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, history of severe glycemic excursions
    - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period
- The patient is currently established on therapy with an insulin pump and ALL of the following criteria are met:
    - The patient has documented frequency of glucose self-testing an average of at least 4 times per day OR the patient is using a continuous glucose monitor (CGM)
    - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

Type 2 Diabetes Mellitus

Authorization may be granted for the requested medical device when the patient has a diagnosis of type 2 diabetes mellitus when the following criteria is met:

- The request is for Omnipod GO and ALL of the following criteria are met:
    - The patient does NOT require bolus or mealtime insulin
    - The patient has completed a comprehensive diabetes education program
    - The patient meets ONE of the following:
        - The patient has documented frequency of glucose self-testing at least once daily
        - The patient has been using a continuous glucose monitor (CGM)
    - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)

Quantity Limits Apply

Omnipod GO: 10 pods (2 kits) per 25 days or 30 pods (6 kits) per 75 days

Other Omnipod products (e.g., Omnipod 5, Omnipod Dash):

Omnipod starter kit: 1 kit per 999 days

Omnipod pod refills: 10 pods per 25 days or 30 pods per 75 days for patients using less than 200 units of insulin per 72-hour period

Omnipod pod refills: 15 pods per 25 days or 45 pods per 75 days for patients using greater than 200 units of insulin per 72-hour period

V-Go: 30 pumps per 25 days or 90 pumps per 75 days

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

Duration of Approval (DOA)

- 3762-C: DOA: 12 months

References

1. Omnipod GO. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/K223372.pdf. Accessed March 11, 2024.
2. Omnipod, Omnipod DASH Insulin Management System. 510(k) Premarket Notification FDA Home Medical Devices Databases. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192659.pdf. Accessed March 13, 2024.
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5. Omnipod DASH User Guide. Acton, MA: Insulet Corporation; October 2023. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf. Accessed March 6, 2024.
6. Omnipod 5 User Guide. Acton, MA: Insulet Corporation: October 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf. Accessed March 5, 2024.
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8. Omnipod System User Guide. Acton, MA. Insulet Corporation: October 2021. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-System_User-Guide_English.pdf. Accessed March 6, 2024.
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11. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. *Endocr Pract.* 2022; 28(10):923-1049.

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14. Grunberger G, Sherr J, Allende M et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus. *Endocrine Pract.* 2021. 27: 505-537.
15. Grunberger G, Handelsman Y, Bloomgarden ZT, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2018 Position Statement on Integration of Insulin Pumps and Continuous Glucose Monitoring in Patients with Diabetes Mellitus. *Endocr Pract*. 2018;24(3):302-308.
16. National Coverage Determination (NCD) for Infusion Pumps (280.14); Revision Effective Date 12/17/2004. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&NCAId=41&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=BC%7cSAD%7cRTC%7cReg&PolicyType=Both&s=47&KeyWord=INSULIN+PUMP&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=EAAAABAAIAAA&. Accessed March 7, 2024.

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

Indicated for:

- Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis 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 in 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 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).

- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitations of Use

Not indicated for the relief of acute bronchospasm or status asthmaticus.

Compendial Uses

- 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 of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.

Continuation requests:

Chart notes or medical record documentation that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

Asthma

Initial requests:

- Chart notes or medical record documentation showing baseline blood eosinophil count (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests:

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

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Initial requests:

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
- 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.

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).
- Chart notes, medical record documentation, or claims history of prerequisite therapies 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 clinical signs and/or symptoms of COPD.

- Chart notes, medical record documentation, or claims history of prerequisite therapies 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.

Prescriber Specialties

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

- Atopic dermatitis: dermatologist or allergist/immunologist
- Asthma: allergist/immunologist or pulmonologist
- Chronic rhinosinusitis with nasal polyps: allergist/immunologist or otolaryngologist
- Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
- Prurigo nodularis: dermatologist or allergist/immunologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist
- Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist or oncologist

Coverage Criteria

Atopic dermatitis

Authorization of 4 months may be granted for members 6 months of age or older who have previously received a biologic (e.g., Adbry) or 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 either of the following in the past year:
        - A medium potency to super-high potency topical corticosteroid (see Appendix A)

    - A topical calcineurin inhibitor
  - The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

Asthma

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

Authorization of 6 months may be granted for treatment of moderate-to-severe asthma in members 6 years of age or older when all of the following criteria are met:

- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
  - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
  - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
  - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member meets either of the following criteria:
  - Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control despite current treatment with both of the following medications at optimized doses:
    - Medium-to-high-dose inhaled corticosteroid
    - Additional controller (i.e., long-acting 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 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 (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

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 2 months unless contraindicated or not tolerated.
- Member has CRSwNP despite one of the following:
    - Prior sino-nasal surgery
    - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
- Member has one of the following:
    - A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.
    - Meltzer Clinical Score of 2 or higher in both nostrils.
    - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
    - Rhinorrhea (anterior/posterior)
    - Reduction or loss of smell
    - Facial pain or pressure
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Eosinophilic esophagitis (EoE)

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 meets either of the following:
    - Member is 1 year of age to less than 11 years of age and has clinical manifestations of disease (e.g., vomiting, heartburn, abdominal pain, food refusal, failure to thrive).
    - Member is 11 years of age or older and has history of an average of at least 2 episodes of dysphagia (with intake of solids) per week.
- 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 both of the following:
    - Proton pump inhibitor
    - Systemic corticosteroid or oral topical corticosteroid therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation] swallowed), unless contraindicated or not tolerated

Prurigo Nodularis

Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when all of the following criteria are met:

- Member has pruritus lasting at least 6 weeks.
- Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
- Member has a minimum of 20 nodular lesions.
- Member meets either of the following:
    - Member has had an inadequate response to one of the following:
        - A medium to super-high potency topical corticosteroid (see Appendix A)
        - A topical calcineurin inhibitor
        - Phototherapy (e.g., UVB, PUVA)
        - Pharmacologic treatment with methotrexate or cyclosporine
    - Member has had an intolerance or a clinical reason to avoid either of the following:
        - Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
        - Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

Chronic obstructive pulmonary disease (COPD)

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.

Immune checkpoint inhibitor-related toxicity

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has a refractory case of immune-therapy related severe (G3) pruritis.

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 moderate (G2) or severe (G3) bullous dermatitis.

Continuation of Therapy

Atopic dermatitis

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

Asthma

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 (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

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, 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.

Eosinophilic Esophagitis (EoE)

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

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

Chronic obstructive pulmonary disease (COPD)

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.

Immune checkpoint inhibitor-related toxicities

All members (including new members) requesting authorization for continuation of therapy for severe (G3) pruritis must meet all requirements in the coverage criteria section.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate (G2) or severe (G3) 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.

Other

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

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

Appendix

Appendix A: Table. Relative potency of select topical corticosteroid products

Potency	Drug	Dosage form	Strength
Super-high potency (Group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
Super-high potency (Group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
Super-high potency (Group 1)	Fluocinonide	Cream	0.1%
Super-high potency (Group 1)	Flurandrenolide	Tape	4 mcg/cm^2
Super-high potency (Group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
High potency (Group 2)	Amcinonide	Ointment	0.1%
High potency (Group 2)	Augmented betamethasone dipropionate	Cream	0.05%
High potency (Group 2)	Betamethasone dipropionate	Ointment	0.05%
High potency (Group 2)	Clobetasol propionate	Cream	0.025%

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

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

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

BRAND NAME
(generic)

ELIDEL
(pimecrolimus)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Elidel (pimecrolimus) Cream, 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Elidel Cream, 1% is not indicated for use in children less than 2 years of age.

Compendial Uses
Psoriasis[3] - on the face, genitals, or skin folds[6]
Atopic Dermatitis for patients under 2 years of age[4,5]
Vitiligo on the head or neck[7,8]

COVERAGE CRITERIA

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (eczema) when ONE of the following criteria are met:

- The patient is less than 2 years of age
- The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE first line therapy agent (e.g., medium or higher potency topical corticosteroid)

Psoriasis
Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds.

Vitiligo
Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck.

CONTINUATION OF THERAPY

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (eczema) when the following criteria is met:

- 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)]

Psoriasis
Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.)

Vitiligo
Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)

DURATION OF APPROVAL (DOA)

- 491-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Less than 2 years of age: DOA: 3 months
- 759-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 36 months
  - Less than 2 years of age: DOA: 3 months

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Reference number(s)
2003-A

SPECIALTY GUIDELINE MANAGEMENT

ENBREL (etanercept)

POLICY

I. 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.

A. FDA-Approved Indications
1. Moderately to severely active rheumatoid arthritis (RA)
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients aged 2 years and older
3. Active psoriatic arthritis (PsA)
4. Active ankylosing spondylitis (AS)
5. Chronic moderate to severe plaque psoriasis (PsO) in patients aged 4 years or older who are candidates for systemic therapy or phototherapy
6. Juvenile psoriatic arthritis in patients aged 2 years and older (JPsA)

B. Compendial Uses
1. Non-radiographic axial spondyloarthritis
2. Oligoarticular juvenile idiopathic arthritis
3. Reactive arthritis
4. Hidradenitis suppurativa, severe, refractory
5. Behcet's disease
6. Graft versus host disease
7. Immune checkpoint inhibitor-related toxicity

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
1. For initial requests:
   i. 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.
   ii. 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).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Articular juvenile idiopathic arthritis (JIA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), reactive arthritis, and hidradenitis suppurativa, immune checkpoint inhibitor-related inflammatory arthritis
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Plaque psoriasis (PsO)
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

E. 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.

F. Behcet's disease (initial requests only)
   Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

III. PRESCRIBER SPECIALTIES

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

A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, reactive arthritis, and Behcet's disease: rheumatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Plaque psoriasis: dermatologist
D. Graft versus host disease: oncologist or hematologist
E. Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
F. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or dermatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:
      a. Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Articular juvenile idiopathic arthritis (JIA)

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. Member has risk factors for disease severity and potentially a more refractory disease course (see Appendix B) and member also meets one of the following:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
      b. High disease activity.
      c. Is judged to be at high risk for disabling joint disease.

C. Psoriatic arthritis (PsA)

1. 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.

2. 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:

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

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:
   i. Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

E. Plaque psoriasis (PsO)

1. 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.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

F. Reactive arthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

2. Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:
   i. Member has had an inadequate response to methotrexate or sulfasalazine.
   ii. Member has an intolerance or contraindication to methotrexate (see Appendix A) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

G. Hidradenitis suppurativa

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of severe, refractory hidradenitis suppurativa.

2. Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:
   i. 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.
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

H. Graft versus host disease

Authorization of 12 months may be granted for treatment of graft versus host disease when either of the following criteria is met:
1. Member has had an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

I. Behcet's disease

1. 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.

2. 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).

J. Immune checkpoint inhibitor-related toxicity

1. 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.

2. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has severe immunotherapy-related inflammatory arthritis and meets either of the following:
   i. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
   ii. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Articular juvenile idiopathic arthritis (JIA)

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:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement

3. Functional ability

C. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

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:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Plaque psoriasis (PsO)

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:

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

F. Reactive arthritis

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).

G. Hidradenitis suppurativa

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:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline

4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

H. 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.

I. 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.

J. 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 Section IV 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.

VI. OTHER

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.

VII. 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.

VIII. APPENDICES

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Leflunomide, Cyclosporine, or Acitretin
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction

3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

IX. REFERENCES

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PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ENTRESTO
(sacubitril and valsartan)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Adult Heart Failure
Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal.

LVEF is a variable measure, so use clinical judgment in deciding whom to treat.

Pediatric Heart Failure
Entresto is indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older. Entresto reduces NT-proBNP and is expected to improve cardiovascular outcomes.

COVERAGE CRITERIA

Adult Heart Failure
Authorization may be granted when the requested drug is being prescribed to reduce the risk of cardiovascular death and hospitalization for heart failure when ALL of the following criteria are met:

- The patient is 18 years of age or older
- The patient has a diagnosis of symptomatic chronic heart failure and ONE of the following criteria are met:
    - The patient has ANY of the following: left ventricular ejection fraction less than or equal to 40 percent (i.e., Heart Failure with reduced Ejection Fraction [HFrEF]), previous left ventricular ejection fraction less than or equal to 40 percent and a follow-up left ventricular ejection fraction measurement of greater than 40 percent (i.e., Heart Failure with improved Ejection Fraction [HFimpEF]). [ACTION REQUIRED: Documentation is required for approval]. In addition, the patient meets ONE of the following criteria:
        - The patient will receive concomitant treatment with a maximally tolerated dose of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
        - The patient has experienced an intolerance to a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
        - The patient has a contraindication that would prohibit a trial of a beta-blocker (e.g., carvedilol, metoprolol succinate, bisoprolol)
    - The patient has ANY of the following: left ventricular ejection fraction of 41 to 49 percent (i.e., Heart Failure with mildly reduced Ejection Fraction [HFmrEF]), left ventricular ejection fraction greater than or equal to 50 percent (i.e., Heart Failure with preserved Ejection Fraction [HFpEF]). In addition, the patient meets the following criteria:

        - The patient has evidence or history of spontaneous or provokable increased left ventricular filling pressures (e.g., elevated natriuretic peptide, noninvasive and invasive hemodynamic measurement). [ACTION REQUIRED: Documentation is required for approval].
- If the patient has a diagnosis of diabetes, the requested drug will NOT be used in combination with Tekturna (aliskiren)
- If the patient has renal impairment (estimated Glomerular Filtration Rate [eGFR] less than 60 milliliters per minute per 1.73 meters squared [mL/min/1.73m^2]), 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)

DURATION OF APPROVAL (DOA)
- 1277-A: DOA: 36 months
- 1276-A: DOA: 12 months

REFERENCES

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Reference number(s)
2004-A

SPECIALTY GUIDELINE MANAGEMENT

ENTYVIO (vedolizumab)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Adult patients with moderately to severely active ulcerative colitis (UC).
   2. Adult patients with moderately to severely active Crohn's disease (CD).

B. Compendial Uses
   Immune checkpoint inhibitor-related toxicity

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

II. DOCUMENTATION

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

A. Ulcerative colitis (UC) and Crohn's disease (CD)
   Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

B. 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.

III. PRESCRIBER SPECIALTIES

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

A. Crohn's disease and ulcerative colitis: gastroenterologist
B. Immune checkpoint inhibitor-related toxicity: gastroenterologist, hematologist, or oncologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Ulcerative colitis (UC)
Authorization of 12 months may be granted for adult members for treatment of moderately to severely active ulcerative colitis.

B. Crohn's disease (CD)

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

C. Immune checkpoint inhibitor-related toxicity
Authorization of 6 months may be granted for the treatment of immune checkpoint inhibitor-related diarrhea or colitis when the member has experienced an inadequate response, intolerance, or contraindication to systemic corticosteroids or infliximab.

V. CONTINUATION OF THERAPY

A. Ulcerative colitis (UC)

1. 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 ulcerative colitis and who achieve or maintain remission.

2. 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 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

B. Crohn's disease (CD)

1. 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.

2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

C. Immune checkpoint inhibitor-related toxicity
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. OTHER

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. REFERENCES

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PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

EUCRISA
(crisaborole)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS
Eucrisa is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

COVERAGE CRITERIA

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The patient is 3 months of age or older
- The patient meets ONE of the following criteria:
  - The patient is less than 2 years of age
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds) and the following criteria is met:
    - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid
- If additional quantities are being requested, then 5 percent or greater body surface area is affected

CONTINUATION OF THERAPY

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for mild to moderate atopic dermatitis when ALL of the following criteria are met:

- The patient is 3 months of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]
- If additional quantities are being requested, then 5 percent or greater body surface area is affected

QUANTITY LIMITS APPLY
60 grams per 25 days* or 180 grams per 75 days*
Greater than 5% 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)
2413-A

SPECIALTY GUIDELINE MANAGEMENT

FASENRA (benralizumab)

POLICY

I. 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
Fasenra is indicated for:

A. Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype

Limitations of Use:
Not indicated for the relief of acute bronchospasm or status asthmaticus

B. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

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

II. DOCUMENTATION

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

A. Asthma:
   1. For initial requests:
      i. Chart notes or medical record documentation showing baseline blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. EGPA
   1. For initial requests:
      i. Chart notes or medical record documentation showing pretreatment blood eosinophil count.
      ii. 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.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

III. PRESCRIBER SPECIALTIES

For the indication of asthma: This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

IV. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. 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.

2. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   i. Member is 6 years of age or older.
   ii. Member meets either of the following criteria:
      a. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
      b. Member is dependent on systemic corticosteroids.
   iii. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      b. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
      c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
   iv. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
      a. High-dose inhaled corticosteroid
      b. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   v. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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

1. Member is 18 years of age or older.
2. 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%.
3. Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. Member has at least two of the following disease characteristics of EGPA:
   i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   iii. Pulmonary infiltrates, non-fixed
   iv. Sino-nasal abnormality
   v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   vii. Alveolar hemorrhage (by bronchoalveolar lavage)
   viii. Palpable purpura
   ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. 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.

V. CONTINUATION OF THERAPY

A. Asthma

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

1. Member is 6 years of age or older.
2. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. 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:

1. Member is 18 years of age or older.
2. Member has a beneficial response to treatment with the requested medication as demonstrated by any of the following:
   i. A reduction in the frequency of relapses
   ii. A reduction or discontinuation of daily oral corticosteroid dose
   iii. No active vasculitis

VI. 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.

VII. REFERENCES

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med.* 2017;376:2448-2458.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06-WMS.pdf. Accessed March 8, 2024.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 8, 2024.
5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA.* 2020;324(22): 2301-2317.
6. AstraZeneca. Efficacy and Safety of Benralizumab in EGPA Compared to Mepolizumab. (MANDARA) Available from https://clinicaltrials.gov/ct2/show/record/NCT04157348. NLM identifier: NCT04157348. Accessed September 20, 2024.
7. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force Recommendations for evaluation and management. *Eur J Intern Med*. 2015;26(7):545-553.

8. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. *Arthritis Rheumato*l. 2021;73(8):1366-1383.

Reference number(s)
1842-A

SPECIALTY GUIDELINE MANAGEMENT

GILENYA (fingolimod hydrochloride)
TASCENSO ODT (fingolimod lauryl sulfate)
fingolimod hydrochloride (generic)

POLICY

I. 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
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 patients 10 years of age and older.

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

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER

Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

VI. REFERENCES

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Fingolimod [package insert]. Weston, FL: Apotex Corp.; June 2024.
3. Tascenso ODT [package insert]. Swindon, UK: Catalent Pharma Solutions (UK); June 2024.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **GENERAL FORMULARY EXCEPTION**

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C25463-A***

CRITERIA FOR APPROVAL

1	Has the patient previously been through the CountyCare formulary exception process and has a received a prior authorization in the past 12 months? [If no, then skip to question 4.]	Yes	No
2	Is the patient established on the requested non-formulary drug? [If no, then no further questions.]	Yes	No
3	Does the patient have a documented positive clinical response to the requested therapy? [No further questions.]	Yes	No
4	Is the request for a drug that is within any of the following CMS protected drug classes: A) anticonvulsants, B) antidepressants, C) antineoplastics, D) antipsychotics, E) antiretrovirals, F) immunosuppressants? [If yes, then no further questions.]	Yes	No
5	Is the requested drug used to treat an urgent condition (e.g., situations requiring anticoagulation, acute psychotic episodes, acute bleeding, neutropenia)? [If yes, then no further questions.]	Yes	No
6	Is the patient on a stable regimen and disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation? [If yes, then no further questions.]	Yes	No
7	Is the drug being used for an FDA-approved (labeled) indication? [If yes, then skip to question 9.]	Yes	No
8	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [If no, then no further questions.]	Yes	No
9	Is the request for a glucose monitor or test strips? [If no, then skip to question 14.]	Yes	No

10	Is there a documented contraindication to a preferred glucose monitor or test strips pursuant to the pharmaceutical manufacturers prescribing information? [If yes, then no further questions.]	Yes	No
11	Is there documented medical rationale that the requested glucose monitor or test strips would be safer and/or more efficacious than using a formulary product? [If yes, then no further questions.]	Yes	No
12	Does the patient use an insulin pump that requires use of a specific meter and test strips? [Note: Insulin pump must already be approved on the patient's current plan.] [If yes, then no further questions.]	Yes	No
13	Is there documentation that use of a preferred product could result in one of the following to the patient: A) An adverse reaction, B) Decreased ability to achieve or maintain reasonable functional ability to do routine blood glucose testing and/or perform daily activities, or C) Physical or mental harm? [No further questions.]	Yes	No
14	Does the patient have a documented contraindication to preferred products pursuant to the pharmaceutical manufacturer's prescribing information? [If yes, then no further questions.]	Yes	No
15	Is there documented medical rationale that the requested product would be safer and/or more efficacious than using the formulary products? [If yes, then no further questions.]	Yes	No
16	Is there documentation that use of a preferred product could result in one of the following to the patient: A) An adverse reaction, B) Decreased ability to achieve or maintain reasonable functional ability in performing daily activities, or C) Physical or mental harm? [If yes, then no further questions.]	Yes	No
17	Has the patient tried and failed TWO clinically appropriate formulary alternatives within the requested drug class for the requested indication? [Note: If there are two clinically appropriate formulary alternatives AND the patient has tried and failed one preferred and one non-preferred agent within the same drug class and with the same indication, the non-preferred agent should be considered as meeting the requirement.] [If yes, then no further questions.]	Yes	No
18	Are there two or more clinically appropriate formulary alternatives within the requested drug class for the requested indication? [If yes, then no further questions.]	Yes	No
19	Has the patient tried and failed one preferred clinically appropriate formulary alternative within the requested drug class for the requested indication? [If yes, then no further questions.]	Yes	No
20	Is there a preferred clinically appropriate formulary alternative within the requested drug class for the requested indication? [If yes, then no further questions.]	Yes	No
21	Is the request for a combination agent? [If no, then skip to question 24.]	Yes	No

22	Has the patient tried the preferred single agents within the requested drug classes and indicated for the specified indication? [If yes, then no further questions.]	Yes	No
23	Has the patient tried and failed two clinically appropriate alternatives within the requested drug class for the requested indication? [If yes, then no further questions.] [If no, then skip to question 25.]	Yes	No
24	Has the patient tried and failed two clinically appropriate formulary alternatives, which are indicated for the specified diagnosis, or have compendia data or guideline data to support their use (the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation)? [If yes, then no further questions.]	Yes	No
25	Are there two or more clinically appropriate formulary alternatives, which are indicated for the specified diagnosis? [If yes, then no further questions.]	Yes	No
26	Has the patient tried and failed one clinically appropriate formulary alternative which is indicated for the specified diagnosis? [If yes, then no further questions.]	Yes	No
27	Is there a clinically appropriate formulary alternative which is indicated for the specified diagnosis?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

Written by: UM Development (VLS)
Date Written: 06/2023
Revised: (VLS) 04/2024
Reviewed: Medical Affairs: (APN) 08/2023, 11/2023, 07/2024

Reference number(s)
6086-C

Initial Prior Authorization with Quantity Limit
Glucose-Dependent Insulinotropic Polypeptide (GIP)/Glucagon-Like Peptide 1 (GLP-1) Receptor Agonist
Mounjaro

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
Mounjaro	tirzepatide

FDA-approved Indications

Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

Reference number(s)
6086-C

Coverage Criteria

Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when ALL of the following criteria are met:

- The patient meets ONE of the following:
    - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
        - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months

Continuation of Therapy

Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when ALL of the following criteria are met:

- The patient meets ONE of the following:
    - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]

    - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
        - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months
    - The patient has demonstrated a reduction in A1C since starting this therapy

Quantity Limits Apply

4 single-dose pens or single-dose vials (2 mL) per 21 days OR 12 single-dose pens or single-dose vials (6 mL) 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.

Duration of Approval (DOA)

- 6086-C: DOA: 12 months

References

1. Mounjaro [package insert]. Indianapolis, IN: Lilly USA, LLC; July 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 11, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/11/2024).
4. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. Diabetes Care. 2024;47(Suppl. 1):S1-S322.

Reference number(s)
1841-A

SPECIALTY GUIDELINE MANAGEMENT

COPAXONE (glatiramer acetate)
GLATOPA (glatiramer acetate)
glatiramer acetate

POLICY

I. 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
Indicated for the treatment of patients with 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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. CONTINUATION OF THERAPY

For all indications: Authorization of 12 months may be granted for members who are experiencing disease stability or improvement while receiving Copaxone, Glatopa, or glatiramer acetate.

V. OTHER

Members will not use Copaxone, Glatopa, or glatiramer acetate concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

VI. REFERENCES

1. Copaxone [package insert]. Parsippany, NY: Teva Pharmaceuticals USA, Inc.; November 2023.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; December 2023.
3. Glatiramer acetate 20mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
4. Glatiramer acetate 40mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2024.
5. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. April 14, 2024.
6. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 14, 2024.
7. The Multiple Sclerosis Coalition. *The use of disease-modifying therapies in multiple sclerosis: principles and current evidence.* https://ms-coalition.org/wp-content/uploads/2019/06/MSC_DMTPaper_062019.pdf. Accessed March 01, 2024.

Reference number(s)
3318- C

Initial Prior Authorization with Quantity Limit
Glucagon-Like Peptide 1 (GLP-1) Receptor Agonist
Rybelsus

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
Rybelsus	semaglutide

Indications

FDA-Approved Indications

Rybelsus is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Rybelsus has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Rybelsus is not indicated for use in patients with type 1 diabetes mellitus.

Coverage Criteria

Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when ALL of the following criteria are met:

- The patient meets ONE of the following:
    - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
        - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient has NOT been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza] and ONE of the following criteria are met:
    - The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to metformin
    - The patient requires combination therapy AND has an A1C of 7.5 percent or greater

Continuation of Therapy

Type 2 Diabetes Mellitus

Authorization may be granted for a diagnosis of type 2 diabetes mellitus when ALL of the following criteria are met:

- The patient meets ONE of the following:
    - The patient has a history of an A1C greater than or equal to 6.5 percent. [ACTION REQUIRED: Documentation is required for approval.]

    - The patient has a history of a 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test (OGTT). [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of symptoms of hyperglycemia (e.g., polyuria, polydipsia, polyphagia) or hyperglycemic crisis and a random plasma glucose greater than or equal to 200 mg/dL. [ACTION REQUIRED: Documentation is required for approval.]
    - The patient has a history of a fasting plasma glucose (FPG) greater than or equal to 126 mg/dL [ACTION REQUIRED: Documentation is required for approval.] when the following criteria is met:
        - The patient fasted for at least 8 hours prior to the fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- The patient has been receiving a stable maintenance dose of a GLP-1 (glucagon-like peptide 1) Agonist for at least 3 months [Note: Examples of GLP-1 Agonists are Adlyxin, Bydureon, Byetta, Ozempic, Rybelsus, Trulicity, Victoza] and the following criteria is met:
    - The patient has demonstrated a reduction in A1C since starting GLP-1 Agonist therapy

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)

- 3318-C: 12 months

References

1. Rybelsus [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; January 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed March 11, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 03/11/2024).
4. Blonde L, Umpierrez GE, Reddy SS et. al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan – 2022 Update. Endocr Pract. 2022;28(10):923-1049.
5. Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.

6. American Diabetes Association Professional Practice Committee. American Diabetes Association, Standards of Care in Diabetes – 2024. Diabetes Care. 2024;47(Suppl. 1):S1-S322.
7. Samson SL, Vellank P, Blonde L, et. Al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. Endocr Pract. 2023; 29: 305-340.

Reference number(s)
1905-A

SPECIALTY GUIDELINE MANAGEMENT

HERCEPTIN (trastuzumab)
OGIVRI (trastuzumab-dkst)
KANJINTI (trastuzumab-anns)
TRAZIMERA (trastuzumab-qyyp)
HERZUMA (trastuzumab-pkrb)
ONTRUZANT (trastuzumab-dttb)
HERCESSI (trastuzumab-strf)

POLICY

I. 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.

A. FDA-Approved Indications
1. Adjuvant breast cancer
   Adjuvant treatment of human epidermal growth factor receptor 2 (HER2)-overexpressing node positive or node negative (estrogen receptor (ER)/progesterone receptor (PR) negative or with one high risk feature) breast cancer:
   a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   b. As part of a treatment regimen with docetaxel and carboplatin
   c. As a single agent following multi-modality anthracycline based therapy
2. Metastatic breast cancer
   a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
   b. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
3. Metastatic gastric cancer
   In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease

B. Compendial Uses
1. HER2-positive breast cancer
   a. Neoadjuvant therapy
   b. Treatment of recurrent, advanced, unresectable, or stage IV (M1) disease
   c. Treatment for no response to preoperative systemic therapy
2. Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from HER2-positive breast cancer
3. HER2-positive esophageal and esophagogastric junction cancer
4. HER2-positive uterine serous carcinoma and carcinosarcoma
5. HER2-amplified/positive and RAS and BRAF wild-type colorectal cancer
6. HER2-positive salivary gland tumor
7. HER2-positive biliary tract cancers

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status (where applicable), RAS mutation status (where applicable), BRAF mutation status (where applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer

1. Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.
2. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
3. Authorization of 12 months may be granted for treatment of HER2-positive breast cancer with no response to preoperative systemic therapy, recurrent, advanced, unresectable, or metastatic (including brain metastases) disease.
4. Authorization of 12 months may be granted for intra-CSF treatment for leptomeningeal metastases from HER2-positive breast cancer.

B. Esophageal, Gastric, or Esophagogastric Junction Cancer

Authorization of 12 months may be granted for treatment or palliative therapy of HER2-positive esophageal, gastric, or esophagogastric junction cancer in combination with chemotherapy.

C. Uterine Serous Carcinoma or Carcinosarcoma

Authorization of 12 months may be granted for treatment of HER2-positive stage III-IV, recurrent, or metastatic uterine serous carcinoma or carcinosarcoma in combination with carboplatin and paclitaxel.

D. Colorectal Cancer

Authorization of 12 months may be granted for treatment of unresectable, inoperable, advanced, or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, when all of the following criteria are met:

1. Member has HER2-positive/amplified disease
2. The disease is negative (wild-type) for RAS (KRAS and NRAS) and BRAF mutations
3. The requested medication will be used in combination with tucatinib, pertuzumab, or lapatinib
4. Member has received prior therapy for the disease or is not appropriate for intensive therapy

E. Salivary Gland Tumor

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic HER2-positive salivary gland tumors when used as a single agent or in combination with docetaxel or pertuzumab.

F. Biliary Tract Cancers

Authorization of 12 months may be granted for subsequent treatment of unresectable, resected gross residual, or metastatic HER2-positive biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer) when used in combination with pertuzumab or tucatinib.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

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Reference number(s)
3017-A

SPECIALTY GUIDELINE MANAGEMENT

HERCEPTIN HYLECTA (trastuzumab and hyaluronidase-oysk)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Herceptin Hylecta is indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer:
      a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. As part of a treatment regimen with docetaxel and carboplatin
      c. As a single agent following multi-modality anthracycline based therapy

   2. Herceptin Hylecta is indicated in adults:
      a. In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
      b. As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease

B. Compendial Uses
   HER2-positive breast cancer: may be substituted for intravenous trastuzumab and used as a single agent or in combination with other systemic therapies

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

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

Breast Cancer

1. Authorization of up to 12 months may be granted for adjuvant treatment of HER2-positive breast cancer.
2. Authorization of 12 months may be granted for treatment of HER2-positive breast cancer with no response to preoperative systemic therapy, recurrent, unresectable, advanced, or metastatic (including brain metastases) disease.
3. Authorization of up to 12 months may be granted for neoadjuvant treatment of HER2-positive breast cancer as part of a complete treatment regimen.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication outlined in section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. Adjuvant and neoadjuvant treatment of breast cancer will be approved for a total of 12 months of therapy.

V. REFERENCES

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Reference number(s)
2008-A

SPECIALTY GUIDELINE MANAGEMENT

HUMIRA (adalimumab)
ABRILADA (adalimumab-afzb)
AMJEVITA (adalimumab-atto)
CYLTEZO (adalimumab-adbm)
HADLIMA (adalimumab-bwwd)
HULIO (adalimumab-fkjp)
HYRIMOZ (adalimumab-adaz)
IDACIO (adalimumab-aacf)
SIMLANDI (adalimumab-ryvk)
YUFLYMA (adalimumab-aaty)
YUSIMRY (adalimumab-aqvh)
adalimumab
adalimumab-aacf
adalimumab-aaty
adalimumab-adaz
adalimumab-adbm
adalimumab-fkjp
adalimumab-ryvk

POLICY

I. 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.

A. FDA-Approved Indications
1. Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).
2. Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older.
3. Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (PsA).
4. Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS).
5. The treatment of moderately to severely active Crohn's disease (CD) in adult and pediatric patients 6 years of age and older.
6. The treatment of moderately to severely active ulcerative colitis (UC) in adults and pediatric patients 5 years of age and older.
   Limitations of Use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to tumor necrosis factor (TNF) blockers.

7. The treatment of adult patients with moderate to severe chronic plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
8. The treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.
9. The treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

B. Compendial Uses
1. Non-radiographic axial spondyloarthritis
2. Behcet's disease
3. Pyoderma gangrenosum
4. Oligoarticular juvenile idiopathic arthritis
5. Immune checkpoint inhibitor-related toxicity- inflammatory arthritis

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
1. Initial requests:
   i. 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.
   ii. 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).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Articular juvenile idiopathic arthritis (JIA)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), hidradenitis suppurativa, uveitis (non-infectious intermediate, posterior and panuveitis), and immune checkpoint inhibitor-related toxicity
1. 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.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Crohn’s disease (CD)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E. Ulcerative colitis (UC)

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

F. Plaque psoriasis (PsO)
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

G. Behcet's disease: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

H. Pyoderma gangrenosum (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.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, articular juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and Behcet's disease: rheumatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Crohn's disease and ulcerative colitis: gastroenterologist
D. Plaque psoriasis and pyoderma gangrenosum: dermatologist
E. Uveitis: ophthalmologist or rheumatologist
F. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when both of the following are criteria are met:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:

a. Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Articular juvenile idiopathic arthritis (JIA)

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. 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:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip)
      b. High disease activity
      c. Is judged to be at high risk for disabling joint disease

C. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:

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

E. Crohn's disease (CD)
Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active CD.

F. Ulcerative colitis (UC)
Authorization of 12 months may be granted for members 5 years of age or older for treatment of moderately to severely active ulcerative colitis.

G. Plaque psoriasis (PsO)
1. 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.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix A).

H. Hidradenitis suppurativa
1. Authorization of 12 months may be granted for members 12 years of age or older who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.

2. Authorization of 12 months may be granted for members 12 years of age or older for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
   i. 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).
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

I. Uveitis (non-infectious intermediate, posterior and panuveitis)
1. Authorization of 12 months may be granted for members 2 years of age or older who have previously received a biologic indicated for non-infectious intermediate, posterior, and panuveitis.

2. Authorization of 12 months may be granted for members 2 years of age or older for treatment of non-infectious intermediate, posterior and panuveitis when either of the following is met:
   i. Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).

J. Behcet's disease

1. 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.

2. 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).

K. Pyoderma gangrenosum

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.

2. Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:
   i. Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine or mycophenolate mofetil).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

L. Immune checkpoint inhibitor-related toxicity

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

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

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Articular juvenile idiopathic arthritis (JIA)

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:

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

C. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints

2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
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:
1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Crohn's disease (CD)
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 moderately to severely active Crohn's disease and who achieve or maintain remission.

2. 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 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

F. Ulcerative colitis (UC)
1. Authorization of 12 months may be granted for all members 5 years of age and older (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members 5 years of age and older (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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation

iv. C-reactive protein (CRP)
v. Fecal calprotectin (FC)
vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

G. Plaque psoriasis (PsO)

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:

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

H. Hidradenitis suppurativa

Authorization of 12 months may be granted for all members 12 years of age and older (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:

1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

I. Uveitis (non-infectious intermediate, posterior and panuveitis)

Authorization of 12 months may be granted for all members 2 years of age and older (including new members) who are using the requested medication for non-infectious intermediate, posterior, and panuveitis 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:

1. Reduced frequency of disease flares compared to baseline
2. Stability or improvement in anterior chamber (AC) cell grade compared to baseline
3. Stability or improvement in vitreous haze (VH) grade compared to baseline
4. Stability or improvement in visual acuity compared to baseline
5. Reduction in glucocorticoid requirements from baseline
6. No new active inflammatory chorioretinal and/or inflammatory retinal vascular lesions relative to baseline

J. 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.

K. 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 Section IV and who achieve or maintain a positive

clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. For rheumatoid arthritis, member must initiate treatment with every other week dosing.

VIII. APPENDICES

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

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

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

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Reference number
1801-A

SPECIALTY GUIDELINE MANAGEMENT

ILARIS (canakinumab)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Periodic Fever Syndromes:
      a. 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).
      b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
         Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients.
      c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
         Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients.
      d. Familial Mediterranean Fever (FMF)
         Ilaris is indicated for the treatment of FMF in adult and pediatric patients.
   2. 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 aged 2 years and older.
   3. 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.

B. Compendial Use
   Pseudogout

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

II. DOCUMENTATION

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

A. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) and Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD): For 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.

B. Familial Mediterranean Fever (FMF) (initial requests only):

1. Chart notes or medical record documentation indicating number of active flares within the last 6 months.
2. Laboratory results, chart notes, or medical record documentation of CRP level.
3. 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.

C. Systemic Juvenile Idiopathic Arthritis (sJIA) and Adult-onset Still's disease (AOSD)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. 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.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Cryopyrin-associated periodic syndromes (CAPS), TRAPS, HIDS/MKD, and FMF: rheumatologist or immunologist
B. Systemic juvenile idiopathic arthritis (sJIA), AOSD, gout, and pseudogout: rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Periodic fever syndromes

1. 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:
   a. 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).
   b. Member has functional impairment limiting the activities of daily living.

2. Authorization of 12 months may be granted for treatment of TRAPS when both of the following criteria are met:
   a. Member has chronic or recurrent disease activity with active flares within the last 6 months.
   b. Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

3. Authorization of 12 months may be granted for treatment of HIDS/MKD when both of the following criteria are met:
   a. Member has had active flares within the last 6 months.
   b. Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

4. Authorization of 12 months may be granted for treatment of FMF when all of the following criteria are met:
   a. Member has active disease with flares within the last 6 months.
   b. C-reactive protein (CRP) greater than 10 mg/L.
   c. Member has had an inadequate response or intolerance to or has a contraindication to colchicine.

B. Systemic juvenile idiopathic arthritis (sJIA)

1. 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.

2. Authorization of 12 months may be granted for members 2 years of age or older for treatment of active sJIA when both of the following criteria are met:
   a. Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).
   b. Member has had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids.

C. Adult-onset Still's disease (AOSD)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for active AOSD.

2. Authorization of 12 months may be granted for adult members for treatment of active AOSD when both of the following criteria are met:
   a. Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
   b. Member meets any of the following:
      i. Member has had an inadequate response to a trial of non-steroidal anti-inflammatory drugs (NSAIDs).
      ii. Member has had an inadequate response to a trial of corticosteroids.
      iii. Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

D. Gout and pseudogout flares

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:

1. Member has experienced at least three flares in the last 12 months.
2. Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

V. CONTINUATION OF THERAPY

A. Systemic juvenile idiopathic arthritis (sJIA)

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:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement

3. Functional ability
4. Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

B. Adult-onset Still's disease (AOSD)

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:

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

C. Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

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.

D. 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 Section IV and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

VI. OTHER

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.

VII. REFERENCES

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Reference number
2538-A

SPECIALTY GUIDELINE MANAGEMENT

ILUMYA (tildrakizumab-asmn)

POLICY

I. 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
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.

II. DOCUMENTATION

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

A. Initial requests:
   1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   2. 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.

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

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Plaque psoriasis (PsO)

A. 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.

B. 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:
   1. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. At least 10% of body surface area (BSA) is affected.
   3. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:

i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

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

VI. 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 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.

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

IX. REFERENCES

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Reference number
2182-A

SPECIALTY GUIDELINE MANAGEMENT

REMICADE (infliximab)
AVSOLA (infliximab-axxq)
INFLECTRA (infliximab-dyyb)
RENFLEXIS (infliximab-abda)
ZYMFENTRA (infliximab-dyyb)
infliximab

POLICY

I. 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.

A. FDA-Approved Indications
1. infliximab/Avsola/Inflectra/Remicade/Renflexis
   i. Adult patients with moderately to severely active Crohn's disease (CD) and fistulizing CD who have had an inadequate response to conventional therapy
   ii. 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
   iii. Moderately to severely active ulcerative colitis (UC) in patients 6 years of age or older who have had an inadequate response to conventional therapy
   iv. Adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
   v. Adult patients with active ankylosing spondylitis (AS)
   vi. Adult patients with active psoriatic arthritis (PsA)
   vii. Adult patients with chronic severe plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

2. Zymfentra
   i. Maintenance treatment of moderately to severely active ulcerative colitis in adults following treatment with an infliximab product administered intravenously
   ii. Maintenance treatment of moderately to severely active Crohn's disease in adults following treatment with an infliximab product administered intravenously

B. Compendial Uses
1. Non-radiographic axial spondyloarthritis
2. Behcet's disease
3. Hidradenitis suppurativa
4. Pyoderma gangrenosum
5. Sarcoidosis
6. Takayasu's arteritis
7. Uveitis

8. Reactive arthritis
9. Immune checkpoint inhibitor-related toxicity
10. Acute graft versus host disease
11. Moderate to severe plaque psoriasis

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

II. DOCUMENTATION

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

A. Crohn's disease (CD) and ulcerative colitis (UC)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

B. Rheumatoid arthritis (RA)
   1. For initial requests:
      i. 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.
      ii. 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).
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), reactive arthritis, hidradenitis suppurativa, uveitis, and immune checkpoint inhibitor-related inflammatory arthritis
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D. Plaque psoriasis (PsO)
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

E. Behcet's disease (initial requests only)
Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).

F. 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.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Crohn's disease and ulcerative colitis: gastroenterologist
B. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Behcet's disease, Takayasu's arteritis, and reactive arthritis: rheumatologist
C. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
D. Plaque psoriasis and pyoderma gangrenosum: dermatologist
E. Sarcoidosis: dermatologist, pulmonologist, rheumatologist, cardiologist, neurologist, or ophthalmologist
F. Uveitis: ophthalmologist or rheumatologist
G. Immune checkpoint inhibitor-related inflammatory arthritis: oncologist, hematologist, or rheumatologist
H. Immune checkpoint inhibitor-related toxicity and acute graft versus host disease: oncologist or hematologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Crohn's disease (CD)

1. Avsola/Inflectra/infliximab/Remicade/Renflexis
Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active CD.

2. Zymfentra
Authorization of 12 months may be granted for adult members for treatment of moderately to severely active CD.

B. Ulcerative colitis (UC)

1. Avsola/Inflectra/infliximab/Remicade/Renflexis
Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active UC.

2. Zymfentra
Authorization of 12 months may be granted for adult members for treatment of moderately to severely active UC.

C. Rheumatoid arthritis (RA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. 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. 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).

2. 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:

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

ii. 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).

iii. Member meets either of the following criteria:
   a. Member has had an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
   b. Member has an intolerance or contraindication to methotrexate (see Appendix).

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. 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.

2. 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:
   i. Member has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

E. Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis or predominantly axial disease.
   ii. Member has severe disease.

F. Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. 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.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

ii. At least 10% of body surface area (BSA) is affected.
iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
   a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
   b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

G. Behcet's disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for treatment of Behcet's disease.

2. 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).

H. Hidradenitis suppurativa (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of severe, refractory hidradenitis suppurativa.

2. Authorization of 12 months may be granted for treatment of severe, refractory hidradenitis suppurativa when either of the following is met:
   i. 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.
   ii. Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

I. Pyoderma gangrenosum (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for treatment of pyoderma gangrenosum.

2. Authorization of 12 months may be granted for treatment of pyoderma gangrenosum when either of the following is met:
   i. Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., cyclosporine, mycophenolate mofetil).

J. Sarcoidosis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

Authorization of 12 months may be granted for treatment of sarcoidosis in members when either of the following criteria is met:
1. Member has had an inadequate response to corticosteroids or immunosuppressive therapy.
2. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy.

K. Takayasu's arteritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

Authorization of 12 months may be granted for treatment of refractory Takayasu's arteritis when either of the following criteria is met:
1. Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil).

2. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate mofetil).

L. Uveitis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for members who have previous received a biologic indicated for uveitis.

2. Authorization of 12 months may be granted for treatment of uveitis when either of the following criteria is met:
   i. Member has had an inadequate response to corticosteroids or immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
   ii. Member has an intolerance or contraindication to corticosteroids and immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).

M. Reactive arthritis (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for reactive arthritis.

2. Authorization of 12 months may be granted for treatment of reactive arthritis when either of the following criteria is met:
   i. Member has had an inadequate response to methotrexate or sulfasalazine.
   ii. Member has an intolerance or contraindication to methotrexate (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

N. Immune checkpoint inhibitor-related toxicity (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

1. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has severe immunotherapy-related inflammatory arthritis and meets either of the following:
   i. Member has had an inadequate response to corticosteroids or a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).
   ii. Member has an intolerance or contraindication to corticosteroids and a conventional synthetic drug (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine).

2. Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when either of the following criteria is met:
   i. Member has had an inadequate response to systemic corticosteroids.
   ii. Member has an intolerance or contraindication to corticosteroids.

O. Acute graft versus host disease (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

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

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

V. CONTINUATION OF THERAPY

A. Crohn's disease (CD)

1. Authorization of 12 months may be granted for all members 6 years of age or older (adult members for Zymfentra requests) (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members 6 years of age or older (adult members for Zymfentra requests) (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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

B. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for all members 6 years of age or older (adult members for Zymfentra requests) (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members 6 years of age or older (adult members for Zymfentra requests) (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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

C. Rheumatoid arthritis (RA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

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.

D. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)

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:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)

4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E. Psoriatic arthritis (PsA) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)
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:
1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

F. Plaque psoriasis (PsO) (Avsola/Inflectra/infliximab/Remicade/Renflexis only)
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:
1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

G. Hidradenitis suppurativa (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 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:
1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

H. Uveitis (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 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:
1. Reduced frequency of flare recurrence compared to baseline
2. Zero anterior chamber inflammation or reduction in anterior chamber inflammation compared to baseline
3. Decreased reliance on topical corticosteroids

I. Reactive 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 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).

J. 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.

K. 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 initial authorization criteria.

L. 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 Section IV and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction

3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

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1750-A

SPECIALTY GUIDELINE MANAGEMENT

INGREZZA (valbenazine)

POLICY

I. 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 adults with:
A. Tardive dyskinesia
B. Chorea associated with Huntington's disease

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for initial requests:
A. Tardive dyskinesia: Chart notes or medical record documentation of clinical manifestations of disease.
B. Chorea associated with Huntington's disease: Chart notes or medical record documentation of characteristic motor examination features.

III. CRITERIA FOR INITIAL APPROVAL

A. Tardive dyskinesia
Authorization of 6 months may be granted for treatment of tardive dyskinesia when both of the following criteria are met:
1. Member exhibits clinical manifestations of disease.
2. 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]).

B. Chorea associated with Huntington's disease
Authorization of 6 months may be granted for treatment of chorea associated with Huntington's disease when both of the following criteria are met:
1. Member demonstrates characteristic motor examination features.
2. Member meets one of the following conditions:
   i. Laboratory results indicate an expanded *HTT* CAG repeat sequence of at least 36
   ii. Member has a positive family history for Huntington's disease

IV. CONTINUATION OF THERAPY

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

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Reference number(s)
1703-A

SPECIALTY GUIDELINE MANAGEMENT

INTRON A (interferon alfa-2b)

POLICY

I. 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.

A. FDA-Approved Indications
1. Malignant melanoma
2. Condylomata acuminata
3. Hairy cell leukemia
4. AIDS-related Kaposi sarcoma
5. Chronic hepatitis B virus infection
6. Chronic hepatitis C virus infection
7. Follicular non-Hodgkin's lymphoma

B. Compendial Uses
1. Renal cell carcinoma
2. Chronic myeloid leukemia (CML)
3. Ocular surface neoplasia (conjunctival and corneal neoplasm)

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

II. CRITERIA FOR INITIAL APPROVAL

A. Malignant melanoma
Authorization of 12 months may be granted for treatment of malignant melanoma.

B. Hairy cell leukemia
Authorization of 6 months may be granted for treatment of hairy cell leukemia.

C. Follicular lymphoma
Authorization of 12 months may be granted for treatment of follicular lymphoma (clinically aggressive).

D. Renal cell carcinoma
Authorization of 12 months may be granted for treatment of renal cell carcinoma when the requested medication will be used in combination with bevacizumab.

E. Condylomata acuminata
Authorization of 12 months may be granted for treatment of condylomata acuminata.

F. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma

G. Chronic myeloid leukemia (CML)
Authorization of 6 months may be granted for treatment of CML.

H. Chronic hepatitis C virus infection
Authorization of 16 weeks may be granted for treatment of chronic hepatitis C virus infection.

I. Chronic hepatitis B (including hepatitis D virus co-infection) virus infection
Authorization of 16 weeks may be granted for treatment of chronic hepatitis B (including hepatitis D virus co-infection) virus infection.

J. Ocular surface neoplasia (conjunctival and corneal neoplasm)
Authorization of 12 months may be granted for treatment of ocular surface neoplasia (conjunctival and corneal neoplasm).

III. CONTINUATION OF THERAPY

A. Chronic Hepatitis C
Authorization of 52 weeks, up to a total of 96 weeks, may be granted for continued treatment of chronic hepatitis C when the member is receiving clinical benefit and there is no evidence of unacceptable toxicity while on the current regimen.

B. Chronic Hepatitis B
Authorization of up to a total of 24 weeks may be granted for continued treatment of chronic hepatitis B when the member is receiving clinical benefit and there is no evidence of unacceptable toxicity while on the current regimen.

C. Hairy Cell Leukemia
Authorization of up to a total of 6 months may be granted for continued treatment of hairy cell leukemia when the member is receiving clinical benefit and there is no evidence of unacceptable toxicity while on the current regimen.

D. All Other Indications
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II, other than hairy cell leukemia, chronic hepatitis C and chronic hepatitis B, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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Reference number(s)
4129-A

SPECIALTY GUIDELINE MANAGEMENT

KESIMPTA (ofatumumab)

POLICY

I. 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
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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER CRITERIA

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

VI. REFERENCES

Reference number(s)
4129-A

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Reference number
1957-A

SPECIALTY GUIDELINE MANAGEMENT

KEVZARA (sarilumab)

POLICY

I. 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

A. 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).
B. Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.
C. Patients with active polyarticular juvenile idiopathic arthritis (pJIA) who weigh 63 kg or greater

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis
    1. Initial requests:
        i. 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.
        ii. 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).
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Polymyalgia rheumatica
    1. 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.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Polyarticular juvenile idiopathic arthritis
    1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. Member meets either of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Polymyalgia rheumatica (PMR)

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

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has experienced a disease flare during a taper with systemic corticosteroids.
3. Member has experienced an inadequate response to methotrexate.
4. Member has experienced an intolerance or contraindication to both systemic corticosteroids and methotrexate (see Appendix A).

C. Polyarticular juvenile idiopathic arthritis

1. Authorization of 12 months may be granted for members weighing 63 kg or greater who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active polyarticular juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for members weighing 63 kg or greater for treatment of active polyarticular juvenile idiopathic arthritis when any of the following criteria is met:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers

e. Symmetric disease

iii. 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:
   a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
   b. High disease activity.
   c. Is judged to be at high risk for disabling joint disease.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Polymyalgia rheumatica (PMR)

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:

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

C. Polyarticular juvenile idiopathic arthritis

Authorization of 12 months may be granted for all members (including new members) weighing 63 kg or 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:

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

VI. OTHER

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* 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. 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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

Appendix A: Examples of Contraindications to Methotrexate

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

Appendix B: Risk factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

IX. REFERENCES

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Reference number
1802-A

SPECIALTY GUIDELINE MANAGEMENT

KINERET (anakinra)

POLICY

I. 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.

A. 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)
2. Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

B. Compendial Uses
1. Systemic juvenile idiopathic arthritis (sJIA)
2. Adult-onset Still's disease (AOSD)
3. Multicentric Castleman disease
4. Recurrent pericarditis (RP)
5. Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
6. Schnitzler syndrome
7. Gout and pseudogout (calcium pyrophosphate deposition)
8. Chimeric antigen receptor (CAR) T-Cell-Related Toxicities – Cytokine release syndrome (CRS)
9. Erdheim-Chester Disease

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
1. For initial requests
   i. 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.
   ii. 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).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Neonatal-onset multisystem inflammatory disease (NOMID): For continuation requests: Chart notes, medical record documentation, or laboratory results supporting positive clinical response.

D. Deficiency of interleukin-1 receptor antagonist (DIRA): For initial requests: *IL1RN* mutation status.

E. Recurrent pericarditis (RP)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

F. Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD): For 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.

G. Gout and pseudogout flares and CAR T-Cell-related toxicities: For 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.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis (RA), adult-onset Still's disease (AOSD), systemic juvenile idiopathic arthritis (sJIA), gout, and pseudogout: rheumatologist
B. 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
C. Recurrent pericarditis (RP): cardiologist, rheumatologist, or immunologist
D. Schnitzler syndrome: rheumatologist, dermatologist, or immunologist
E. Multicentric Castleman disease, CAR T-cell-related toxicities, and Erdheim-Chester disease: oncologist or hematologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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.

2. 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:
   i. Member meets either of the following criteria:

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

ii. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week), or the member has an intolerance or contraindication to methotrexate (see Appendix).

B. Adult-onset Still's disease (AOSD)

1. Authorization of 12 months may be granted for members who have received a biologic indicated for active adult-onset Still's disease.

2. Authorization of 12 months may be granted for treatment of active adult-onset Still's disease when both of the following criteria are met:
   i. Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
   ii. Member meets any of the following:
      a. Member has had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs).
      b. Member has had an inadequate response to a trial of corticosteroids.
      c. Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

C. Systemic juvenile idiopathic arthritis (sJIA)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active systemic juvenile idiopathic arthritis.

2. Authorization of 12 months may be granted for treatment of active systemic juvenile idiopathic arthritis when both of the following criteria are met:
   i. Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis).
   ii. Member has had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids.

D. Neonatal-onset multisystem inflammatory disease (NOMID)

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).

E. Deficiency of interleukin-1 receptor antagonist (DIRA)

Authorization of 12 months may be granted for treatment of genetically confirmed deficiency of interleukin-1 receptor antagonist (DIRA) due to *IL1RN* mutations.

F. Recurrent pericarditis (RP)

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

1. Member has had at least two episodes of pericarditis.

2. Member has failed at least 2 agents of standard therapy (e.g., colchicine, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroids).

G. Multicentric Castleman disease

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

1. The requested medication will be used as a single agent.
2. The disease has progressed following treatment of relapsed/refractory or progressive disease.

H. Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Authorization of 12 months may be granted for treatment of HIDS/MKD when both of the following criteria are met:

1. Member has had active flares within the last 6 months.
2. Physician's Global Assessment (PGA) score greater than or equal to 2 or C-reactive protein (CRP) greater than 10 mg/L.

I. Schnitzler syndrome

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

1. 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).
2. 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.

J. Gout and pseudogout flares

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:

1. Member has experienced at least three gout flares in the last 12 months.
2. Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

K. Cytokine release syndrome (CRS)

Authorization of 1 month may be granted for the management of chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome when either of the following criteria is met:

1. Cytokine release syndrome is refractory to high-dose corticosteroids and anti-IL-6 therapy.
2. Kineret will be used as a replacement for the second dose of tocilizumab when supplies are limited or unavailable.

L. Erdheim-Chester Disease

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

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Adult-onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)
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:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability
4. Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

C. Neonatal-onset multisystem inflammatory disease (NOMID)
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:
1. Fever
2. Skin rash
3. Joint pain and/or inflammation
4. Central nervous system (CNS) symptoms (e.g., meningitis, headache, cerebral atrophy, uveitis, hearing loss)
5. Inflammatory markers (e.g., serum amyloid A [SAA], C-reactive protein [CRP], erythrocyte sedimentation rate [ESR])

D. Recurrent pericarditis (RP)
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:
1. Pericarditic or pleuritic chest pain
2. Pericardial or pleural rubs
3. Findings on electrocardiogram (ECG)
4. Pericardial effusion
5. C-reactive protein (CRP)

E. 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.

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

G. 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 Section IV and who achieve or maintain a positive

clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX: Examples of clinical reasons to avoid pharmacologic treatment with methotrexate

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

IX. REFERENCES

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Reference number(s)
2104-A

Specialty Guideline Management
Kisqali Femara Co-Pack

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
Kisqali Femara Co-Pack	ribociclib tablets; letrozole tablets

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

Kisqali Femara Co-Pack is indicated for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

Kisqali Femara Co-Pack is indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

Compendial Uses

- Breast cancer
- Endometrial carcinoma

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 members requesting initiation of therapy for the treatment of breast cancer: documentation of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status.
- For members requesting initiation of therapy for the treatment of endometrial carcinoma: documentation of laboratory results confirming estrogen receptor (ER) status.

Coverage Criteria

Breast cancer

Authorization of 12 months may be granted to members for the treatment of HR-positive, HER2-negative recurrent, advanced or metastatic breast cancer.

Authorization of 12 months may be granted to members for adjuvant treatment of HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence.

Endometrial carcinoma

Authorization of 12 months may be granted to members for treatment of advanced, recurrent or metastatic endometrial carcinoma with ER-positive tumors.

Continuation of Therapy

Early Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of early-stage, HR-positive, HER2-negative breast cancer with high risk of recurrence until completion of 3 years of treatment or until disease recurrence or unacceptable toxicity while on the current regimen.

Recurrent, Advanced, or Metastatic Breast Cancer or Endometrial Carcinoma

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic breast cancer or endometrial carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Reference number(s)
2104-A

References

1. Kisqali Femara Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.
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Reference number(s)
1639-A

Specialty Guideline Management
Kisqali

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
Kisqali	ribociclib

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

Kisqali is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence.

Kisqali is indicated for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with:

- An aromatase inhibitor as initial endocrine-based therapy; or
- Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy.

Compendial Uses

- Breast cancer

- Endometrial carcinoma

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 members requesting initiation of therapy for the treatment of breast cancer: documentation of laboratory results confirming hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status.
- For members requesting initiation of therapy for the treatment of endometrial carcinoma: documentation of laboratory results confirming estrogen receptor (ER) status.

Coverage Criteria

Breast cancer

Authorization of 12 months may be granted to members for treatment of HR-positive, HER2-negative recurrent, advanced, or metastatic breast cancer when used in combination with an aromatase inhibitor or fulvestrant.

Authorization of 12 months may be granted to members for adjuvant treatment of HR-positive, HER2-negative stage II and III early breast cancer at high risk of recurrence when used in combination with an aromatase inhibitor.

Endometrial carcinoma

Authorization of 12 months may be granted to members for treatment of advanced, recurrent, or metastatic endometrial carcinoma with ER-positive tumors when used in combination with letrozole.

Continuation of Therapy

Early Breast Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of early-stage, HR-positive, HER2-negative breast cancer with high risk of recurrence until completion of 3 years of treatment or until disease recurrence or unacceptable toxicity while on the current regimen.

Reference number(s)
1639-A

Recurrent, Advanced, or Metastatic Breast Cancer or Endometrial Carcinoma

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for recurrent, advanced, or metastatic breast cancer or endometrial carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.
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Reference number(s)
1843-A

SPECIALTY GUIDELINE MANAGEMENT

LEMTRADA (alemtuzumab)

POLICY

I. 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
Lemtrada is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

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

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR APPROVAL

A. First Course – Relapsing forms of multiple sclerosis
Authorization of 30 days (5 doses) may be granted to members with a diagnosis of a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) who have had an inadequate response to two or more drugs indicated for multiple sclerosis.

B. Subsequent Courses – Relapsing forms of multiple sclerosis
Authorization of 30 days (3 doses) may be granted to members with a diagnosis of a relapsing form of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapse) who have completed at least one previous course of therapy and treatment will start at least 12 months after the last dose of the prior treatment course.

IV. OTHER CRITERIA

A. Members will not use Lemtrada concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

V. REFERENCE

1. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.

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

SPECIALTY GUIDELINE MANAGEMENT

leuprolide acetate injection

POLICY

I. 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.

A. FDA-Approved Indication
Leuprolide acetate is indicated in the palliative treatment of advanced prostate cancer.

B. Compendial Uses
1. Central precocious puberty (CPP)
2. Use as a stimulation test to confirm the diagnosis of CPP
3. Use in combination with growth hormone for children with growth failure and advancing puberty
4. Prostate cancer
5. Inhibition of premature luteinizing hormone (LH) surges in members undergoing ovulation induction or assisted reproductive technology
6. Androgen receptor positive salivary gland tumors
7. Triggering of oocyte maturation and ovulation in assisted reproductive technology cycle

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

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)
1. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
   i. Member has been evaluated for intracranial tumors (e.g., lab tests, computed tomography [CT] scan, magnetic resonance imaging [MRI]).
   ii. 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.
   iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   iv. The member was less than 8 years of age at the onset of secondary sexual characteristics.
2. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
   i. Member has been evaluated for intracranial tumors (e.g., lab tests, CT scan, MRI).

ii. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third-generation LH assay.
iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
iv. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Stimulation test for CPP diagnosis
Authorization of one dose may be granted for use as a stimulation test to confirm the diagnosis of CPP.

C. Advancing puberty and growth failure
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.

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

E. Salivary gland tumors
Authorization of 12 months may be granted for treatment of recurrent, unresectable or metastatic salivary gland tumors as a single agent when the tumor is androgen receptor positive.

F. Inhibition of premature luteinizing hormone (LH) surges‡
Authorization of 12 months may be granted for the inhibition of premature LH surges in members undergoing ovulation induction or assisted reproductive technology (ART).

G. Oocyte maturation and ovulation trigger‡
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 in Section III. 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 in Section III.*

IV. CONTINUATION OF THERAPY

A. Central precocious puberty
1. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following criteria:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).
2. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

B. 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.

C. Salivary gland tumors
Authorization of 12 months may be granted for continued treatment of salivary gland tumors in members requesting authorization who are experiencing clinical benefit to therapy and who have not experienced an unacceptable toxicity.

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

V. REFERENCES

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

SPECIALTY GUIDELINE MANAGEMENT

LUPRON DEPOT 1-Month 7.5 mg
LUPRON DEPOT 3-Month 22.5 mg
LUPRON DEPOT 4-Month 30 mg
LUPRON DEPOT 6-Month 45 mg
(leuprolide acetate for depot suspension)

leuprolide acetate depot 3-month 22.5 mg

POLICY

I. 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.

A. FDA-Approved Indication
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, and Lupron Depot 6-Month 45 mg are indicated for the treatment of advanced prostatic cancer.

B. Compendial Uses
1. Prostate cancer
2. Ovarian cancer - Malignant sex cord-stromal tumors
3. Gender dysphoria (also known as transgender and gender diverse [TGD] persons)
4. Breast cancer (7.5 mg and 22.5 mg)

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

II. PRESCRIBER SPECIALTIES

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.

III. CRITERIA FOR INITIAL APPROVAL

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

B. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

C. Ovarian cancer

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors (granulosa cell tumors) as a single agent.

D. Breast cancer (7.5 mg and 22.5 mg only)

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

IV. CONTINUATION OF THERAPY

A. Ovarian cancer and breast 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.

B. 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.

C. Gender dysphoria

1. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has previously reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.
2. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive the requested medication concomitantly with gender-affirming hormones.

iv. The member's comorbid conditions are reasonably controlled.
v. The member has been educated on any contraindications and side effects to therapy.
vi. Before the start of therapy, the member has been informed of fertility preservation options**.**

V. OTHER

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

VI. REFERENCES

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3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 6, 2024.
4. 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.
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6. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
7. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017;5:816-26.
8. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**LIDOCAINE, LIDOCAINE-PRILOCAINE, LIDOCAINE-TETRACAINE DERMATOLOGICAL TOPICAL**
BRAND NAME (generic)	
	(lidocaine HCl 2% gel)
	(lidocaine HCl-collagen-aloe vera 2% gel)
	(lidocaine HCl 4% gel)
	(lidocaine HCl urethral/mucosal 2% gel)
	(lidocaine HCl urethral/mucosal 2% gel prefilled syringe)
	(lidocaine HCl 4% solution)
	(lidocaine 5% ointment)
	(lidocaine 2.5% and prilocaine 2.5% cream)
	PLIAGLIS (lidocaine and tetracaine 7-7% cream)
	SYNERA (lidocaine and tetracaine 70-70 mg patch)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

Lidocaine HCl 2% Gel

Lidocaine HCl 2% gel is intended to be used under the supervision of a healthcare professional to be used as local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes

- 1st and 2nd degree burns

Lidocaine HCl 4% Gel
Lidocaine 4% Gel is indicated for the following:
- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

Lidocaine HCl Urethral/Mucosal 2% Gel
Lidocaine HCl 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl Urethral/Mucosal 2% Gel Prefilled Syringe
Lidocaine HCl jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl 4% Topical Solution
Lidocaine HCl 4% topical solution 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 USP, 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 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

The requested product will be covered with prior authorization when the following criteria are met:
- Lidocaine-prilocaine 2.5-2.5 percent cream is being prescribed as a topical anesthetic for use on either:
    A) Normal intact skin for local analgesia
    B) Genital mucous membranes for superficial minor surgery or as pretreatment for infiltration anesthesia

  OR
- Lidocaine 5 percent ointment is being prescribed for any of the following:

A) Production of anesthesia of accessible mucous membranes of the oropharynx
B) As an anesthetic lubricant for intubation
C) Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, or insect bites

OR

- Lidocaine urethral/mucosal 2 percent gel is being prescribed for any of the following:
  A) Prevention and control of pain in procedures involving the urethra
  B) Topical treatment of painful urethritis
  C) As an anesthetic lubricant for endotracheal intubation (oral or nasal)

OR

- 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

OR

- 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

OR

- 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

OR

- 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:
  A) Pressure ulcers
  B) Venous stasis ulcers
  C) Superficial wounds or scrapes
  D) 1st or 2nd degree burns

  AND

  - 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

OR

- Lidocaine 4 percent gel is being prescribed for any of the following:
  A) Stage I - IV pressure ulcers
  B) Venous stasis ulcers
  C) Ulcerations caused by mixed vascular etiologies
  D) Diabetic skin ulcers
  E) First or second degree burns
  F) Post-surgical incisions, cuts or abrasions

  AND

  - 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

AND

- The requested product will not be used as part of a compound

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.

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% cream Lidocaine-tetracaine 7-7% cream	60 gm / 25 days	Does Not Apply*
Synera 70-70mg patch Lidocaine-tetracaine 70-70mg patch	10 patches / 25 days	Does Not Apply*

** 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 mail limit will be the same as the retail limit. The intent is for prescriptions of the requested product to be filled one month at a time, even if at mail order; there should be no 3 month supplies filled.***

Duration of Approval (DOA):

- 1331-C: DOA: 3 months

REFERENCES

1. 7T Lido (lidocaine 2% gel) [package insert]. Los Angeles, CA: 7T Pharma, LLC; October 2018.
2. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
3. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
4. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
5. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
6. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; September 2022.
7. Lidocaine HCl 4% topical solution [package insert]. Buena, NJ: Teligent Pharma, Inc; November 2019.
8. Lidocaine 5% ointment [package insert]. Bridgewater, NJ: Alembic Pharmaceuticals, Inc.; December 2022.
9. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Parsippany, NJ: Actavis Pharma, Inc; July 2019.
10. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
11. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
12. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.
13. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed July 26, 2023.
14. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/26/2023).
15. Human Drug Compounding. Available at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding. Accessed July 2023.
16. Medical Devices. Available at: https://www.fda.gov/medical-devices. Accessed July 2023.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**LIDOCAINE, LIDOCAINE-PRILOCAINE, LIDOCAINE-TETRACAINE DERMATOLOGICAL TOPICAL**
BRAND NAME (generic)	
	(lidocaine HCl 2% gel)
	(lidocaine HCl-collagen-aloe vera 2% gel)
	(lidocaine HCl 4% gel)
	(lidocaine HCl urethral/mucosal 2% gel)
	(lidocaine HCl urethral/mucosal 2% gel prefilled syringe)
	(lidocaine HCl 4% solution)
	(lidocaine 5% ointment)
	(lidocaine 2.5% and prilocaine 2.5% cream)
	PLIAGLIS (lidocaine and tetracaine 7-7% cream)
	SYNERA (lidocaine and tetracaine 70-70 mg patch)

Status: CVS Caremark® Criteria
Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Lidocaine HCl 2% Gel

Lidocaine HCl 2% gel is intended to be used under the supervision of a healthcare professional to be used as local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl 4% Gel
Lidocaine 4% Gel is indicated for the following:

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions

Lidocaine HCl Urethral/Mucosal 2% Gel
Lidocaine HCl 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl Urethral/Mucosal 2% Gel Prefilled Syringe
Lidocaine HCl jelly USP, 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

Lidocaine HCl 4% Topical Solution
Lidocaine HCl 4% topical solution 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 USP, 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 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

The requested product will be covered with prior authorization when the following criteria are met:

- Lidocaine-prilocaine 2.5-2.5 percent cream is being prescribed as a topical anesthetic for use on either:
    A) Normal intact skin for local analgesia
    B) Genital mucous membranes for superficial minor surgery or as pretreatment for infiltration anesthesia

  OR
- Lidocaine 5 percent ointment is being prescribed for any of the following:
    A) Production of anesthesia of accessible mucous membranes of the oropharynx

B) As an anesthetic lubricant for intubation
C) Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, or insect bites

OR

- Lidocaine urethral/mucosal 2 percent gel is being prescribed for any of the following:
  A) Prevention and control of pain in procedures involving the urethra
  B) Topical treatment of painful urethritis
  C) As an anesthetic lubricant for endotracheal intubation (oral or nasal)

OR

- 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

OR

- 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

OR

- Lidocaine-tetracaine 70-70mg 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

OR

- 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:
  A) Pressure ulcers
  B) Venous stasis ulcers
  C) Superficial wounds or scrapes
  D) 1st or 2nd degree burns

  AND

  - 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

OR

- Lidocaine 4 percent gel is being prescribed for any of the following:
  A) Stage I - IV pressure ulcers
  B) Venous stasis ulcers
  C) Ulcerations caused by mixed vascular etiologies
  D) Diabetic skin ulcers
  E) First or second degree burns
  F) Post-surgical incisions, cuts or abrasions

  AND

  - 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

AND

- The requested product will not be used as part of a compound.

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.

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% cream Lidocaine-tetracaine 7-7% cream	60 gm / 25 days	Does Not Apply*
Synera 70-70mg patch Lidocaine-tetracaine 70-70mg patch	10 patches / 25 days	Does Not Apply*

** 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 mail limit will be the same as the retail limit. The intent is for prescriptions of the requested product to be filled one month at a time, even if at mail order; there should be no 3 month supplies filled.***

Duration of Approval (DOA):

- 1330-J: DOA: 3 months

REFERENCES

1. 7T Lido (lidocaine 2% gel) [package insert]. Los Angeles, CA: 7T Pharma, LLC; October 2018.
2. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
3. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
4. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
5. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
6. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; September 2022.
7. Lidocaine HCl 4% topical solution [package insert]. Buena, NJ: Teligent Pharma, Inc; November 2019.
8. Lidocaine 5% ointment [package insert]. Bridgewater, NJ: Alembic Pharmaceuticals, Inc.; December 2022.
9. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Parsippany, NJ: Actavis Pharma, Inc; July 2019.
10. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
11. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
12. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.
13. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed July 26, 2023.
14. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 07/26/2023).
15. Human Drug Compounding. Available at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding. Accessed July 2023.
16. Medical Devices. Available at: https://www.fda.gov/medical-devices. Accessed July 2023.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ABILIFY ASUMTUFII
(aripiprazole monohydrate)

ABILIFY MAINTENA
(aripiprazole)

ARISTADA
(aripiprazole lauroxil)

ARISTADA INITIO
(aripiprazole lauroxil)

INVEGA SUSTENNA
(paliperidone palmitate)

INVEGA TRINZA
(paliperidone palmitate)

INVEGA HAFYERA
(paliperidone palmitate)

PERSERIS
(risperidone)

RISPERDAL CONSTA
(risperidone microspheres)

UZEDY
(risperidone)

ZYPREXA RELPREVV
(olanzapine pamoate)

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C25429-A***

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of an FDA-approved indication for the requested drug? [If no, then no further questions.]	Yes	No

2	Is this request for continuation of therapy? [If no, then skip to question 7.]	Yes	No
3	Does the physician attest that the patient is tolerating the requested medication? [If no, then no further questions.]	Yes	No
4	Does the patient have a documented clinical response to the requested therapy? [If no, then no further questions.]	Yes	No
5	Does the patient have documented compliance with outpatient follow up appointments? [If no, then no further questions.]	Yes	No
6	Is the patient 18 years of age or older? [No further questions.]	Yes	No
7	Does the patient have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar 1 in accordance with the requested medication's specific FDA labeling? [If no, then no further questions.]	Yes	No
8	Does the patient have a documented history of nonadherence to oral antipsychotics? [If yes, then skip to question 10.]	Yes	No
9	Does the patient have a documented history of stabilization on a long-acting injection antipsychotic while in a mental health facility? [If no, then no further questions.]	Yes	No
10	Does the patient have a documented oral tolerability of the active ingredient in the requested long-acting injection antipsychotic, in accordance with the requested medication's specific FDA labeling? [If no, then no further questions.]	Yes	No
11	Is the treatment regimen prescribed outside the medication's FDA labeling? [If yes, then no further questions.]	Yes	No
12	Do any contraindications or significant drug interactions to the requested treatment exist? [If yes, then no further questions.]	Yes	No
13	Is the patient 18 years of age or older? [If no, then no further questions.]	Yes	No
14	Is the request for Invega Sustenna? [If no, then skip to question 16.]	Yes	No
15	Does the patient have an established tolerability with oral paliperidone or oral risperidone? [No further questions.]	Yes	No
16	Is the request for Invega Trinza? [If no, then skip to question 18.]	Yes	No
17	Does the patient have a documented trial of Invega Sustenna of at least 4 months? [No further questions.]	Yes	No

18	Is the request for Invega Hafyera? [If no, then skip to question 21.]	Yes	No
19	Does the patient have a documented trial of Invega Sustenna for at least 4 months? [If yes, then no further questions.]	Yes	No
20	Does the patient have a documented trial of Invega Trinza of at least one 3-month cycle? [No further questions.]	Yes	No
21	Is the request for any other preferred long-acting injection antipsychotic? [If yes, then no further questions.]	Yes	No
22	Does the patient have a documented clinically significant treatment failure, intolerance or contraindication to preferred long-acting injection antipsychotic agents?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Approval Policy.

Written by: UM Development (VLS)
Date Written: 06/2023
Revised: (VLS) 05/2024
Reviewed: Medical Affairs: (APN) 08/2023, (APN) 06/2024

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

SPECIALTY GUIDELINE MANAGEMENT

LUPRON DEPOT 1-Month 3.75 mg
LUPRON DEPOT 3-Month 11.25 mg
(leuprolide acetate for depot suspension)

POLICY

I. 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.

A. FDA-Approved Indications

1. Endometriosis
   Lupron Depot 1-Month 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 1-Month 3.75 mg 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.

2. Uterine Leiomyomata (Fibroids)
   When used concomitantly with iron therapy, Lupron Depot 1-Month 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. The clinician may wish to 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 endometriosis: The total duration of therapy with Lupron Depot 3.75 mg and 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

   For uterine leiomyomata: 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.

B. Compendial Uses

1. Breast cancer
2. 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. Androgen receptor positive salivary gland tumors
4. Gender dysphoria (also known as transgender and gender diverse [TGD] persons)
5. Preservation of ovarian function
6. Prevention of recurrent menstrual related attacks in acute porphyria

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

II. PRESCRIBER SPECIALTIES

A. 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.

B. 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.

III. CRITERIA FOR INITIAL APPROVAL

A. Endometriosis
Authorization of up to 6 months (one treatment course) may be granted to members for initial treatment of endometriosis.

B. Uterine leiomyomata (fibroids)
Authorization of up to 3 months may be granted for initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:
1. Member has anemia due to uterine leiomyomata
2. Lupron Depot will be used prior to surgery for uterine leiomyomata.

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

D. Ovarian cancer
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:
1. Epithelial ovarian cancer
2. Fallopian tube cancer
3. Primary peritoneal cancer
4. Grade 1 endometrioid carcinoma
5. Low-grade serous carcinoma
6. Carcinosarcoma (malignant mixed Müllerian tumors)
7. Mucinous carcinoma of the ovary
8. Clear cell carcinoma of the ovary

E. Salivary gland tumors

Authorization of 12 months may be granted for treatment of recurrent, unresectable, or metastatic salivary gland tumors as a single agent when the tumor is androgen receptor positive.

F. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

G. Preservation of ovarian function

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

H. Prevention of recurrent menstrual related attacks in acute porphyria

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

IV. CONTINUATION OF THERAPY

A. Endometriosis

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:

1. The member has had a recurrence of symptoms.
2. The member has a bone mineral density within normal limits.

B. Uterine leiomyomata (fibroids)

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:

1. Member has anemia due to uterine leiomyomata.
2. Lupron Depot will be used prior to surgery for uterine leiomyomata.

C. Breast cancer, ovarian cancer, and salivary gland tumors

Authorization of 12 months may be granted for continued treatment of breast cancer, ovarian cancer, and salivary gland tumors in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

D. Gender dysphoria

1. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has previously reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.
2. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.

E. All members (including new members) requesting authorization for continuation of therapy for the specified indications below must meet all initial authorization criteria:

1. Preservation of ovarian function
2. Prevention of recurrent menstrual related attacks in acute porphyria

V. OTHER

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

VI. REFERENCES

1. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
2. Lupron Depot-3 Month 11.25 mg [package insert.]. North Chicago, IL: AbbVie Inc.; October 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 12, 2024.
4. Management of symptomatic uterine leiomyomas: ACOG Practice Bulletin No. 228. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2021 June 1;137(6):e100-e115.
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14. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.
15. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Head and Neck Cancers. Version 2.2024. Accessed February 15, 2024. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf.

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

SPECIALTY GUIDELINE MANAGEMENT

LUPRON DEPOT-PED (leuprolide acetate for depot suspension)

POLICY

I. 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.

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

B. Compendial Use
Gender dysphoria (also known as transgender and gender diverse [TGD] persons)

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

II. 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.

III. PRESCRIBER SPECIALTIES

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.

IV. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization of 12 months may be granted for treatment of CPP in a female member when all of the following criteria are met:
   i. Member has been evaluated for intracranial tumors (e.g., lab tests, computed tomography [CT] scan, magnetic resonance imaging [MRI]).
   ii. 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.
   iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   iv. The member was less than 8 years of age at the onset of secondary sexual characteristics.

2. Authorization of 12 months may be granted for treatment of CPP in a male member when all of the following criteria are met:
   i. Member has been evaluated for intracranial tumors (e.g., lab tests, CT scan, MRI).
   ii. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   iii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   iv. The member was less than 9 years of age at the onset of secondary sexual characteristics.

B. Gender dysphoria

1. Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has reached Tanner stage 2 of puberty or greater.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.
2. Authorization of 12 months may be granted for gender transition when all of the following criteria are met:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. The member has been informed of fertility preservation options.

V. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).
2. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

B. Gender dysphoria

1. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member has previously reached Tanner stage 2 of puberty or greater.

iv. The member's comorbid conditions are reasonably controlled.
v. The member has been educated on any contraindications and side effects to therapy.
vi. Before the start of therapy, the member has been informed of fertility preservation options.

2. 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:
   i. The member has a diagnosis of gender dysphoria.
   ii. The member is able to make an informed decision to engage in treatment.
   iii. The member will receive the requested medication concomitantly with gender-affirming hormones.
   iv. The member's comorbid conditions are reasonably controlled.
   v. The member has been educated on any contraindications and side effects to therapy.
   vi. Before the start of therapy, the member has been informed of fertility preservation options.

VI. OTHER

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

VII. REFERENCES

1. Lupron Depot-PED [package insert]. North Chicago, IL: AbbVie Inc.; April 2023.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.
3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
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5. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
6. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics.* 2016;137:e20153732.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017:102(11):3869–3903.
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9. Coleman E, Radix AE, Brown GR, et al. Standards of care for the health of transgender and gender diverse people, version 8. 2022;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644
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11. Mahfouda S, Moore JK, Siafarikas A, et al. Puberty suppression in transgender children and adolescents. *Lancet Diabetes Endocrinol*. 2017;5:816-26.
12. Health Care for Transgender and Gender Diverse Individuals. ©2021 The American College of Obstetricians and Gynecologists. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

Reference number(s)
2975-A

SPECIALTY GUIDELINE MANAGEMENT

MAVENCLAD (cladribine)

POLICY

I. 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
Mavenclad is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternative drug indicated for the treatment of MS.

Limitations of Use
Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

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

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

Multiple Sclerosis

A. Initial requests
Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:
1. Inadequate response or unable to tolerate an alternative drug indicated for the treatment of multiple sclerosis.
2. Member does not have clinically isolated syndrome (CIS).
3. Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.

B. Subsequent requests
Authorization of 45 days may be granted for treatment of relapsing forms of multiple sclerosis (including relapsing-remitting and secondary progressive disease for those who continue to experience relapses) and when all of the following criteria are met:
1. Member has not received 2 courses (i.e., 4 cycles) of Mavenclad.
2. The member has not received Mavenclad in the last 43 weeks.

IV. OTHER CRITERIA

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

V. REFERENCES

1. Mavenclad [package insert]. Rockland, MA: EMD Serono, Inc.; September 2022.
2. Giovannoni, G., Comi, G., Cook, S., et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. N Engl J Med 2010;362:416-426.

Reference number(s)
2973-A

SPECIALTY GUIDELINE MANAGEMENT

MAYZENT (siponimod)

POLICY

I. 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
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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER CRITERIA

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

VI. REFERENCES

1. Mayzent [package insert]. East Hanover, NJ: Novartis; August 2023.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **METHYLPHENIDATES**

BRAND NAME
(generic)

DEXMETHYLPHENIDATES:

AZSTARYS (ALL PRODUCTS)
(serdexmethylphenidate / dexmethylphenidate)

FOCALIN (ALL PRODUCTS)
(dexmethylphenidate)

METHYLPHENIDATES:

ADHANSIA (ALL PRODUCTS)
(methylphenidate)

APTENSIO (ALL PRODUCTS)
(methylphenidate)

CONCERTA (ALL PRODUCTS)
(methylphenidate)

COTEMPLA (ALL PRODUCTS)
(methylphenidate)

DAYTRANA (ALL PRODUCTS)
(methylphenidate)

JORNAY (ALL PRODUCTS)
(methylphenidate)

METHYLIN (ALL PRODUCTS)
(methylphenidate)

(methylphenidate) (ALL PRODUCTS)

QUILLICHEW (ALL PRODUCTS)
(methylphenidate)

QUILLIVANT (ALL PRODUCTS)
(methylphenidate)

RELEXXII (ALL PRODUCTS)
(methylphenidate)

RITALIN (ALL PRODUCTS)

(methylphenidate)

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C25530-A***

CRITERIA FOR APPROVAL

1	Does the patient have presence of cardiac disease denoted by one of the following: A) history of cardiac disease (e.g., heart arrhythmia, valvular heart disease, coronary heart disease, heart failure, cardiomyopathy), B) family history of sudden death or ventricular arrhythmia? [If yes, then no further questions.]	Yes	No
2	Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD)? [If no, then skip to question 20.]	Yes	No
3	Is the patient 18 years of age or older? [If no, then skip to question 5.]	Yes	No
4	Is this request for continuation of therapy? [If no, then skip to question 16.] [If yes, then skip to question 29.]	Yes	No
5	Is the patient 6 years of age or older? [If no, then skip to question 13.]	Yes	No
6	Is this request for continuation of therapy? [If yes, then skip to question 29.]	Yes	No
7	Is this request for Cotempla XR (methylphenidate ER orally disintegrating tablet)? [If no, then skip to question 9.]	Yes	No
8	Is the patient between the ages of 6 and 17 years of age? [If no, then no further questions.] [If yes, then skip to question 16.]	Yes	No
9	Is this request for Metadate CD (methylphenidate ER capsule)? [If no, then skip to question 11.]	Yes	No
10	Is the patient between 6 and 15 years of age? [If no, then no further questions.] [If yes then skip to question 16.]	Yes	No
11	Is this request for Ritalin LA (methylphenidate ER 24HR capsule)? [If no, then skip to question 16.]	Yes	No
12	Is the patient between 6 and 12 years of age? [If no, then no further questions.] [If yes, then skip to question 16.]	Yes	No
13	Is the patient 4 years of age or older? [If no, then no further questions.]	Yes	No
14	Is this request for continuation of therapy? [If yes, then skip to question 29.]	Yes	No

15	Is this request for Ritalin tablets (methylphenidate oral tablet), Methylin (methylphenidate oral solution), or Methylin (methylphenidate chewable tablet)? [No further questions.]	Yes	No
16	Is this request for a preferred medication (e.g., A) Concerta Tablets (BRAND ONLY), B) Daytrana Patch (BRAND ONLY), C) dexmethylphenidate tablets (GENERIC ONLY of Focalin IR), D) Focalin XR capsules (BRAND ONLY), E) Jornay PM capsules (BRAND ONLY), F) methylphenidate oral tablets (GENERIC ONLY of Ritalin), G) methylphenidate controlled-release tablets (GENERIC ONLY))? [If yes, then no further questions.]	Yes	No
17	Does the patient have a previous trial of at least TWO of the following preferred medications within the past 18 months: A) Concerta Tablets (BRAND ONLY), B) Daytrana Patch (BRAND ONLY), C) dexmethylphenidate tablets (GENERIC ONLY of Focalin IR), D) Focalin XR capsules (BRAND ONLY), E) Jornay PM capsules (BRAND ONLY), F) methylphenidate oral tablets (GENERIC ONLY of Ritalin), G) methylphenidate controlled-release tablets (GENERIC ONLY)? [If no, then no further questions.]	Yes	No
18	Is the request for any of the following drugs: Cotempla XR ODT, Quillivant XR oral suspension, Quillichew ER and generic methylphenidate chewable tablets, Methylin and generic methylphenidate oral solution? [If no, then no further questions.]	Yes	No
19	Does the patient have difficulty swallowing pills, or is unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [No further questions.]	Yes	No
20	Does the patient have a diagnosis of narcolepsy? [If no, then skip to question 26.]	Yes	No
21	Is the patient 18 years of age or older? [If no, then no further questions.]	Yes	No
22	Is this request for continuation of therapy? [If yes, then skip to question 29.]	Yes	No
23	Is the request for methylphenidate immediate release (generic Methylphenidate IR)? [If yes, then no further questions.]	Yes	No
24	Is the request for any of the following drugs: Ritalin LA or generic methylphenidate LA, Metadate ER or generic methylphenidate ER, or Methylin ER or generic methylphenidate ER capsules or Methylin Oral Solution or generic methylphenidate oral solution? [If no, then no further questions.]	Yes	No
25	Does the patient have a previous trial of at least 1 of the following agents that have an FDA approved indication for Narcolepsy: Preferred: modafinil (generic Provigil), methylphenidate immediate release (generic Ritalin IR), or NON-Preferred: Provigil [Brand], Wakix (pitolisant), Xyrem (sodium oxybate), Sunosi (solriamfetol)? [No further questions.]	Yes	No
26	Does the patient have a diagnosis of idiopathic hypersomnia, Klein-Levin syndrome, or hypersomnia due to other medical conditions? [If no, then no further questions.]	Yes	No

27	Is the patient 18 years of age or older? [If no, then no further questions.]	Yes	No
28	Is this request for continuation of therapy? [If no, then no further questions.]	Yes	No
29	Has the patient experienced or maintained a positive clinical response to therapy (e.g., improvement in hyperactivity, impulsivity, inattention, organizational skills, time management, sleep patterns, emotional management, or self-esteem)?	Yes	No

Quantity Limit Chart

Brand Name	Generic Name	Quantity Limit
CONCERTA TAB CR 18MG, 27MG, 36MG	methylphenidate tab ER osmotic release 18mg, 27mg, 36mg	2 tabs every 1 day
CONCERTA TAB CR 54MG	methylphenidate tab ER osmotic release 54mg	1 tab every 1 day
DAYTRANA PATCH 10MG/9HR, 15MG/9HR, 20MG/9HR, 30MG/9HR	methylphenidate TD patch	1 patch every 1 day
FOCALIN TABS 2.5MG, 5MG	dexmethylphenidate hcl tab 2.5mg, 5mg	4 tabs every 1 day
FOCALIN TABS 10MG	dexmethylphenidate hcl tab 10mg	2 tabs every 1 day
FOCALIN XR CP24 5MG, 10MG, 15MG, 20MG	dexmethylphenidate cap ER 5mg, 10mg, 15mg, 20mg	2 caps every 1 day
FOCALIN XR CP24 25MG, 30MG, 35MG, 40MG	dexmethylphenidate cap ER 25mg, 30mg, 35mg, 40mg	1 cap every 1 day
JORNAY PM CP24 20MG, 40MG	methylphenidate cap delayed ER 24HR PM	2 caps every 1 day
JORNAY PM CP24 60MG, 80MG, 100MG	methylphenidate cap delayed ER 24HR PM	1 cap every 1 day
RITALIN TABS 5MG, 10MG	methylphenidate hcl tabs 5mg, 10mg	6 tabs every 1 day
RITALIN TABS 20MG	methylphenidate hcl tabs 20mg	3 tabs every 1 day
	methylphenidate hcl tb cr 10mg, 20mg	3 tabs every 1 day
RELEXXII TAB ER 18MG, 27MG, 36MG	methylphenidate tab ER osmotic release 18mg, 27mg, 36mg	2 tabs every 1 day
RELEXXII TAB ER 54MG	methylphenidate tab ER osmotic release 54mg	1 tab every 1 day

*Quantity Limits Do Not Apply For Products Not Included in the Quantity Limit Chart

REFERENCES

1. CountyCare Prior Authorization Approval Policy: Methylphenidate Products. October 2024.

DOCUMENT HISTORY

Created: VLS 06/2023
Revised: VLS 12/2023; ANB 10/2024
Reviewed: 10/2023, 06/2024, 11/2024

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.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

Fulphila

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Fulphila is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

Udenyca

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Udenyca is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Udenyca is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Ziextenzo

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Ziextenzo is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Ziextenzo is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Nyvepria

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Nyvepria is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Fylnetra

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Fylnetra is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Stimufend

Patients with Cancer Receiving Myelosuppressive Chemotherapy

Stimufend is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Hematopoietic Subsyndrome of Acute Radiation Syndrome

Stimufend is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Compendial Use

- Stem cell transplantation-related indications
- Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
- Hematopoietic Acute Radiation Syndrome
- Hairy cell leukemia, neutropenic fever

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

Documentation

Primary Prophylaxis of Febrile Neutropenia

- Documentation must be provided of the member's diagnosis and chemotherapeutic regimen.
- If chemotherapeutic regimen has a low or intermediate risk of febrile neutropenia (less than 20%), documentation must be provided outlining the member's risk factors that confirm the member is at high risk for febrile neutropenia.

Coverage Criteria

Prevention of Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy

Authorization of 6 months may be granted for prevention of febrile neutropenia when all of the following criteria are met :

- The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
- The member will not receive chemotherapy at the same time as they receive radiation therapy.

- The requested medication will not be administered with weekly chemotherapy regimens.
- One of the following criteria is met :
    - The requested medication will be used for primary prophylaxis in members with a solid tumor or non-myeloid malignancies who have received, are currently receiving, or will be receiving any of the following:
        - Myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia (FN) (See Appendix A).
        - Myelosuppressive anti-cancer therapy that is expected to result in 10 – 19% risk of FN (See Appendix B) and who are considered to be at high risk of FN because of bone marrow compromise, co-morbidities, or other patient specific risk factors (See Appendix C).
        - Myelosuppressive anti-cancer therapy that is expected to result in less than 10% risk of FN and who have at least 2 patient-related risk factors (See Appendix C).
    - The requested medication will be used for secondary prophylaxis in members with solid tumors or non-myeloid malignancies who experienced a febrile neutropenic complication or a dose-limiting neutropenic event (a nadir or day of treatment count impacting the planned dose of chemotherapy) from a prior cycle of similar chemotherapy, with the same dose and scheduled planned for the current cycle (for which primary prophylaxis was not received).

Other Indications

Authorization of 6 months may be granted for members with any of the following indications:

- Stem cell transplantation-related indications
- Hematopoietic Subsyndrome of Acute Radiation Syndrome
- Treatment for radiation-induced myelosuppression following a radiological/nuclear incident
- Hairy cell leukemia
  Members with hairy cell leukemia with neutropenic fever following chemotherapy

Continuation of Therapy

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

Appendix

APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Acute Lymphoblastic Leukemia

Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)

Bladder Cancer

Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)

Bone Cancer

- VAIA (vincristine, doxorubicin, ifosfamide, and dactinomycin)
- VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide)
- Cisplatin/doxorubicin
- VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
- VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)

Breast Cancer

- Dose-dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel
- TAC (docetaxel, doxorubicin, cyclophosphamide)
- TC (docetaxel, cyclophosphamide)
- TCH (docetaxel, carboplatin, trastuzumab)

Head and Neck Squamous Cell Carcinoma

TPF (docetaxel, cisplatin, 5-fluorouracil)

Hodgkin Lymphoma

- Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
- Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)

Kidney Cancer

Doxorubicin/gemcitabine

Non-Hodgkin's Lymphoma

- CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin

- Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) ± rituximab
- ICE (ifosfamide, carboplatin, etoposide) ± rituximab
- Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
- MINE (mesna, ifosfamide, mitoxantrone, etoposide) ± rituximab
- DHAP (dexamethasone, cisplatin, cytarabine) ± rituximab
- ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) ± rituximab
- HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
- Pola-R-CHP (polatuzumab vedotin-piiq, rituximab, cyclophosphamide, doxorubicin, prednisone)

Melanoma

Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)

Multiple Myeloma

- VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
- DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)

Ovarian Cancer

- Topotecan ± bevacizumab
- Docetaxel

Soft Tissue Sarcoma

- MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
- Doxorubicin
- Ifosfamide/doxorubicin

Small Cell Lung Cancer

Topotecan

Testicular Cancer

- VelP (vinblastine, ifosfamide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- TIP (paclitaxel, ifosfamide, cisplatin)

Gestational Trophoblastic Neoplasia

- EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
- EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)
- EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
- TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)

- BEP (bleomycin, etoposide, cisplatin)
- VIP (etoposide, ifosfamide, cisplatin)
- ICE (ifosfamide, carboplatin, etoposide)

Wilms Tumor

- Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
- Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%

This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

Occult Primary – Adenocarcinoma

Gemcitabine/docetaxel

Breast Cancer

- Docetaxel ± trastuzumab
- AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
- AC + sequential docetaxel + trastuzumab
- Paclitaxel every 21 days ± trastuzumab
- TC (docetaxel, cyclophosphamide)

Cervical Cancer

- Irinotecan
- Cisplatin/topotecan
- Paclitaxel/cisplatin ± bevacizumab
- Topotecan

Colorectal Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Esophageal and Gastric Cancers

Irinotecan/cisplatin

Non-Hodgkin's Lymphomas

- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
- GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
- CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin

- CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin
- Bendamustine

Non-Small Cell Lung Cancer

- Cisplatin/paclitaxel
- Cisplatin/vinorelbine
- Cisplatin/docetaxel
- Cisplatin/etoposide
- Carboplatin/paclitaxel
- Docetaxel

Ovarian Cancer

Carboplatin/docetaxel

Pancreatic Cancer

FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)

Prostate Cancer

Cabazitaxel

Small Cell Lung Cancer

Etoposide/carboplatin

Testicular Cancer

- BEP (bleomycin, etoposide, cisplatin)
- Etoposide/cisplatin

Uterine Sarcoma

Docetaxel

Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)

APPENDIX C: Patient Risk Factors

This list is not all-inclusive.

- Active infections, open wounds, or recent surgery
- Age greater than or equal to 65 years
- Bone marrow involvement by tumor producing cytopenias
- Previous chemotherapy or radiation therapy
- Poor nutritional status
- Poor performance status
- Previous episodes of FN

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

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PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

NEXLETOL
(bempedoic acid)

NEXLIZET
(bempedoic acid/ezetimibe)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Logic

POLICY

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:

- 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

The requested drug will be covered with prior authorization when the following criteria are met:

- 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)
  AND
  - The requested drug is being prescribed as an adjunct to diet
    AND
    - The request is NOT for continuation of therapy
      AND
      - The requested drug will be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies

      OR
      - Concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is not possible

    OR
    - The request is for continuation of therapy
      AND
      - The patient has achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline

OR

- The requested drug is being prescribed to reduce the risk of myocardial infarction and coronary revascularization in an adult
  AND
  - The patient has ANY of the following: A) established cardiovascular disease (CVD), B) a high risk for a cardiovascular disease (CVD) event but without established CVD
    AND
    - The patient experienced an intolerance to the recommended statin therapy

    OR
    - The patient has a contraindication that would prohibit use of statin therapy

Duration of Approval (DOA):

- 3648-D: DOA: 36 months

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Reference number(s)
1655-A

SPECIALTY GUIDELINE MANAGEMENT

NUCALA (mepolizumab)

POLICY

I. 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

A. Nucala is indicated for add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.

   Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus

B. Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
C. 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.
D. Nucala is 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.

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

II. DOCUMENTATION

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

A. Asthma:
   1. For initial requests:
      i. Chart notes or medical record documentation showing baseline blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.
B. EGPA:
   1. For initial requests:
      i. Chart notes or medical record documentation showing pretreatment blood eosinophil count.
      ii. 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.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

C. HES:
   1. For initial requests:
      i. *FIP1L1-PDGFRA* fusion gene test results.
      ii. Chart notes or medical record documentation showing pretreatment blood eosinophil count.
   2. For continuation requests:
      i. *FIP1L1-PDGFRA* fusion gene test results.
      ii. Chart notes or medical record documentation supporting improvement in HES control.

E. CRSwNP:
   1. For initial requests:
      i. Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., polyps location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
      ii. 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.
   2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. EXCLUSIONS

Coverage will not be provided for treatment of HES for members with any of the following exclusions:
A. HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy).
B. *FIP1L1-PDGFRA* kinase-positive HES.

IV. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Asthma: allergist/immunologist or pulmonologist
B. Chronic rhinosinusitis with nasal polyps: allergist/immunologist or otolaryngologist

V. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. 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.

2. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   i. Member is 6 years of age or older.
   ii. Member meets either of the following criteria:
      a. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
      b. Member is dependent on systemic corticosteroids.
   iii. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      b. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)

c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)

iv. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
   a. High-dose inhaled corticosteroid
   b. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

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

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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

1. Member is 18 years of age or older.
2. 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%.
3. Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. Member has at least two of the following disease characteristics of EGPA:
   i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   iii. Pulmonary infiltrates, non-fixed
   iv. Sino-nasal abnormality
   v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   vii. Alveolar hemorrhage (by bronchoalveolar lavage)
   viii. Palpable purpura
   ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. 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.

C. Hypereosinophilic syndrome (HES)

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

1. Member is 12 years of age or older.
2. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
3. Member will not use the requested medication as monotherapy.
4. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
5. Member has had HES for at least 6 months.
6. Member has experienced at least two HES flares within the past 12 months.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

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

2. Authorization of 6 months may be granted for treatment of CRSwNP when all of the following criteria are met:
   i. Member is 18 years of age or older.
   ii. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated.
   iii. Member has CRSwNP despite one of the following:

a. Prior sino-nasal surgery
b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated

iv. Member has one of the following:
a. 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
b. Meltzer Clinical Score of 2 or higher in both nostrils
c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril

v. Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
a. Rhinorrhea (anterior/posterior)
b. Reduction or loss of smell
c. Facial pain or pressure

vi. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

VI. CONTINUATION OF THERAPY

A. Asthma

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

1. Member is 6 years of age or older.
2. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations.
   ii. A reduction in the daily maintenance oral corticosteroid dose.
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. 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:

1. Member is 18 years of age or older.
2. Member has a beneficial response to treatment with the requested medication as demonstrated by any of the following:
   i. A reduction in the frequency of relapses
   ii. A reduction or discontinuance of daily oral corticosteroid dose
   iii. No active vasculitis

C. Hypereosinophilic syndrome (HES)

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

1. Member is 12 years of age or older.
2. Member has experienced a reduction in HES flares since starting treatment with the requested medication.
3. Member will not use the requested medication as monotherapy.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

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

1. Member is 18 years of age or older.
2. 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 and/or facial pressure or pain, or reduction in corticosteroid use).
3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

VII. 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 (ocrelizumab)

POLICY

I. 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

A. Ocrevus 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.
B. Ocrevus is indicated for the treatment of primary progressive MS, in adults.

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

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing Forms of Multiple Sclerosis
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).

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

C. Primary Progressive Multiple Sclerosis
Authorization of 12 months may be granted to members for the treatment of primary progressive multiple sclerosis.

IV. CONTINUATION OF THERAPY

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

V. OTHER

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

VI. REFERENCES

1. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.
2. Clinical Consult: CVS Caremark Clinical Program Review. Focus on Multiple Sclerosis Clinical Programs. June 22, 2017.

Reference number
2597-A

SPECIALTY GUIDELINE MANAGEMENT

OLUMIANT (baricitinib)

POLICY

I. 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

A. Olumiant is indicated for the 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.
B. Olumiant is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
C. Olumiant is indicated for the 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.

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
    1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
    2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.
B. Alopecia areata:
    1. Initial requests: Chart notes or medical record documentation supporting more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
    2. 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]).

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis: rheumatologist
B. Alopecia areata: dermatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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 or intolerance to at least one tumor necrosis factor (TNF) inhibitor.

2. 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.

B. Alopecia areata

Authorization of 12 months may be granted for adult members for treatment of severe alopecia areata when both of the following criteria are met:

1. Member has more than 50% scalp hair loss (e.g., Severity of Alopecia Tool [SALT] score of 50 or higher).
2. Other forms of alopecia have been ruled out (e.g., androgenetic alopecia, trichotillomania, telogen effluvium, chemotherapy-induced hair loss, tinea capitis).

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Alopecia areata

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]).

VI. OTHER

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, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

VII. DOSAGE AND ADMINISTRATION

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

VIII. REFERENCES

1. Olumiant [package insert]. Indianapolis, IN: Lilly USA, LLC; June 2022.
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5. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. *NEJM*. 2022;386(18):1687-1699.
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STEP THERAPY WITH QUANTITY LIMIT AND POST LIMIT PRIOR AUTHORIZATION CRITERIA

DRUG CLASS **EXTENDED-RELEASE OPIOID ANALGESICS**

BRAND NAME*
(generic name, dosage form)

BELBUCA
(buprenorphine buccal film)

BUTRANS
(buprenorphine transdermal system)

CONZIP
(tramadol hydrochloride extended-release capsules)

(fentanyl transdermal system)

(hydrocodone bitartrate extended-release capsules)
(generic Zohydro ER)

(hydromorphone hydrochloride extended-release tablets)
(generic Exalgo)

HYSINGLA ER
(hydrocodone bitartrate extended-release tablets)

METHADONE 5 MG, 10 MG
(methadone hydrochloride tablets)

METHADONE 200 MG/20 ML INJ
(methadone hydrochloride injection)

METHADONE INTENSOL 10 MG/ML
(methadone oral concentrate)

METHADONE 5 MG/5 ML & 10 MG/5 ML ORAL SOLN
(methadone hydrochloride oral solution)

(methadone hydrochloride tablets 5 mg, 10 mg)
(generic Dolophine)

(morphine extended-release capsules)
(generic Avinza)

(morphine extended-release capsules)
(generic Kadian)

MS CONTIN
(morphine extended-release tablets)

NUCYNTA ER
(tapentadol extended-release tablets)

OXYCONTIN
(oxycodone hydrochloride extended-release tablets)

(oxymorphone hydrochloride extended-release tablets)
(generic Opana ER)

(tramadol hydrochloride extended-release)

(tramadol hydrochloride extended-release tablets)
(generic Ultram ER)

XTAMPZA ER
(oxycodone extended-release capsules)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy; Initial Limit; Post Limit PA ***Ref # 2219-M***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Belbuca, Butrans (buprenorphine)

Belbuca, Butrans (buprenorphine) 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 (buprenorphine) 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 (buprenorphine) are not indicated as an as-needed (prn) analgesic.

ConZip (tramadol hydrochloride extended-release)
ConZip (tramadol hydrochloride extended-release) 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 (tramadol hydrochloride extended-release) 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.
- ConZip (tramadol hydrochloride extended-release) 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 hydrocodone per day, or an equianalgesic dose of another opioid.
Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve fentanyl transdermal system for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Fentanyl transdermal system is not indicated as an as-needed (prn) analgesic.

Hydrocodone Bitartrate Extended-Release
Hydrocodone bitartrate extended-release capsules are indicated for the management of 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 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 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 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 (hydrocodone bitartrate extended-release) is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
Limitations of Use
- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Hysingla ER (hydrocodone bitartrate extended-release) 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 (hydrocodone bitartrate extended-release) 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 Intensol (oral concentrate) is indicated for the:
- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
  Limitations of Use
  - Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioids, reserve Methadone Hydrochloride Intensol for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
  - Methadone Hydrochloride Intensol is not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.
  Limitations of Use
  - Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.12.

Methadone Oral Solution
Methadone hydrochloride oral solution is 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 oral solution 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 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 8.2.

Methadone Tablets

Methadone hydrochloride 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 long-acting opioids, reserve methadone hydrochloride tablets for use in patients for whom alternative analgesic treatment options (e.g., non-opioid analgesics or immediate-release opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Methadone hydrochloride tablets are not indicated as an as-needed (prn) analgesic.
- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

Limitations of Use
- Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 42 CFR 8.2.

Conditions For Distribution And Use Of Methadone Products For The Treatment Of Opioid Addiction

Code of Federal Regulations, Title 42, Sec 8

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment. Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment:

During inpatient care, when the patient was admitted for any condition other than concurrent opioid addiction [pursuant to 21CFR 1306.07(c)], to facilitate the treatment of the primary admitting diagnosis.

During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility [pursuant to 21CFR 1306.07(b)].

Morphine Sulfate Extended-Release

Morphine sulfate extended-release capsules are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use
- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Morphine sulfate extended-release capsules for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Morphine sulfate extended-release capsules are not indicated as an as-needed (prn) analgesic.

MS Contin (morphine extended-release)
MS Contin (morphine extended-release) 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 (morphine extended-release) 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 (morphine extended-release) is not indicated as an as-needed (prn) analgesic.

Nucynta ER (tapentadol extended-release)
Nucynta ER (tapentadol) is indicated for the management of:
- Severe and persistent pain in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
- Severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.

Limitations of Use
- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Nucynta ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Nucynta ER is not indicated as an as-needed (prn) analgesic.

OxyContin (oxycodone hydrochloride extended-release)
OxyContin is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate in:
- Adults; and
- Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.

Limitations of Use
- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Oxycontin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- OxyContin is not indicated as an as-needed (prn) analgesic.

Oxymorphone Hydrochloride Extended-Release
Oxymorphone hydrochloride extended-release tablets are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Limitations of Use
- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve oxymorphone hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Oxymorphone hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Tramadol Hydrochloride Extended-Release
Tramadol hydrochloride extended-release tablets are indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Tramadol hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Xtampza ER (oxycodone extended-release)
Xtampza ER is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate.
Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Xtampza ER is not indicated as an as-needed (prn) analgesic.

SCREENOUT LOGIC
If the patient has filled a prescription for at least a 1-day supply of a drug indicating the patient is being treated for cancer or sickle cell disease within the past 365 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If a claim is submitted with an ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient has an ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, then the requested drug will be paid under that prescription benefit.

If the patient has any history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, then the requested drug will be paid under that prescription benefit.

If a claim is submitted using a hospice patient residence code under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

INITIAL STEP THERAPY
For patients with no prescription claims of a cancer drug or a sickle cell disease drug in the past 365 days, no ICD 10 diagnosis code indicating cancer, sickle cell disease, or palliative care submitted with their prescription claim, no ICD 10 diagnosis code indicating cancer or palliative care in their member health profile in the past 365 days, no history of an ICD 10 diagnosis code indicating sickle cell disease in their member health profile, or no hospice patient residence code submitted with their prescription claim:
If the patient has filled a prescription for at least an 8-day supply of an immediate-release (IR) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics ER Quantity Limits Chart below).

If the patient has filled a prescription for at least a 30-day supply of an extended-release (ER) opioid agent indicated for the management of pain within prescription claim history in the past 90 days under a prescription benefit administered by CVS Caremark, then the initial quantity limit criteria will apply (see Column A and Column B in the Opioid Analgesics ER Quantity Limits Chart below).

If the patient does not have at least an 8-day supply of an IR opioid agent indicated for the management of pain OR at least a 30-day supply of an ER opioid agent indicated for the management of pain within prescription claim history in the past 90 days (i.e., the patient has not used an IR opioid prior to the ER opioid OR the patient is not already stable on an ER opioid), then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

[NOTE: These drugs should be prescribed only by healthcare professionals who are knowledgeable about the use of extended-release/long-acting opioids and how to mitigate the associated risks.]

Pain Associated with Cancer, Sickle Cell Disease, a Terminal Condition, or Pain being Managed through Hospice or Palliative Care
Authorization may be granted when the requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care

Chronic Pain
Authorization may be granted when the requested drug is being prescribed for CHRONIC pain severe and persistent enough to require an extended treatment period with a daily opioid analgesic in a patient who has been taking an opioid when ALL of the following criteria are met:
[Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

- The patient can safely take the requested dose based on their history of opioid use [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.]
- The patient has been evaluated and the patient will be monitored regularly for the development of opioid use disorder
- The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety [NOTE: Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.]
- The patient meets ONE of the following:
    - This request is for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days
    - The patient has taken an immediate-release opioid for at least one week
- If the request is for a methadone product, then it is NOT being prescribed for detoxification treatment or as part of a maintenance treatment plan for opioid/substance abuse or addiction

QUANTITY LIMITS MAY APPLY

Opioid Analgesics ER Quantity Limits Chart
Coverage is provided without prior authorization for a 30-day or 90-day supply of an extended-release opioid for a quantity that corresponds to ≤ 90 MME/day (when Step Therapy criteria met). Coverage for quantities that correspond to ≤ 200 MME/day (unless FDA-labeled 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).**

		COLUMN A	COLUMN B	COLUMN C	COLUMN D
Drug/Strength	**Labeled Dosing**	**Initial 1 Month Limit* ≤ 90 MME/day (per 25 days)**	**Initial 3 Month Limit* ≤ 90 MME/day (per 75 days)**	**Post 1 Month Limit* ≤ 200 MME/day** (per 25 days)**	**Post 3 Month Limit* ≤ 200 MME/day** (per 75 days)**
Belbuca 75 mcg	q12h, 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	q12h, 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	q12h, 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	q12h, MAX 900 mcg/12 hrs	60 films/month 2 films/day (27 MME/day)	180 films/3 months 2 films/day (27 MME/day)	90 films/month 3 films/day (40.5 MME/day)	270 films/3 months 3 films/day (40.5 MME/day)
Belbuca 600 mcg	q12h, 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	q12h, 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	q12h, 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	q7d, 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	q7d, 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	q7d, 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	q7d, 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)
Butrans 20 mcg/hr	q7d, 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	qd, MAX 300 mg/day	30 caps/month 1 cap/day (20 MME/day)	90 caps/3 months 1 cap/day (20 MME/day)	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)
ConZip 200 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 cap/day (40 MME/day)	90 caps/3 months 1 cap/day (40 MME/day)
ConZip 300 mg	qd, MAX 300 mg/day	0***	0***	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day (60 MME/day)
Fentanyl transdermal 12 mcg/hr	q72h	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	q72h	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	q72h	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	q72h	0***	0***	10 patches/month 0.334 patch/day (120 MME/day)	30 patches/3 months 0.334 patch/day (120 MME/day)
Fentanyl transdermal 62.5 mcg/hr	q72h	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	q72h	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	q72h	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	q72h	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	q12h	60 caps/month 2 caps/day (20 MME/day)	180 caps/3 months 2 caps/day (20 MME/day)	90 caps/month 3 caps/day (30 MME/day)	270 caps/3 months 3 caps/day (30 MME/day)
Hydrocodone ER (generic Zohydro ER) 15 mg	q12h	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)	90 caps/month 3 caps/day (45 MME/day)	270 caps/3 months 3 caps/day (45 MME/day)
Hydrocodone ER (generic Zohydro ER) 20 mg	q12h	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)	90 caps/month 3 caps/day (60 MME/day)	270 caps/3 months 3 caps/day (60 MME/day)
Hydrocodone ER (generic Zohydro ER) 30 mg	q12h	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Hydrocodone ER (generic Zohydro ER) 40 mg	q12h	60 caps/month 2 caps/day (80 MME/day)	180 caps/3 months 2 caps/day (80 MME/day)	90 caps/month 3 caps/day (120 MME/day)	270 caps/3 months 3 caps/day (120 MME/day)
Hydrocodone ER (generic Zohydro ER) 50 mg	q12h	0***	0***	60 caps/month 2 caps/day (100 MME/day)	180 caps/3 months 2 caps/day (100 MME/day)
Hydromorphone ER (generic Exalgo) 8 mg	qd	30 tabs/month 1 tab/day (40 MME/day)	90 tabs/3 months 1 tab/day (40 MME/day)	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)
Hydromorphone ER (generic Exalgo) 12 mg	qd	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 MME/day)	60 tabs/month 2 tabs/day (120 MME/day)	180 tabs/3 months 2 tabs/day (120 MME/day)
Hydromorphone ER (generic Exalgo) 16 mg	qd	30 tabs/month 1 tab/day (80 MME/day)	90 tabs/3 months 1 tab/day (80 MME/day)	60 tabs/month 2 tabs/day (160 MME/day)	180 tabs/3 months 2 tabs/day (160 MME/day)
Hydromorphone ER (generic Exalgo) 32 mg	qd	0***	0***	30 tabs/month 1 tab/day (160 MME/day)	90 tabs/3 months 1 tab/day (160 MME/day)
Hysingla ER 20 mg	q24h	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)	60 tabs/month 2 tabs/day (40 MME/day)	180 tabs/3 months 2 tabs/day (40 MME/day)
Hysingla ER 30 mg	q24h	30 tabs/month 1 tab/day (30 MME/day)	90 tabs/3 months 1 tab/day (30 MME/day)	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)
Hysingla ER 40 mg	q24h	30 tabs/month	90 tabs/3 months	60 tabs/month	180 tabs/3 months

		1 tab/day (40 MME/day)	1 tab/day (40 MME/day)	2 tabs/day (80 MME/day)	2 tabs/day (80 MME/day)
Hysingla ER 60 mg	q24h	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 MME/day)	60 tabs/month 2 tabs/day (120 MME/day)	180 tabs/3 months 2 tabs/day (120 MME/day)
Hysingla ER 80 mg	q24h	30 tabs/month 1 tab/day (80 MME/day)	90 tabs/3 months 1 tab/day (80 MME/day)	60 tabs/month 2 tabs/day (160 MME/day)	180 tabs/3 months 2 tabs/day (160 MME/day)
Hysingla ER 100 mg	q24h	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
Hysingla ER 120 mg	q24h	0***	0***	30 tabs/month 1 tab/day (120 MME/day)	90 tabs/3 months 1 tab/day (120 MME/day)
Methadone 5 mg	q8-12h	90 tabs/month 3 tabs/day (70.5 MME/day)	270 tabs/3 months 3 tabs/day (70.5 MME/day)	120 tabs/month 4 tabs/day (94 MME/day)	360 tabs/3 months 4 tabs/day (94 MME/day)
Methadone (generic Dolophine) 5 mg	q8-12h	90 tabs/month 3 tabs/day (70.5 MME/day)	270 tabs/3 months 3 tabs/day (70.5 MME/day)	120 tabs/month 4 tabs/day (94 MME/day)	360 tabs/3 months 4 tabs/day (94 MME/day)
Methadone 10 mg	q8-12h	30 tabs/month 1 tab/day (47 MME/day)	90 tabs/3 months 1 tab/day (47 MME/day)	90 tabs/month 3 tabs/day (141 MME/day)	270 tabs/3 months 3 tabs/day (141 MME/day)
Methadone (generic Dolophine) 10 mg	q8-12h	30 tabs/month 1 tab/day (47 MME/day)	90 tabs/3 months 1 tab/day (47 MME/day)	90 tabs/month 3 tabs/day (141 MME/day)	270 tabs/3 months 3 tabs/day (141 MME/day)
Methadone 200 mg/20 mL injection	q8-12h	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)
Methadone 10 mg/mL Intensol soln	q8-12h	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 soln	q8-12h	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 soln	q8-12h	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	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (30 MME/day)	90 caps/3 months 1 cap/day (30 MME/day)	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)
Morphine ER (generic Avinza) 45 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (45 MME/day)	90 caps/3 months 1 cap/day (45 MME/day)	60 caps/month 2 caps/day (90 MME/day)	180 caps/3 months 2 caps/day (90 MME/day)
Morphine ER (generic Avinza) 60 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day (60 MME/day)	60 caps/month 2 caps/day (120 MME/day)	180 caps/3 months 2 caps/day (120 MME/day)
Morphine ER (generic Avinza) 75 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (75 MME/day)	90 caps/3 months 1 cap/day (75 MME/day)	60 caps/month 2 caps/day (150 MME/day)	180 caps/3 months 2 caps/day (150 MME/day)
Morphine ER (generic Avinza) 90 mg	q24h, MAX 1600 mg/day	30 caps/month 1 cap/day (90 MME/day)	90 caps/3 months 1 cap/day (90 MME/day)	60 caps/month 2 caps/day (180 MME/day)	180 caps/3 months 2 caps/day (180 MME/day)
Morphine ER (generic Avinza) 120 mg	q24h, MAX 1600 mg/day	0***	0***	30 caps/month 1 cap/day (120 MME/day)	90 caps/3 months 1 cap/day (120 MME/day)
Morphine ER	q12-24h	60 caps/month	180 caps/3 months	90 caps/month	270 caps/3 months

(generic Kadian) 10 mg		2 caps/day (20 MME/day)	2 caps/day (20 MME/day)	3 caps/day (30 MME/day)	3 caps/day (30 MME/day)
Morphine ER (generic Kadian) 20 mg	q12-24h	60 caps/month 2 caps/day (40 MME/day)	180 caps/3 months 2 caps/day (40 MME/day)	90 caps/month 3 caps/day (60 MME/day)	270 caps/3 months 3 caps/day (60 MME/day)
Morphine ER (generic Kadian) 30 mg	q12-24h	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Morphine ER (generic Kadian) 40 mg	q12-24h	60 caps/month 2 caps/day (80 MME/day)	180 caps/3 months 2 caps/day (80 MME/day)	90 caps/month 3 caps/day (120 MME/day)	270 caps/3 months 3 caps/day (120 MME/day)
Morphine ER (generic Kadian) 50 mg	q12-24h	30 caps/month 1 cap/day (50 MME/day)	90 caps/3 months 1 cap/day (50 MME/day)	60 caps/month 2 caps/day (100 MME/day)	180 caps/3 months 2 caps/day (100 MME/day)
Morphine ER (generic Kadian) 60 mg	q12-24h	30 caps/month 1 cap/day (60 MME/day)	90 caps/3 months 1 cap/day (60 MME/day)	60 caps/month 2 caps/day (120 MME/day)	180 caps/3 months 2 caps/day (120 MME/day)
Morphine ER (generic Kadian) 80 mg	q12-24h	30 caps/month 1 cap/day (80 MME/day)	90 caps/3 months 1 cap/day (80 MME/day)	60 caps/month 2 caps/day (160 MME/day)	180 caps/3 months 2 caps/day (160 MME/day)
Morphine ER (generic Kadian) 100 mg	q12-24h	0***	0***	60 caps/month 2 caps/day (200 MME/day)	180 caps/3 months 2 caps/day (200 MME/day)
MS Contin 15 mg	q8-12h	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)	120 tabs/month 4 tabs/day (60 MME/day)	360 tabs/3 months 4 tabs/day (60 MME/day)
MS Contin 30 mg	q8-12h	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)	120 tabs/month 4 tabs/day (120 MME/day)	360 tabs/3 months 4 tabs/day (120 MME/day)
MS Contin 60 mg	q8-12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
MS Contin 100 mg	q8-12h	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
MS Contin 200 mg	q8-12h	0***	0***	60 tabs/month 2 tabs/day (400 MME/day)	180 tabs/3 months 2 tabs/day (400 MME/day)
Nucynta ER 50 mg	q12h, MAX 500 mg/day	60 tabs/month 2 tabs/day (40 MME/day)	180 tabs/3 months 2 tabs/day (40 MME/day)	90 tabs/month 3 tabs/day (60 MME/day)	270 tabs/3 months 3 tabs/day (60 MME/day)
Nucynta ER 100 mg	q12h, MAX 500 mg/day	60 tabs/month 2 tabs/day (80 MME/day)	180 tabs/3 months 2 tabs/day (80 MME/day)	90 tabs/month 3 tabs/day (120 MME/day)	270 tabs/3 months 3 tabs/day (120 MME/day)
Nucynta ER 150 mg	q12h, MAX 500 mg/day	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
Nucynta ER 200 mg	q12h, MAX 500 mg/day	0***	0***	60 tabs/month 2 tabs/day (160 MME/day)	180 tabs/3 months 2 tabs/day (160 MME/day)
Nucynta ER 250 mg	q12h, MAX 500 mg/day	0***	0***	60 tabs/month 2 tabs/day (200 MME/day)	180 tabs/3 months 2 tabs/day (200 MME/day)
OxyContin 10 mg	q12h	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
OxyContin 15 mg	q12h	60 tabs/month 2 tabs/day	180 tabs/3 months 2 tabs/day	90 tabs/month 3 tabs/day	270 tabs/3 months 3 tabs/day

		(45 MME/day)	(45 MME/day)	(67.5 MME/day)	(67.5 MME/day)
OxyContin 20 mg	q12h	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
OxyContin 30 mg	q12h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	90 tabs/month 3 tabs/day (135 MME/day)	270 tabs/3 months 3 tabs/day (135 MME/day)
OxyContin 40 mg	q12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
OxyContin 60 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (180 MME/day)	180 tabs/3 months 2 tabs/day (180 MME/day)
OxyContin 80 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (240 MME/day)	180 tabs/3 months 2 tabs/day (240 MME/day)
Oxymorphone ER (generic Opana ER) 5 mg	q12h	60 tabs/month 2 tabs/day (30 MME/day)	180 tabs/3 months 2 tabs/day (30 MME/day)	90 tabs/month 3 tabs/day (45 MME/day)	270 tabs/3 months 3 tabs/day (45 MME/day)
Oxymorphone ER (generic Opana ER) 7.5 mg	q12h	60 tabs/month 2 tabs/day (45 MME/day)	180 tabs/3 months 2 tabs/day (45 MME/day)	90 tabs/month 3 tabs/day (67.5 MME/day)	270 tabs/3 months 3 tabs/day (67.5 MME/day)
Oxymorphone ER (generic Opana ER) 10 mg	q12h	60 tabs/month 2 tabs/day (60 MME/day)	180 tabs/3 months 2 tabs/day (60 MME/day)	90 tabs/month 3 tabs/day (90 MME/day)	270 tabs/3 months 3 tabs/day (90 MME/day)
Oxymorphone ER (generic Opana ER) 15 mg	q12h	60 tabs/month 2 tabs/day (90 MME/day)	180 tabs/3 months 2 tabs/day (90 MME/day)	90 tabs/month 3 tabs/day (135 MME/day)	270 tabs/3 months 3 tabs/day (135 MME/day)
Oxymorphone ER (generic Opana ER) 20 mg	q12h	0***	0***	90 tabs/month 3 tabs/day (180 MME/day)	270 tabs/3 months 3 tabs/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 30 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (180 MME/day)	180 tabs/3 months 2 tabs/day (180 MME/day)
Oxymorphone ER (generic Opana ER) 40 mg	q12h	0***	0***	60 tabs/month 2 tabs/day (240 MME/day)	180 tabs/3 months 2 tabs/day (240 MME/day)
Tramadol ER 100 mg	qd, MAX 300 mg/day	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)	60 tabs/month 2 tabs/day (40 MME/day)	180 tabs/3 months 2 tabs/day (40 MME/day)
Tramadol ER (generic Ultram ER) 100 mg	qd, MAX 300 mg/day	30 tabs/month 1 tab/day (20 MME/day)	90 tabs/3 months 1 tab/day (20 MME/day)	60 tabs/month 2 tabs/day (40 MME/day	180 tabs/3 months 2 tabs/day (40 MME/day
Tramadol ER 200 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (40 MME/day)	90 tabs/3 months 1 tab/day (40 MME/day)
Tramadol ER (generic Ultram ER) 200 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (40 MME/day)	90 tabs/3 months 1 tab/day (40 MME/day)
Tramadol ER 300 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 MME/day)
Tramadol ER (generic Ultram ER) 300 mg	qd, MAX 300 mg/day	0***	0***	30 tabs/month 1 tab/day (60 MME/day)	90 tabs/3 months 1 tab/day (60 MME/day)
Xtampza ER 9 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (30 MME/day)	180 caps/3 months 2 caps/day (30 MME/day)	90 caps/month 3 caps/day (45 MME/day)	270 caps/3 months 3 caps/day (45 MME/day)

Xtampza ER 13.5 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (45 MME/day)	180 caps/3 months 2 caps/day (45 MME/day)	90 caps/month 3 caps/day (67.5 MME/day)	270 caps/3 months 3 caps/day (67.5 MME/day)
Xtampza ER 18 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (60 MME/day)	180 caps/3 months 2 caps/day (60 MME/day)	90 caps/month 3 caps/day (90 MME/day)	270 caps/3 months 3 caps/day (90 MME/day)
Xtampza ER 27 mg	q12h, MAX 288 mg/day	60 caps/month 2 caps/day (90 MME/day)	180 caps/3 months 2 caps/day (90 MME/day)	90 caps/month 3 caps/day (135 MME/day)	270 caps/3 months 3 caps/day (135 MME/day)
Xtampza ER 36 mg	q12h, MAX 288 mg/day	0***	0***	90 caps/month 3 caps/day (180 MME/day)	270 caps/3 months 3 caps/day (180 MME/day)

**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.*
***Unless minimum FDA-labeled strength/dose/frequency exceeds 200 MME/day.*
****The initial limit is zero. All requests for this drug and strength will be considered through post limit prior authorization.*
‡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.

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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Written by:	UM Development (CF/JH)
Date Written:	04/2016
Revised:	06/2016, 08/2016 (added Troxyca ER), 10/2016, 01/2017 (added Arymo ER, Vantrela ER), 03/2017 (removed prescriber specialty question/added prescriber note, added Methadone Intensol), 05/2017 (updated Belbuca MME), 07/2017 (updated Rationale), 08/2017 (combined step therapy and limit/PL criteria, no clinical changes), 08/2017 (decreased methadone quantities), 01/2018, 06/2018 (updated MorphaBond ER QLs); (CF/DS) 01/2019 (added SCD), 05/2019 (added ICD10 code and hospice screenouts), 07/2019 (added member health profile screenout), 01/2020 (member health profile lifetime for SCD); (DS) 07/2020 (decreased DOA for chronic pain to 6 months), 01/2021 (added subsequent fill requirement; updated to Flex QLs), 01/2022 (removed Embeda); (DRS/DFW) 01/2023 (decreased initial limit for methadone 10 mg tab, 10 mg/mL Intensol sol and 10 mg/5 mL oral solution; removed inactive products); 01/2024 (removed brand Duragesic and brand Zohydro ER, updated chronic pain question)
Reviewed:	Medical Affairs: (DNC) 05/2016, 06/2016, 08/2016, 10/2016, 01/2017, 03/2017, 05/2017, 07/2017, 08/2017, 01/2018, 06/2018; (TKP) 03/2019; (DNC) 05/2019, 07/2019; (CHART) 01/30/2020, 07/23/20, 01/28/2021, 02/03/2022, 02/16/2023, 02/01/2024 External Review: 06/2016, 10/2016, 12/2016, 04/2017, 06/2017, 10/2017, 04/2018, 08/2018, 04/2019, 06/2019 (FYI), 08/2019 (FYI), 04/2020, 10/2020, 04/2021, 04/2022, 04/2023, 04/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care? [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the requested drug 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? [NOTE: Chronic pain is generally defined as pain that typically lasts greater than 3 months.] [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Can the patient safely take the requested dose based on their history of opioid use? [NOTE: The lowest dosage necessary to achieve adequate analgesia should be prescribed.] [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Has the patient been evaluated and will the patient be monitored regularly for the development of opioid use disorder?	Yes	No

	[If Yes, then go to 5. If No, then no further questions.]		
5	Will the patient's pain 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.] [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Is this request for continuation of therapy for a patient who has been receiving an extended-release opioid agent for at least 30 days? [If Yes, then go to 8. If No, then go to 7.]	Yes	No
7	Has the patient taken an immediate-release opioid for at least one week? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Which drug is being requested? [NOTE: Please check the drug being requested. 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.]		
	[] Belbuca (buprenorphine buccal film) (If checked, go to 13)		
	[] Butrans (buprenorphine transdermal system) (If checked, go to 14)		
	[] ConZip (tramadol hydrochloride extended-release capsules) (If checked, go to 15)		
	[] Fentanyl transdermal system (If checked, go to 16)		
	[] Hydrocodone bitartrate extended-release capsules (generic Zohydro ER) (If checked, go to 9)		
	[] Hydromorphone hydrochloride extended-release tablets (generic Exalgo) (If checked, go to 17)		
	[] Hysingla ER (hydrocodone bitartrate extended-release tablets) (If checked, go to 9)		
	[] Methadone 5 mg, 10 mg (methadone hydrochloride tablets) (If checked, go to 10)		
	[] Methadone 5 mg, 10 mg hydrochloride tablets (generic Dolophine) (If checked, go to 10)		

	[] Methadone 10 mg/mL Intensol soln (If checked, go to 10) [] Methadone 5 mg/5 mL,10 mg/5 mL oral soln, 200 mg/20 mL injection (If checked, go to 10) [] Morphine extended-release capsules (generic Avinza) (If checked, go to 12) [] Morphine extended-release capsules (generic Kadian) (If checked, go to 18) [] MS Contin (morphine extended-release tablets) (If checked, go to 19) [] Nucynta ER (tapentadol extended-release tablets) (If checked, go to 20) [] OxyContin (oxycodone hydrochloride extended-release tablets) (If checked, go to 22) [] Oxymorphone hydrochloride extended-release tablets (generic Opana ER) (If checked, go to 21) [] Tramadol hydrochloride extended-release (If checked, go to 15) [] Tramadol hydrochloride extended-release (generic Ultram ER) (If checked, go to 15) [] Xtampza ER (oxycodone extended-release capsules) (If checked, go to 23)		
9	Does the patient require use of MORE than the plan allowance of any of the following: A) 3 units per day of hydrocodone bitartrate ER capsules (generic Zohydro ER) 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, B) 2 units per day of Hysingla ER 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg OR hydrocodone bitartrate ER capsules (generic Zohydro ER) 50 mg, C) 1 unit per day of Hysingla ER 120 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
10	Is the requested methadone product being prescribed for detoxification treatment or as part of a maintenance treatment plan for opioid/substance abuse or addiction? [If Yes, then no further questions. If No, then go to 11.]	Yes	No
11	Does the patient require use of MORE than the plan allowance of any of the following: A) 4 tablets per day of methadone (generic Dolophine) 5 mg or Methadone 5 mg, B) 3 tablets per day of	Yes	No

	methadone (generic Dolophine) 10 mg or Methadone 10 mg, C) 20 mL per day of Methadone 5 mg/5 mL oral solution, D) 15 mL per day of Methadone 10 mg/5 mL oral solution, E) 3 mL per day of Methadone 10 mg/mL Intensol solution, F) 1.334 mL per day (i.e., 2 multidose vials per month) of Methadone 200 mg/20 mL injection? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.		
12	Does the patient require use of MORE than the plan allowance of 2 capsules per day of morphine ER (generic Avinza) 30 mg, 45 mg, 60 mg, 75 mg, 90 mg OR MORE than the plan allowance of 1 capsule per day of morphine ER (generic Avinza) 120 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
13	Does the patient require use of MORE than the plan allowance of 3 films per day of Belbuca 75 mcg, 150 mcg, 300 mcg, 450 mcg OR MORE than the plan allowance of 2 films per day of Belbuca 600 mcg, 750 mcg, 900 mcg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
14	Does the patient require use of MORE than the plan allowance of 0.287 patch per day (i.e., 2 patches per week) of Butrans 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr OR MORE than the plan allowance of 0.144 patch per day (i.e., 1 patch per week) of Butrans 15 mcg/hr, 20 mcg/hr? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
15	Does the patient require use of MORE than the plan allowance of 2 units per day of ConZip 100 mg, tramadol ER 100 mg, or tramadol ER (generic Ultram ER) 100 mg, OR MORE than the plan allowance of 1 unit per day of ConZip 200 mg, 300 mg, or tramadol ER 200 mg, 300 mg, or tramadol ER (generic Ultram ER) 200 mg, 300 mg?	Yes	No

	[No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.		
16	Does the patient require use of MORE than the plan allowance of 0.667 patch per day (i.e., 2 patches per 3 days) of fentanyl transdermal 12 mcg/hr, 25 mcg/hr, or 37.5 mcg/hr OR MORE than the plan allowance of 0.334 patch per day (i.e., 1 patch per 3 days) of fentanyl transdermal 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr, or 100 mcg/hr? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
17	Does the patient require use of MORE than the plan allowance of 2 tablets per day of hydromorphone ER (generic Exalgo) 8 mg, 12 mg, 16 mg OR MORE than the plan allowance of 1 tablet per day of hydromorphone ER (generic Exalgo) 32 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
18	Does the patient require use of MORE than the plan allowance of 3 capsules per day of morphine ER (generic Kadian) 10 mg, 20 mg, 30 mg, 40 mg OR MORE than the plan allowance of 2 capsules per day of morphine ER (generic Kadian) 50 mg, 60 mg, 80 mg, 100 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
19	Does the patient require use of MORE than the plan allowance of any of the following: A) 4 tablets per day of MS Contin 15 mg, 30 mg, B) 3 tablets per day of MS Contin 60 mg, C) 2 tablets per day of MS Contin 100 mg, 200 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column	Yes	No

	D for a 3 month supply) or quantity limits within the question.		
20	Does the patient require use of MORE than the plan allowance of 3 tablets per day of Nucynta ER 50 mg, 100 mg, 150 mg OR MORE than the plan allowance of 2 tablets per day of Nucynta ER 200 mg, 250 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
21	Does the patient require use of MORE than the plan allowance of 3 tablets per day of oxymorphone ER (generic Opana ER) 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, OR MORE than the plan allowance of 2 tablets per day of oxymorphone ER (generic Opana ER) 30 mg, 40 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
22	Does the patient require use of MORE than the plan allowance of 3 tablets per day of OxyContin 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, OR MORE than the plan allowance of 2 tablets per day of OxyContin 60 mg, 80 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No
23	Does the patient require use of MORE than the plan allowance of 3 capsules per day of Xtampza ER? [No further questions] RPh Note: If yes, then deny and enter a partial approval based on guidelines (for the requested drug, formulation and strength). Refer to Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply) or quantity limits within the question.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	[PA approved for 12 months. No set post	Go to 2	

	limit quantity. Enter approval for quantity of 999999.]. Approve, 12 Months		
2.	Go to 3	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for A) Pain due to cancer, sickle cell disease, or a terminal condition; B) Pain being managed through hospice or palliative care; C) Chronic pain severe and persistent enough to require long-term treatment with a daily opioid when you have been taking an opioid. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
3.	Go to 4	Deny	Your plan only covers this drug when you can safely take the requested dose based on your history of opioid use. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Safely take requested dose]
4.	Go to 5	Deny	Your plan only covers this drug when you will be monitored regularly. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Monitored regularly]
5.	Go to 6	Deny	Your plan only covers this drug when your pain will be checked the first month after your first prescription or after a dose increase and every 3 months after that, and the benefits outweigh the risks of taking the medication. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Patient reassessment]

6.	Go to 8	Go to 7	
7.	Go to 8	Deny	Your plan only covers this drug if you have been taking an extended-release opioid for at least 30 days or have been taking an immediate-release opioid for at least 1 week. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Disease category/stage/severity – Opioid Use]
8.	1=13 ;2=14 ;3=15 ;4=16 ;5=9 ;6=17 ;7=9 ;8=10 ;9=10 ;10=10 ;11=10 ;12=12 ;13=18 ;14=19 ;15=20 ;16=22 ;17=21 ;18=15 ;19=15 ;20=23		
9.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 units per day of hydrocodone bitartrate ER capsules (generic Zohydro ER) 10 mg, 15 mg, 20 mg, 30 mg, or 40 mg; B) 2 units per day of Hysingla ER 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, or 100 mg; C) 2 units per day of hydrocodone bitartrate ER capsules (generic Zohydro ER) 50 mg; D) 1 unit per day of Hysingla ER 120 mg.) Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Hydrocodone bitartrate ER capsules (generic Zohydro ER), Hysingla ER]
10.	Deny	Go to 11	We have denied your request because your plan does not cover this drug for detoxification treatment or as part of a treatment plan for opioid/substance abuse or addiction. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.

			[Short Description: Exclusion]
11.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 4 tablets per day of methadone (generic Dolophine) 5 mg, B) 4 tablets per day of Methadone 5 mg, C) 3 tablets per day of methadone (generic Dolophine) 10 mg, D) 3 tablets per day of Methadone 10 mg, E) 20 mL per day of Methadone 5 mg/5 mL oral solution, F) 15 mL per day of Methadone 10 mg/5 mL oral solution, G) 3 mL per day of Methadone 10 mg/mL Intensol solution, H) 1.334 mL per day (2 multidose vials per month) of Methadone 200 mg/20 mL injection). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – methadone (generic Dolophine), Methadone]
12.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 2 capsules per day of morphine ER [generic Avinza] 30 mg, 45 mg, 60 mg, 75 mg, or 90 mg; B) 1 capsule per day of morphine ER [generic Avinza] 120 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – morphine ER (generic Avinza)]
13.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 films per day of Belbuca 75 mcg, 150 mcg, 300 mcg, or 450 mcg; B) 2 films per day of Belbuca 600 mcg, 750 mcg, or 900 mcg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Belbuca]

14.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 0.287 patch per day [2 patches per week] of Butrans 5 mcg/hr, 7.5 mcg/hr, or 10 mcg/hr; B) 0.144 patch per day [1 patch per week] of Butrans 15 mcg/hr or 20 mcg/hr). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Butrans]
15.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 2 units per day of ConZip 100 mg, B) 2 units per day of tramadol ER 100 mg, C) 2 units per day of tramadol ER (generic Ultram ER) 100 mg, D) 1 unit per day of ConZip 200 mg, 300 mg, E) 1 unit per day of tramadol ER 200 mg or 300 mg, F) 1 unit per day of tramadol ER (generic Ultram ER) 200 mg or 300 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – ConZip, tramadol ER, tramadol ER (generic Ultram ER)]
16.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 0.667 patch per day [2 patches per 3 days] of fentanyl transdermal 12 mcg/hr, 25 mcg/hr, or 37.5 mcg/hr; B) 0.334 patch per day [1 patch per 3 days] of fentanyl transdermal 50 mcg/hr, 62.5 mcg/hr, 75 mcg/hr, 87.5 mcg/hr, or 100 mcg/hr). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Fentanyl transdermal]
17.	[Please select appropriate denial close option. For the denial verbiage, only	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 2 tablets per day of hydromorphone ER [generic Exalgo] 8 mg, 12 mg, or 16 mg; B) 1 tablet per day of hydromorphone ER [generic Exalgo] 32 mg). Your request for more drug has been denied. Your doctor can send us

	include the requested drug. Remove all other drugs from verbiage.]. Deny	(Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – hydromorphone ER (generic Exalgo)]
18.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 capsules per day of morphine ER [generic Kadian] 10 mg, 20 mg, 30 mg, or 40 mg; B) 2 capsules per day of morphine ER [generic Kadian] 50 mg, 60 mg, 80 mg, or 100 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – morphine ER (generic Kadian)]
19.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 4 tablets per day of MS Contin 15 mg or 30 mg, B) 3 tablets per day of MS Contin 60 mg, C) 2 tablets per day of MS Contin 100 mg or 200 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – MS Contin]
20.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 tablets per day of Nucynta ER 50 mg, 100 mg, or 150 mg; B) 2 tablets per day of Nucynta ER 200 mg or 250 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Nucynta ER]

		Months	
21.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 tablets per day of oxymorphone ER (generic Opana ER) 5 mg, 7.5 mg, 10 mg, 15 mg, or 20 mg; B) 2 tablets per day of oxymorphone ER (generic Opana ER) 30 mg or 40 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – oxymorphone ER (generic Opana ER)]
22.	[Please select appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all other drugs from verbiage.]. Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 3 tablets per day of OxyContin 10 mg, 15 mg, 20 mg, 30 mg, or 40 mg; B) 2 tablets per day of OxyContin 60 mg or 80 mg). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – OxyContin]
23.	Deny	[PA Approved for 6 months. See Opioid Analgesics ER Quantity Limits Chart (Column C for 1 month supply or Column D for a 3 month supply).]. Approve, 6 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (3 capsules per day). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial – Xtampza ER]

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

OPZELURA
(ruxolitinib cream)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit

POLICY

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 12 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 JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.

COVERAGE CRITERIA

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 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 12 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 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 12 years of age or older

- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]
- The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires more than 60 grams per 28 days

QUANTITY LIMITS APPLY

60 grams per 21 days* or 180 grams per 63 days**
For larger BSA: 240 grams per 21 days* or 720 grams per 63 days**
**The duration of 21 days is used for a 28-day fill period and 63 days is used for an 84-day fill period to allow time for refill processing.*
***** The intent is for prescriptions of the requested drug to be filled one month at a time for new starts; there should be no 3-month supplies filled for new starts.***

DURATION OF APPROVAL (DOA)

- 5556-C: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months

REFERENCES

1. Opzelura [package insert]. Wilmington, DE: Incyte Corporation; September 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed February 13, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/13/2024).
4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014; 70:338-51.
5. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol* 2014; 71:116-32.
6. Papp K, Szepietowski JC, Kircik L, et. al. Efficacy and safety of ruxolitinib cream for the treatment of atopic dermatitis: Results from 2 phase 3, randomized, double-blind studies. *J Am Acad Dermatol* 2021;85:863-72.
7. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. February 12, 2024. Available at: https://chemm.hhs.gov/burns.htm. Accessed February 13, 2024.
8. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023: 89(1): e1-e20.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ORAL FENTANYL PRODUCTS**
BRAND NAME* **(generic)**	**ACTIQ** **(fentanyl citrate oral transmucosal lozenge)**
	FENTORA **(fentanyl citrate buccal tablet)**
	SUBSYS **(fentanyl sublingual spray)**
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization with Quantity Limit*	***Ref # 288-C***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*
***No Tech Approval; criteria requires a pharmacist to approve.*

FDA-APPROVED INDICATIONS

Actiq
Actiq (fentanyl citrate oral transmucosal lozenge) 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 (fentanyl citrate buccal tablet) 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.

Subsys
Subsys (fentanyl sublingual spray) is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

For All Oral Fentanyl Products:
Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer. 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 Access program, oral fentanyl products may be dispensed only to outpatients enrolled in the program. For inpatient administration of oral fentanyl products (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

COVERAGE CRITERIA

[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.]

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: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.]
- If additional quantities are being requested, then the patient must meet ONE of the following:
    - 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.
Actiq (all strengths), Fentora (all strengths), Subsys (100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg): 120 units per 25 days* OR 360 units per 75 days*
Subsys (1200 mcg, 1600 mcg): 240 sprays (i.e., 120 blisters) per 25 days* or 720 sprays (i.e., 360 blisters) 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.*

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:
Actiq (all strengths), Fentora (all strengths), Subsys (100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg): 180 units per 25 days* OR 540 units per 75 days*
Subsys (1200 mcg, 1600 mcg): 360 sprays (i.e., 180 blisters) per 25 days* or 1080 sprays (i.e., 540 blisters) 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)

- 288-C: DOA: 12 months

REFERENCES

1. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2023.
3. Subsys [package insert]. Northbrook, IL: West Therapeutic Development LLC.; March 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed December 5, 2023.

5. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/05/2023).
6. Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 5, 2023.

Written by:	UM Development (JG)
Date Written:	04/2002
Revised:	(MB) 08/2004; (NB) 08/2005; (CT) 08/2006; (NB) 11/2006 (Added Fentora); (RP) 03/2007 (update label); (CT) 07/2007; (AM) 08/2008; (SE) 08/2009; (RB/AH/SE) 06/2010; (SE) 01/2011 (Added Abstral; Clarified age restriction question), 08/2011, 01/2012 added Subsys (08-2011 (2)), 03/2012, 03/2013, 07/2013 (changed to commercial reference number); (SE/MT) 01/2014; (SE) 06/2014, 01/2015; (CF) 08/2015 (added Onsolis, additional cancer question, documentation/tech notes), 10/2015 (added questions for additional quantities), 01/2016 (added Lazanda questions for macro compatibility, no clinical changes), 06/2016 (new strength of Lazanda – 300 mcg), 12/2016 (updated denial reasons, no clinical changes); (JH/CF) 01/2017, 07/2017 (clarified qty for Subsys 1200 mcg and 1600 mcg), 01/2018, 06/2018 (added note); (CF/DS) 01/2019 (no clinical changes), 01/2020 (removed Onsolis); (DS) 01/2021 (updated questions to reflect updated REMS; updated document title); (PM) 08/2021 (updated denial verbiage); (DS) 01/2022 (no clinical changes), (DFW) 01/2023 (removed Abstral and Lazanda, updated document title), 01/2024 (no clinical changes)
Reviewed:	Medical Affairs: 04/2002; (MM) 08/2004, 08/2005, 08/2006; (WF) MD 07/2007, 08/2008, 08/2009; (KP) 06/2010, 01/2011, 08/2011, 01/2012, 03/2012; (DNC) 03/2013; (LMS) 07/2013; (KP) 01/2014; (SES) 06/2014, 01/2015; (ADA) 08/2015; (DNC) 10/2015; (ME) 06/2016; (DNC) 01/2017, 07/2017, 01/2018; (MC) 06/2018; (CHART) 01/30/2020, 01/28/2021, 02/03/2022, 02/16/2023, 02/01/2024
External Review:	12/2004, 12/2006, 02/2008, 12/2008, 09/2009, 12/2010, 10/2011, 1/2012, 02/2012, 08/2012, 06/2013, 06/2014, 04/2015, 12/2015, 04/2016, 04/2017, 08/2017, 04/2018, 04/2019, 04/2020, 04/2021, 04/2022, 04/2023, 04/2024

CRITERIA FOR APPROVAL

1	The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. Is the requested drug being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain? ACTION REQUIRED: If yes, then prescriber MUST submit chart notes or other documentation supporting a diagnosis of cancer-related pain AND list type of cancer. For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS. [If Yes, then go to 2. If No, then no further questions.] Tech Note: Leave response as answered by prescriber. Verification of chart notes will be addressed in the next question.	Yes	No
2	Have chart notes or other documentation supporting a diagnosis of cancer-related pain been submitted to CVS Health? *ACTION REQUIRED: Submit supporting documentation* [If Yes, then go to 3. If No, then no further questions.] Tech Note: If the PA is worked over the phone, then the prescriber still MUST submit physical chart notes or other documentation. RPh Note: MUST obtain a physical copy of chart notes or other documentation supporting a diagnosis of cancer-related pain AND verify that the prescriber has listed the type of cancer. If a physical copy of documentation of a diagnosis of cancer-related pain is not received, then the PA should be denied.	Yes	No
3	Is the patient currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain? [If Yes, then go to 4. If No, then no further questions.]	Yes	No

4	The requested drug is intended only for use in opioid tolerant patients. Can the patient safely take the requested dose based on their current opioid use history? [NOTE: Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25 mcg per hour of transdermal fentanyl, at least 30 mg of oral oxycodone per day, at least 60 mg of oral hydrocodone per day, at least 8 mg of oral hydromorphone per day, at least 25 mg of oral oxymorphone per day, or an equianalgesic dose of another opioid medication daily for one week or longer.] [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Which drug is being requested? [NOTE: Please check the drug being requested. 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.] [] Actiq (fentanyl citrate oral transmucosal lozenge) (all strengths) (If checked, go to 6) [] Fentora (fentanyl citrate buccal tablet) (all strengths) (If checked, go to 6) [] Subsys (fentanyl sublingual spray) 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg (If checked, go to 6) [] Subsys (fentanyl sublingual spray) 1200 mcg, 1600 mcg (If checked, go to 7)		
6	Coverage is provided for up to 120 units per month of the following: A) Actiq (all strengths), B) Fentora (all strengths), C) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, or 800 mcg. If additional quantities are needed, then additional questions are required. Is MORE than this quantity needed to manage the patient's pain? [NOTE Subsys packaging: Supplied as 1 spray per blister for Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.] [If Yes, then go to 8. If No, then no further questions.]	Yes	No
7	Coverage is provided for up to 240 sprays per month (i.e., 120 blisters per month) of Subsys 1200 mcg or 1600 mcg. If additional quantities are needed, then additional questions are required. Is MORE than this quantity needed to manage the patient's pain? [NOTE Subsys packaging: Supplied as 2 sprays per blister for Subsys 1200 mcg and 1600 mcg.] [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Is the patient's dose of a concomitant long-acting analgesic being increased? [If Yes, then go to 10. If No, then go to 9.]	Yes	No

9	Are additional quantities of the requested drug needed for breakthrough pain because the dose of the patient's long-acting analgesic is unable to be increased? [If Yes, then go to 10. If No, then no further questions.] RPh Note: If no, then deny and enter a partial approval for one the following: A) 120 units per month of Actiq (all strengths), B) 120 units per month of Fentora (all strengths), C) 120 units per month of Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, or 800 mcg, D) 240 sprays per month (i.e., 120 blisters per month) of Subsys 1200 mcg or 1600 mcg.	Yes	No
10	Which drug is being requested? [NOTE: Please check the drug being requested. 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.] [] Actiq (fentanyl citrate oral transmucosal lozenge) (all strengths) (If checked, go to 11) [] Fentora (fentanyl citrate buccal tablet) (all strengths) (If checked, go to 11) [] Subsys (fentanyl sublingual spray) 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg (If checked, go to 11) [] Subsys (fentanyl sublingual spray) 1200 mcg, 1600 mcg (If checked, go to 12)		
11	Does the patient's pain require use of MORE than 180 units per month of any of the following: A) Actiq (all strengths), B) Fentora (all strengths), C) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, or 800 mcg? [NOTE Subsys packaging: Supplied as 1 spray per blister for Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.] [No further questions] RPh Note: If yes, then deny and enter a partial approval for 180 units per month of one of the following: A) Actiq (all strengths), B) Fentora (all strengths), C) Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, or 800 mcg.	Yes	No
12	Does the patient's pain require use of MORE than 360 sprays per month (i.e., 180 blisters per month) of Subsys 1200 mcg or 1600 mcg? [NOTE Subsys packaging: Supplied as 2 sprays per blister for Subsys 1200 mcg and 1600 mcg.] [No further questions] RPh Note: If yes, then deny and enter a partial approval for 360 sprays per month (i.e., 180 blisters per month) of Subsys 1200 mcg or 1600 mcg.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for breakthrough cancer-related pain in someone with cancer and underlying cancer pain. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Deny	Your plan only covers this drug when records saying you have pain caused by cancer are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records, or your records did not show all of the following: A) You have pain caused by cancer, B) The type of cancer you have, and C) A diagnosis code that shows you have cancer. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis – Chart Notes]
3.	Go to 4	Deny	Your plan only covers this drug if you will be taking it with around-the-clock opioid pain medicine for your underlying cancer pain. We have denied your request because you are not (or will not be) taking it. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Not on required concurrent therapy]
4.	Go to 5	Deny	Your plan only covers this drug when you can safely take the drug based on your history of opioid use. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Patient cannot safely take requested dose]

5.	1=6 ;2=6 ;3=6 ;4=7		
6.	Go to 8	[PA approved for 12 month(s). Approve 120 units per 25 days* OR 360 units per 75 days* of: Actiq (all strengths), Fentora (all strengths), Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg. No Tech Approval.]. Approve, 12 Months	
7.	Go to 8	[PA approved for 12 month(s). Approve 240 sprays (i.e., 120 blisters) per 25 days* OR 720 sprays (i.e., 360 blisters) per 75 days* of Subsys 1200 mcg or 1600 mcg. No Tech Approval.]. Approve, 12 Months	
8.	Go to 10	Go to 9	
9.	Go to 10	[Please select the appropriate denial close option. For the denial verbiage, only include the requested	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (A) 120 units per month of Actiq, B) 120 units per month of Fentora, C) 120 units per month of Subsys 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg and 800 mcg, and D) 240 sprays (i.e., 120 blisters) of Subsys 1200 mcg and 1600 mcg). Your request for more drug has been denied. Your doctor can send us any new or

		drug. Remove all the other drugs from the verbiage.]. Deny	missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Post limit criteria not met, Partial denial]
10.	1=11 ;2=11 ;3=11 ;4=12		
11.	[Please select the appropriate denial close option. For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.]. Deny	[PA approved for 12 month(s). Approve 180 units per 25 days* OR 540 units per 75 days* of: Actiq (all strengths), Fentora (all strengths), Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg. No Tech Approval.]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan covers up to A) 180 units per month of Actiq, B) 180 units per month of Fentora, and C) 180 units per month of Subsys 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit]
12.	[Please select the appropriate denial close option. RPh Note: For the denial verbiage, only include the requested drug. Remove all the other drugs from the verbiage.]. Deny	[PA approved for 12 month(s). Approve 360 sprays (i.e., 180 blisters) per 25 days* OR 1080 sprays (i.e., 540 blisters) per 75 days* of Subsys 1200 mcg or 1600 mcg. No Tech Approval.]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan covers up to 360 sprays (i.e., 180 blisters) per month of Subsys 1200 mcg and 1600 mcg. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit – Subsys 1200 mcg, 1600 mcg]

Reference number(s)
2127-A

Specialty Guideline Management
Orencia

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
Orencia	abatacept

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

- Moderately to severely active rheumatoid arthritis (RA) in adults
- Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- Active psoriatic arthritis (PsA) in patients 2 years of age and older
- Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

Compendial Uses

- Oligoarticular juvenile idiopathic arthritis
- Chronic graft versus host disease
- Immune checkpoint inhibitor-related toxicity

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)

- 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.

Chronic Graft Versus Host Disease

- For 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.

Immune Checkpoint Inhibitor-Related Toxicity

For 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 and articular juvenile idiopathic arthritis: rheumatologist
- Psoriatic arthritis: rheumatologist or dermatologist
- Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: oncologist or hematologist

Coverage Criteria

Rheumatoid Arthritis (RA)

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 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 either of the following criteria:
    - Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
    - Member has an intolerance or contraindication to methotrexate (see Appendix A).

Articular Juvenile Idiopathic Arthritis (JIA)

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

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

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

Psoriatic Arthritis (PsA)

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.
- Member has severe disease.

Prophylaxis of Acute Graft Versus Host Disease

Authorization of 1 month may be granted for prophylaxis of acute graft versus host disease in members 2 years of age or older when both of the following criteria are met:

- Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.
- The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

Chronic Graft Versus Host Disease

Authorization of 12 months may be granted for treatment of chronic 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.

Immune Checkpoint Inhibitor-Related Toxicity

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has myocarditis and meets any of the following:

- Member has had an inadequate response to systemic corticosteroids.
- Member has an intolerance or contraindication to corticosteroids.
- Member has concomitant myositis and the requested medication will be used in combination with ruxolitinib.

Continuation of Therapy

Rheumatoid Arthritis (RA)

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 (JIA)

Authorization of 12 months may be granted for all members 2 years of age or older (including new members) who are using the requested medication for moderately to severely active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease

activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

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

Psoriatic Arthritis (PsA)

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

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.

Prophylaxis of 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.

Other

For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA]) within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

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

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

Dosage and Administration

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

Appendix

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Leflunomide

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

Appendix B: Risk Factors for Articular Juvenile Idiopathic Arthritis

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

References

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; May 2024.

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8. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 14, 2024.
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13. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. Ann Rheum Dis. 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531.
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15. Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6): 1445-86.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

ORIAHNN
(elagolix/estradiol/norethindrone acetate)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization ***Ref # 3960-A***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Oriahnn is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.

Limitation of Use:
Use of Oriahnn should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

COVERAGE CRITERIA

Heavy Menstrual Bleeding Associated with Uterine Leiomyomas (Fibroids)
Authorization may be granted when the requested drug is being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) when ALL of the following criteria are met:

- The patient is premenopausal
- If the patient has previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree), the patient has not 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

REFERENCES

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Written by:	UM Development (KC)
Date Written:	06/2020
Revised:	(CJM) 12/2020 (Changed criteria for approval and added DOA limit); CJH 06/2021 (Added Myfembree to q-set); (DRS) 01/2022 added prescriber note), (SS) 12/2022 (no clinical changes); (KMB) 12/2023 (no clinical changes)
Reviewed:	Medical Affairs (CHART) 06/18/2020, 12/31/2020, 06/10/2021, 12/30/2021, 12/29/2022, 12/21/2023 External Review: 08/2020, 04/2021, 06/2021, 04/2022, 04/2023, 04/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a premenopausal patient? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient previously received treatment with an elagolix-containing product (e.g., Oriahnn, Orilissa) or a relugolix-containing product (e.g., Myfembree)? [Note: Use of elagolix-containing products and relugolix-containing products should be limited due to the risk of continued bone loss, which may not be reversible. The risk of bone loss is increased if multiple agents are used that can cause this effect.] [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Has the patient already received ANY of the following: A) 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), B) Greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	How many cumulative months has the patient received treatment with elagolix-containing products (e.g., Oriahnn, Orilissa) and/or relugolix-containing products (e.g., Myfembree)? Please check the total cumulative months of treatment. [Note: The use of Orilissa 200 mg twice daily may cause rapid bone mineral density (BMD) loss due to dose-related effects. Please take into consideration when prescribing and assessing total cumulative months if prior use was less than 6 months.] [] 12 months or less (If checked, no further questions) [] 13 months (If checked, no further questions)		

[] 14 months (If checked, no further questions)

[] 15 months (If checked, no further questions)

[] 16 months (If checked, no further questions)

[] 17 months (If checked, no further questions)

[] 18 months (If checked, no further questions)

[] 19 months (If checked, no further questions)

[] 20 months (If checked, no further questions)

[] 21 months (If checked, no further questions)

[] 22 months (If checked, no further questions)

[] 23 months (If checked, no further questions)

[] 24 months or greater (If checked, no further questions)

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are for heavy period bleeding due to uterine fibroids in premenopausal patients. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
2.	Go to 3	Approve, 12 Months	
3.	Deny	Go to 4	We have denied your request because your plan does not cover this drug when you have already received greater than or equal to 24 total months of treatment with certain drugs (e.g., Myfembree, Oriahnn, Orilissa) or you have already received greater than or equal to 6 months of treatment with Orilissa 200 mg twice daily. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exceeds max duration of use]

4.	1=Approve, 12 Months ;2=Approve, 11 Months ;3=Approve, 10 Months ;4=Approve, 9 Months ;5=Approve, 8 Months ;6=Approve, 7 Months ;7=Approve, 6 Months ;8=Approve, 5 Months ;9=Approve, 4 Months ;10=Approve, 3 Months ;11=Approve, 2 Months ;12=Approve, 1 Months ;13=Deny		Your plan only covers this drug for total cumulative treatment of 24 months with certain drugs (e.g., Myfembree, Oriahnn, Orilissa) for your health condition. We have denied your request for this drug because it is for longer treatment. We reviewed the information we had. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exceeds total cumulative duration of therapy]

Reference number(s)
3426-A

SPECIALTY GUIDELINE MANAGEMENT

OXBRYTA (voxelotor)

POLICY

I. 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
Oxbryta is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older.

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

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a hematologist or specialist in sickle cell disease.

III. CRITERIA FOR INITIAL APPROVAL

Sickle cell disease (SCD)
Authorization of 6 months may be granted for treatment of sickle cell disease in members 4 years of age or older with a pretreatment hemoglobin level of 10.5 g/dL or less, when either of the following criteria is met:

A. Member has sickle hemoglobin C (HbSC) or sickle β^+-thalassemia (HbSβ^+) genotype.
B. Member has homozygous hemoglobin S (HbSS) or sickle β^0-thalassemia (HbSβ^0) genotype AND meets any of the following:
    1. Has experienced, at any time in the past, an inadequate response or intolerance to a trial of hydroxyurea.
    2. Has a contraindication to hydroxyurea.
    3. Will be using Oxbryta with concurrent hydroxyurea therapy.

Note: Requirements regarding pretreatment hemoglobin level exclude values due to a recent transfusion.

IV. CONTINUATION OF THERAPY

Sickle cell disease (SCD)
Authorization of 12 months may be granted for continued treatment in members experiencing benefit from therapy as demonstrated by increased hemoglobin levels or maintenance of increased hemoglobin levels since starting treatment.

V. REFERENCES

Reference number(s)
3426-A

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

SPECIALTY GUIDELINE MANAGEMENT

PEGASYS (peginterferon alfa-2a)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Chronic Hepatitis C
      i. 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.
      ii. In combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease.
   2. Chronic Hepatitis B
      i. 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.
      ii. 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).

B. Compendial Uses
   1. Myeloproliferative neoplasms (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis)
   2. Systemic mastocytosis
   3. Adult T-cell leukemia/lymphoma
   4. Mycosis fungoides/Sezary syndrome
   5. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
   6. Hairy cell leukemia
   7. Erdheim-Chester disease
   8. Chronic myeloid leukemia

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

II. INITIAL CRITERIA FOR APPROVAL

A. Chronic hepatitis C virus (HCV) infection
Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

B. Chronic hepatitis B virus (HBV) infection (including hepatitis D virus [HDV] coinfection)
Authorization of up to 48 weeks total may be granted for treatment of chronic HBV infection, including HDV coinfection.

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

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

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

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

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

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

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

J. Chronic myeloid leukemia
Authorization of 12 months may be granted for treatment of chronic myeloid leukemia in pregnancy.

III. CONTINUATION OF THERAPY

A. Chronic HCV infection and chronic HBV infection (including HDV coinfection)
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

B. Myeloproliferative neoplasm
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).

C. Systemic mastocytosis
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).

D. All other indications
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in Section II, not previously listed, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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Reference number(s)
4631-A

SPECIALTY GUIDELINE MANAGEMENT

PONVORY (ponesimod)

POLICY

I. 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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER

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

VI. REFERENCES

1. Ponvory [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; August 2023.

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

ACIPHEX
(rabeprazole)

DEXILANT
(dexlansoprazole)

NEXIUM
(esomeprazole)

PREVACID
(lansoprazole)

PRILOSEC
(omeprazole)

PROTONIX
(pantoprazole)

Status: Client Requested Criteria
Type: Initial Prior Authorization ***Ref # C25428-A***

CRITERIA FOR APPROVAL

1	Is the request for a preferred proton pump inhibitor (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [If yes, then skip to question 19.]	Yes	No
2	Is the patient 21 years of age or older? [If yes, then skip to question 6.]	Yes	No
3	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 5.]	Yes	No
4	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No
5	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No

6	Is this request for continuation of therapy? [If no, then skip to question 13.]	Yes	No
7	Has the patient experienced or maintained a documented positive clinical response to therapy? [If no, then no further questions.]	Yes	No
8	Has the patient previously been through the CountyCare prior authorization process and has received an authorization in the past 12 months? [If yes, then no further questions.]	Yes	No
9	Is the patient on a stable regimen and disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation? [If yes, then no further questions.]	Yes	No
10	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 12.]	Yes	No
11	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No
12	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No
13	Is the patient under the care of a gastroenterologist? [If no, then no further questions.]	Yes	No
14	Does the patient have one of the following conditions: A) GI bleed, B) Erosive esophagitis, C) Pathological hypersecretory syndrome, D) Unhealed gastric, duodenal or peptic ulcer, E) Barret's esophagus, F) Zollinger-Ellison syndrome, G) Helicobacter pylori infection? [If yes, then skip to question 16.]	Yes	No
15	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation? [If no, then no further questions.]	Yes	No
16	Does the patient have difficulty swallowing pills, or unable to swallow requiring an alternative method of feeding (pureed meals, PEG tube, IV nutrition)? [If no, then skip to question 18.]	Yes	No
17	Has the patient tried and failed or have a contraindication to the preferred product lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab)? [No further questions.]	Yes	No

18	Does the patient have at least a 90-day history of at least TWO of the following PDL preferred proton pump inhibitors (PPI): A) lansoprazole oral disintegrating tablet (generic of Prevacid SoluTab), B) omeprazole delayed-release capsule (generic of Prilosec), C) omeprazole enteric-coated tablet (generic of Prilosec), D) omeprazole magnesium enteric-coated tablet (generic of Prilosec OTC), and E) pantoprazole sodium enteric-coated tablet (generic of Protonix)? [No further questions.]	Yes	No
19	Is the patient 21 years of age or older? [If no, then no further questions.]	Yes	No
20	Is this request for continuation of therapy? [If no, then skip to question 24.]	Yes	No
21	Has the patient experienced or maintained a documented positive clinical response to therapy? [If no, then no further questions.]	Yes	No
22	Has the patient previously been through the CountyCare prior authorization process and has received an authorization in the past 12 months? [If yes, then no further questions.]	Yes	No
23	Is the patient on a stable regimen and disruption of treatment could result in harm to the patient including significant loss of function, hospitalization, or exacerbation? [If yes, then no further questions.]	Yes	No
24	Is the patient under the care of a gastroenterologist? [If no, then no further questions.]	Yes	No
25	Does the patient have one of the following conditions: A) GI bleed, B) Erosive esophagitis, C) Pathological hypersecretory syndrome, D) Unhealed gastric, duodenal or peptic ulcer, E) Barret's esophagus, F) Zollinger-Ellison syndrome, G) Helicobacter pylori infection? [If yes, then no further questions.]	Yes	No
26	Does the patient have NON-complicated gastroesophageal reflux disease (GERD)?	Yes	No
27	Is the drug requested for a non-FDA approved indication for a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in two peer-reviewed medical literature articles, accepted standards of medical practice, or in one of the following compendia: A) American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use, B) Clinical Pharmacology: Contains narrative text supporting use, C) National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A, D) Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb, E) Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation?	Yes	No

REFERENCES

1. CountyCare Prior Authorization Criteria: Proton Pump Inhibitors. 03/2024.

DOCUMENT HISTORY

Created: VLS 06/2023
Revised: VLS 03/2024; ANB 09/2024
Reviewed: 08/2023, 06/2024, 09/2024

Reference number(s)
4179-A

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

Treatment of Plaque Psoriasis

Abrilada, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, infliximab, Otezla, Remicade, Renflexis, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Wezlana, Yuflyma, Yusimry

I. 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-fkjp, adalimumab-ryvk, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, infliximab, Otezla, Remicade, Renflexis, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, Wezlana, 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 approval criteria are met and the member has no exclusions to the prescribed therapy.

II. DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

A. For initial requests:
   1. Chart notes or medical record documentation of the following at the time of diagnosis (where applicable): a 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.
   2. 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.

B. For continuation: 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.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. 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:

1. The member has met one of following criteria:
   i. At least 10% of body surface area (BSA) is affected.
   ii. At least 3% of BSA is affected and has a Psoriasis Area Severity Index (PASI) score of ≥ 10.
   iii. 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).
2. The member had an inadequate response at the maximum tolerated dose with all of the following:
   i. 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:
      a. BSA > 10% is affected.
      b. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
      c. Failure of topical pharmacologic therapy at the maximum tolerated dose and specified duration from any of the following classes:
         1. Medium to super-high potency topical corticosteroid therapy (see Appendix A) for a duration of at least 4 weeks.
         2. Topical calcineurin inhibitor therapy for a duration of at least 8 weeks.
         3. Topical vitamin D analog therapy for a duration of at least 12 weeks.
         4. Topical retinoid therapy for a duration of at least 12 weeks.
         5. Topical aryl hydrocarbon receptor agonist therapy for a duration of at least 12 weeks.
         6. Topical phosphodiesterase 4 inhibitor therapy for a duration of at least 8 weeks.
   ii. 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.
   iii. Any of the following:
      a. Methotrexate at a dose of at least 25 mg/week or at the maximum tolerated dose for a duration of at least 3 months.
      b. 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.
      c. 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.
      d. The member has a clinical reason to avoid systemic pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix B).

V. 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 section IV 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 when any of the following criteria is met:

A. Member has a psoriasis involvement of ≤ 3% body surface area (BSA)
B. Member has a ≥ 75% BSA improvement from baseline
C. Member has at least a 75% reduction in the PASI score from baseline

D. Member has at least a 50% reduction in the PASI score from baseline and a Dermatology Life Quality Index (DLQI) score 5 or less

VI. OTHER

For all drugs other than Otezla, 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.

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

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

Potency	Drug	Dosage form	Strength
III. High potency (group 3)	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%
	Mometasone furoate	Cream, Lotion, Solution	0.1%
	Triamcinolone acetonide	Cream	0.1%
		Ointment	0.05% and 0.1%
		Aerosol Spray	0.2 mg per 2-second spray
V. Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%
	Desonide	Ointment, Gel	0.05%
	Fluocinolone acetonide	Cream	0.025%
	Flurandrenolide	Cream, Lotion	0.05%
	Fluticasone propionate	Cream, Lotion	0.05%
	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
	Hydrocortisone probutate	Cream	0.1%
	Hydrocortisone valerate	Cream	0.2%
	Prednicarbate	Cream (emollient), Ointment	0.1%
	Triamcinolone acetonide	Lotion	0.1%
		Ointment	0.025%
VI. Low potency (group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
	Betamethasone valerate	Lotion	0.1%
	Desonide	Cream, Lotion, Foam	0.05%
	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
	Triamcinolone acetonide	Cream, lotion	0.025%
VII. Least potent (group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%
		Lotion	2%
	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
		Cream, Ointment	0.5%
	Hydrocortisone acetate	Cream	2.5%
		Lotion	2%

Potency	Drug	Dosage form	Strength
		Cream	1%

Appendix B. Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin

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

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Reference number(s)
3373-E

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit
Reyvow (lasmiditan)

Products Referenced by this Document

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

Brand Name	Generic Name
Reyvow	lasmiditan

Indications

FDA-approved Indications

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

Limitations of Use

Reyvow is not indicated for the preventive treatment of migraine.

Initial Step Therapy with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30-day supply of TWO triptan 5-HT1 agonists (include combinations) within the past 180 days under a prescription benefit administered by CVS Caremark, then

the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

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

Initial Limit Criteria

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

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

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

Drug	**1 Month Limit**	**3 Month Limit**
Reyvow 50 mg	4 tablets / 25 days	12 tablets / 75 days
Reyvow 100 mg	8 tablets / 25 days	24 tablets / 75 days

Coverage Criteria

Authorization may be granted when the requested drug is being prescribed for the acute treatment of migraine with or without aura in an adult patient when ALL of the following criteria are met:

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response or an intolerance to TWO triptan 5-HT1agonists
  - The patient has a contraindication that would prohibit a trial of triptan 5-HT1 agonists
- If additional quantities are being requested, 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.]
  - 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
1987-D

ENHANCED SPECIALTY GUIDELINE MANAGEMENT

Treatment of Rheumatoid Arthritis

Abrilada, Actemra, adalimumab, adalimumab-aacf, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, infliximab, Kevzara, Kineret, Orencia, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, Tofidence, Tyenne, Yuflyma, Yusimry

I. 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, 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.

II. DOCUMENTATION

The following information must be submitted:

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

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. Authorization of 12 months may be granted when the member has not previously received a biologic or targeted synthetic drug indicated for RA when all of the following criteria are met:

1. Member meets either of the following:
    i. Member has been tested for either of the following biomarkers and the test was positive:
        a. Rheumatoid factor (RF)
        b. Anti-cyclic citrullinated peptide (anti-CCP)

ii. Member has been tested for ALL of the following biomarkers:
   a. RF
   b. Anti-CCP
   c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)

2. Member meets ONE of the following:

   i. 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:
      a. 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).
      b. Member has experienced a documented intolerable adverse event to hydroxychloroquine or sulfasalazine.
      c. Member has a documented contraindication to hydroxychloroquine (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).
      d. Member has moderate to high disease activity.

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

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

   iv. The requested product is Actemra, Tofidence, or Tyenne.

3. 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).

4. 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.

V. CONTINUATION OF THERAPY

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

VI. 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 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.

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

Examples of clinical reasons to avoid pharmacologic treatment with methotrexate, hydroxychloroquine, or leflunomide

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

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Reference number(s)
3173-A

SPECIALTY GUIDELINE MANAGEMENT

RINVOQ (upadacitinib)

POLICY

I. 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
Rinvoq is indicated for:

A. 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.
B. 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.
C. 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.
D. Adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response or intolerance to one or more TNF blockers.
E. Adults with active ankylosing spondylitis (AS) who have had an inadequate response or intolerance to one or more TNF blockers.
F. 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.
G. Adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response or intolerance to one or more TNF blockers.
H. 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.

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and polyarticular juvenile idiopathic arthritis (pJIA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Atopic dermatitis
   1. Initial requests:
      i. Chart notes or medical records showing affected area(s) and affected body surface area (where applicable).

ii. Chart notes, medical record documentation, or claims history of prerequisite therapies, including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.

2. Continuation requests: Documentation (e.g., chart notes) supporting positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

C. Ulcerative colitis (UC)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

D. Crohn's disease (CD)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Atopic dermatitis: dermatologist or allergist/immunologist
D. Ulcerative colitis and Crohn's disease: gastroenterologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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 or intolerance to at least one tumor necrosis factor (TNF) inhibitor.

2. 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., Xeljanz, Olumiant) indicated for moderately to severely active RA.

B. Psoriatic arthritis (PsA)

1. 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 or intolerance to at least one TNF inhibitor.

2. 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 (e.g., Xeljanz, Otezla) indicated for active psoriatic arthritis.

C. Atopic dermatitis

1. 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 experienced an inadequate response or intolerance to at least one biologic (e.g., Dupixent, Adbry) or a targeted synthetic drug (e.g., Cibinqo) in the past year.

2. 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:
   i. 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.
   ii. Member meets one of the following:
      a. Member has had an inadequate treatment response with one of the following in the past year:
         1. A medium potency to super-high potency topical corticosteroid (see Appendix)
         2. A topical calcineurin inhibitor
      b. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances).
   iii. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) indicated for the treatment of atopic dermatitis, or use of these therapies are not advisable for the member.

D. Ulcerative colitis (UC)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active UC when the member has had an inadequate response or intolerance to at least one TNF inhibitor.

2. 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., Xeljanz) indicated for moderately to severely active ulcerative colitis.

E. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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., Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

F. Crohn's disease (CD)

1. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active CD when the member has had an inadequate response or intolerance to at least one TNF inhibitor.

2. Authorization of 12 months may be granted for adult members who have previously received a biologic (other than a TNF inhibitor) indicated for moderately to severely active Crohn's disease.

G. 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 or intolerance to at least one TNF inhibitor.

2. 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 polyarticular juvenile idiopathic arthritis.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Psoriatic arthritis

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. 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 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).

D. Ulcerative colitis (UC)

1. 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 ulcerative colitis and who achieve or maintain remission.

2. 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 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

E. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
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:
1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

F. Crohn's disease (CD)
1. 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.

2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

G. Polyarticular juvenile idiopathic arthritis (pJIA)
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:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

VI. OTHER

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, targeted synthetic drug, or potent immunosuppressant such as azathioprine or cyclosporine.

VII. DOSAGE AND ADMINISTRATION

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

VIII. 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%
	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
	Fluocinonide	Cream	0.1%
	Flurandrenolide	Tape	4 mcg/cm^2
	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
II. High potency (group 2)	Amcinonide	Ointment	0.1%
	Augmented betamethasone dipropionate	Cream	0.05%
	Betamethasone dipropionate	Ointment	0.05%
	Clobetasol propionate	Cream	0.025%
	Desoximetasone	Cream, Ointment, Spray	0.25%
		Gel	0.05%
	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
	Halcinonide	Cream, Ointment	0.1%
	Halobetasol propionate	Lotion	0.01%
III. High potency (group 3)	Amcinonide	Cream, Lotion	0.1%
	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
	Betamethasone valerate	Ointment	0.1%
		Foam	0.12%
	Desoximetasone	Cream, Ointment	0.05%
	Diflorasone diacetate	Cream	0.05%
	Fluocinonide	Cream, aqueous emollient	0.05%
	Fluticasone propionate	Ointment	0.005%
	Mometasone furoate	Ointment	0.1%
	Triamcinolone acetonide	Cream, Ointment	0.5%
IV. Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	Fluocinolone acetonide	Ointment	0.025%
	Flurandrenolide	Ointment	0.05%
	Hydrocortisone valerate	Ointment	0.2%

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

IX. REFERENCES

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Reference number(s)
2099-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN HYCELA (rituximab and hyaluronidase human)

POLICY

I. 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.

A. FDA-Approved Indications
1. Adult patients with follicular lymphoma (FL):
   a. Relapsed or refractory, follicular lymphoma as a single agent
   b. 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
   c. Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
2. 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
3. Adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC)

Limitations of Use:
Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.
Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

B. Compendial Uses
1. B-cell lymphomas:
   a. Castleman's disease (CD)
   b. 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)
   c. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
   d. Marginal zone lymphomas
      i. Nodal marginal zone lymphoma
      ii. Splenic marginal zone lymphoma
      iii. Extranodal Marginal Zone Lymphoma (Gastric and Nongastric mucosa associated lymphoid tissue {MALT} lymphoma)
   e. Mantle cell lymphoma
2. Post-transplant lymphoproliferative disorder (PTLD)
3. Hairy cell leukemia
4. Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
5. Small lymphocytic lymphoma (SLL)
6. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
7. Hodgkin lymphoma, nodular lymphocyte-predominant

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

II. 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

III. CRITERIA FOR INITIAL APPROVAL

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.

A. Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)
Authorization of 12 months may be granted for treatment of CD20 positive CLL or SLL.

B. Hairy cell leukemia (HCL)
Authorization of 12 months may be granted for treatment of CD20 positive HCL.

C. B-cell lymphomas
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:

1. Castleman's disease (CD)
2. Diffuse large B-cell lymphoma (DLBCL)
3. 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)
5. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
6. Mantle cell lymphoma
7. Post-transplant lymphoproliferative disorder (PTLD)
8. Marginal zone lymphomas
    i. Nodal marginal zone lymphoma
    ii. Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
    iii. Splenic marginal zone lymphoma

D. Primary cutaneous B-cell lymphoma
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).

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

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

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity.

V. REFERENCES

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Reference number(s)
1704-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)
RIABNI (rituximab-arrx)

Treatment of Hematologic and Oncologic Conditions

POLICY

I. 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.

A. FDA-Approved Indications
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:
1. Non-Hodgkin's lymphoma (NHL) in adult patients with:
   a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
   b. 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
   c. 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
   d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. 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.
3. 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)
4. 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)

B. Compendial Uses
1. Autoimmune hemolytic anemia
2. B-cell acute lymphoblastic leukemia (ALL)

3. B-cell lymphomas
    a. Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas
    b. B-cell lymphoblastic lymphoma
    c. Burkitt lymphoma
    d. Castleman's disease
    e. Diffuse Large B-Cell lymphoma
    f. Follicular lymphoma
    g. 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)
    h. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
    i. Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
    j. Mantle cell lymphoma
    k. Marginal zone lymphomas
        i. Nodal marginal zone lymphoma
        ii. Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma)
        iii. Splenic marginal zone lymphoma
    l. Post-transplant lymphoproliferative disorder (PTLD)
    m. Pediatric Aggressive Mature B-Cell Lymphomas
    n. Primary Mediastinal Large B-Cell Lymphoma
4. Central nervous system (CNS) cancers
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphomas
5. Chronic graft-versus-host disease (GVHD)
6. CLL/Small lymphocytic lymphoma (SLL)
7. Hairy cell leukemia
8. Rosai-Dorfman disease
9. Hodgkin's lymphoma, nodular lymphocyte-predominant
10. Immune checkpoint inhibitor-related toxicities
11. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
12. Primary cutaneous B-cell lymphoma
13. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
14. Thrombotic thrombocytopenic purpura
15. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/ Bing-Neel syndrome
16. Allogeneic transplant conditioning
17. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM

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

II. 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)

III. CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications

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:

1. B-cell acute lymphoblastic leukemia (ALL)
2. B-cell lymphomas:
    i. HIV-Related B-Cell Lymphomas
    ii. B-cell lymphoblastic lymphoma
    iii. Burkitt lymphoma
    iv. Castleman's disease
    v. Diffuse large B-cell lymphoma
    vi. Follicular lymphoma
    vii. 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)
    viii. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
    ix. Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
    x. Mantle cell lymphoma
    xi. Marginal zone lymphomas
        a. Nodal marginal zone lymphoma
        b. Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
        c. Splenic marginal zone lymphoma
    xii. Post-transplant lymphoproliferative disorder (PTLD)
    xiii. Pediatric Aggressive Mature B-Cell Lymphomas
    xiv. Primary Mediastinal Large B-Cell Lymphoma
3. Central nervous system (CNS) cancers:
    i. Leptomeningeal metastases from lymphomas
    ii. Primary CNS lymphoma
4. CLL/Small lymphocytic lymphoma (SLL)
5. Hairy cell leukemia
6. Rosai-Dorfman disease
7. Hodgkin's lymphoma, nodular lymphocyte-predominant
8. Primary cutaneous B-cell lymphoma
9. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/Bing-Neel syndrome

B. Hematologic indications

Authorization of 12 months may be granted for treatment of any of the following indications:

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
2. Autoimmune hemolytic anemia
3. Thrombotic thrombocytopenic purpura
4. Chronic graft-versus-host disease (GVHD)
5. Prevention of Epstein-Barr virus (EBV)-related PTLD
6. As part of a non-myeloablative conditioning regimen for allogeneic transplant

C. Immune checkpoint inhibitor-related toxicities

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

IV. CONTINUATION OF THERAPY

For oncologic indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in Section III A. when there is no evidence of unacceptable toxicity.

For 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.

For all other indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III B. who are experiencing benefit from therapy.

V. REFERENCES

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Reference number(s)
1651-A

SPECIALTY GUIDELINE MANAGEMENT

REVATIO (sildenafil)
LIQREV (sildenafil)
sildenafil

POLICY

I. 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.

A. FDA-Approved Indications
1. Revatio/Liqrev/sildenafil is 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.
2. Revatio/sildenafil is 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 underly improvements in exercise.

B. Compendial Uses
1. Secondary Raynaud's phenomenon
2. PAH (WHO Group I) in pediatric members less than 1 year of age

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

II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist for the diagnosis of pulmonary arterial hypertension (PAH).

III. CRITERIA FOR INITIAL APPROVAL

A. Pulmonary arterial hypertension (PAH)
Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:
1. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
2. PAH was confirmed by either criterion (i) or criterion (ii) below:
   i. Pretreatment right heart catheterization with all of the following results:
      a. Mean pulmonary arterial pressure (mPAP) > 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
      c. Pulmonary vascular resistance (PVR) ≥ 3 Wood units in adult members or pulmonary vascular resistance index (PVRI) ≥ 3 Wood units x m^2 in pediatric members

ii. For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

B. Secondary Raynaud's phenomenon

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:

1. Calcium channel blockers
2. Angiotensin II receptor blockers
3. Selective serotonin reuptake inhibitors
4. Alpha blockers
5. Angiotensin-converting enzyme inhibitors
6. Topical nitrates

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in Section III 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.

V. APPENDIX

WHO Classification of Pulmonary Hypertension (PH)

1 Pulmonary arterial hypertension (PAH)

1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4. PAH associated with:
- 1.4.1 Connective tissue disease
- 1.4.2 Human immunodeficiency virus (HIV) infection
- 1.4.3 Portal hypertension
- 1.4.4 Congenital heart disease
- 1.4.5 Schistosomiasis

1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
1.7 Persistent PH of the newborn syndrome

2 PH due to left heart disease

2.1 PH due to heart failure with preserved left ventricular ejection fraction (LVEF)
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH

3 PH due to lung diseases and/or hypoxia

3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders

4 PH due to pulmonary artery obstructions

4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
- 4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
- 4.2.2 Other malignant tumors
  - Renal carcinoma
  - Uterine carcinoma
  - Germ cell tumors of the testis
  - Other tumors
- 4.2.3 Non-malignant tumors
  - Uterine leiomyoma
- 4.2.4 Arteritis without connective tissue disease
- 4.2.5 Congenital pulmonary artery stenosis
- 4.2.6 Parasites
  - Hydatidosis

5 PH with unclear and/or multifactorial mechanisms

5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
5.3 Others: Chronic renal failure with or without hemodialysis, fibrosing mediastinitis
5.4 Complex congenital heart disease

VI. REFERENCES

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Reference number(s)
2014-A

SPECIALTY GUIDELINE MANAGEMENT

SIMPONI (golimumab for subcutaneous injection)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Moderately to severely active rheumatoid arthritis (RA) in adults, in combination with methotrexate.
   2. Active psoriatic arthritis (PsA) in adults, alone or in combination with methotrexate.
   3. Active ankylosing spondylitis (AS) in adults.
   4. 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.

B. Compendial Uses
   1. Non-radiographic axial spondyloarthritis
   2. Immune checkpoint inhibitor-related toxicities - inflammatory arthritis

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
   1. Initial requests:
      i. 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.
      ii. 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).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), and immune checkpoint inhibitor-related toxicity
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Ulcerative colitis (UC)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Ulcerative colitis: gastroenterologist
D. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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. 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).

2. 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. 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).
   iii. Member meets either of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix).

B. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.

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

ii. Member has severe disease.

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:
   i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Ulcerative colitis (UC)

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active ulcerative colitis.

E. Immune checkpoint inhibitor-related toxicity

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

1. Member has experienced an inadequate response to corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

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:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Ulcerative colitis (UC)

1. 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 ulcerative colitis and who achieve or maintain remission.

2. 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 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

E. 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.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Leflunomide

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

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Reference number
2015-A

SPECIALTY GUIDELINE MANAGEMENT

SIMPONI ARIA (golimumab injection for intravenous use)

POLICY

I. 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.

A. FDA-Approved Indications
   1. Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
   2. Active psoriatic arthritis (PsA) in patients 2 years of age and older
   3. Adult patients with active ankylosing spondylitis (AS)
   4. Active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

B. Compendial Uses
   1. Non-radiographic axial spondyloarthritis
   2. Oligoarticular juvenile idiopathic arthritis
   3. Immune checkpoint inhibitor-related toxicities - inflammatory arthritis

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

II. DOCUMENTATION

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

A. Rheumatoid arthritis (RA)
   1. Initial requests:
      i. 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.
      ii. 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).
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Psoriatic arthritis (PsA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and immune checkpoint inhibitor-related toxicity
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Articular juvenile idiopathic arthritis (JIA)
   1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and articular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Immune checkpoint inhibitor-related toxicity: oncologist, hematologist, or rheumatologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Rheumatoid arthritis (RA)

1. 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. 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).

2. 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:
   i. Member meets either of the following criteria:
      a. Member has been tested for either of the following biomarkers and the test was positive:
         1. Rheumatoid factor (RF)
         2. Anti-cyclic citrullinated peptide (anti-CCP)
      b. Member has been tested for ALL of the following biomarkers:
         1. RF
         2. Anti-CCP
         3. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   ii. 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).
   iii. Member meets either of the following criteria:
      a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week).
      b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B. Psoriatic arthritis (PsA)

1. 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.
2. 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:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.

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

ii. Member has severe disease.

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

1. 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.

2. 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:
   i. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   ii. Member has an intolerance or contraindication to two or more NSAIDs.

D. Articular juvenile idiopathic arthritis (JIA)

1. 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.

2. 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:
   i. 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.
   ii. 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:
      a. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)
      b. Presence of erosive disease or enthesitis
      c. Delay in diagnosis
      d. Elevated levels of inflammation markers
      e. Symmetric disease
   iii. 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:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip)
      b. High disease activity
      c. Is judged to be at high risk for disabling joint disease

E. Immune checkpoint inhibitor-related toxicity

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

1. Member has experienced an inadequate response to corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

V. CONTINUATION OF THERAPY

A. Rheumatoid arthritis (RA)

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.

B. Psoriatic arthritis (PsA)
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:
1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
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:
1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

D. Articular juvenile idiopathic arthritis (JIA)
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:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

E. 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.

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDICES

Appendix A: Examples of clinical reasons to avoid pharmacologic treatment with methotrexate or leflunomide

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

Appendix B: Risk factors for Articular Juvenile Idiopathic Arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

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Reference number
3047-A

SPECIALTY GUIDELINE MANAGEMENT

SKYRIZI (risankizumab-rzaa)

POLICY

I. 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

A. Treatment of moderate-to-severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy
B. Treatment of active psoriatic arthritis (PsA) in adults
C. Treatment of moderately to severely active Crohn's disease (CD) in adults
D. Treatment of moderately to severely active ulcerative colitis (UC) in adults

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

II. DOCUMENTATION

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

A. Plaque psoriasis (PsO)
   1. Initial requests:
      i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
      ii. 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.
   2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

B. Psoriatic arthritis (PsA)
   1. 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.
   2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

C. Crohn's disease (CD) and ulcerative colitis (UC)
   Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Plaque psoriasis: dermatologist

B. Psoriatic arthritis: rheumatologist or dermatologist
C. Crohn's disease and ulcerative colitis: gastroenterologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis (PsO)

1. 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 the treatment of moderate to severe plaque psoriasis.

2. 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:
   i. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   ii. At least 10% of body surface area (BSA) is affected.
   iii. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
      a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
      b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

B. Psoriatic arthritis (PsA)

1. 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.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   i. Member has mild to moderate disease and meets one of the following criteria:
      a. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      b. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
      c. Member has enthesitis.
   ii. Member has severe disease.

C. Crohn's disease (CD)

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

D. Ulcerative colitis (UC)

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active ulcerative colitis.

V. CONTINUATION OF THERAPY

A. Plaque psoriasis (PsO)

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:

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

B. Psoriatic arthritis (PsA)

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:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement
6. Functional status
7. C-reactive protein (CRP)

C. Crohn's Disease (CD)

1. 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.

2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

D. Ulcerative colitis

1. 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 ulcerative colitis and who achieve or maintain remission.

2. 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 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)

vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

VI. OTHER

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.

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

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

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

IX. REFERENCES

1. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
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Reference number
5600-A

SPECIALTY GUIDELINE MANAGEMENT

SOTYKTU (deucravacitinib)

POLICY

I. 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
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.

II. DOCUMENTATION

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

A. Initial requests:
   1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   2. 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.

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

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

Plaque psoriasis (PsO)

A. 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.

B. 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:
   1. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   2. At least 10% of body surface area (BSA) is affected.

3. At least 3% of body surface area (BSA) is affected and the member meets either of the following criteria:
   i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
   ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

V. 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:

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

VI. 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 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.

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

VII. DOSAGE AND ADMINISTRATION

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

VIII. APPENDIX

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

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity

8. History of intolerance or adverse event

IX. REFERENCES

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022.
2. Armstrong, AW, Gooderham M, Warren RB, et al. Deucravacitinib versus placebo and apremilast in moderate to severe plaque psoriasis: efficacy and safety results from the 52-week, randomized, double-blinded, placebo-controlled phase 3 POETYK PSO-1 trial. *J AM Acad Dermatol*. 2023;88(1):29-39. doi:10.1016/j.jaad.2022.07.002.
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5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019;80(4):1029-1072.
6. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
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Reference number
1539-D

SPECIALTY GENERICS FIRST CRITERIA

POLICY

I. 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.

II. CRITERIA FOR APPROVAL

Authorization may be granted for a requested medication when all of the following criteria are met:

A. The patient has failed treatment with the generic medication due to an intolerable adverse event (e.g., rash, nausea, vomiting).
B. 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).
C. The adverse event is documented in member's chart note(s) or medical record. Submission of one of the following is required for approval:
    1. 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).
    2. MedWatch form of this trial and failure including the adverse reaction.

III. 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.

Reference number
1539-D

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

(tacrolimus ointment)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Tacrolimus ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated as *second-line therapy* for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.
Tacrolimus ointment is not indicated for children younger than 2 years of age.

Compendial Uses
Psoriasis[3] - on the face, genitals, or skin folds[5]
Vitiligo on the head or neck[3,6,7]
Atopic Dermatitis for patients under 2 years of age (tacrolimus ointment 0.03%)[3,4]

COVERAGE CRITERIA

Atopic Dermatitis (Eczema)
Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) when ONE of the following criteria are met:

- The request is for tacrolimus 0.03% ointment and ONE of the following criteria is met:
  - The patient is less than 2 years of age
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
  - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE first line therapy agent (e.g., medium or higher potency topical corticosteroid)
- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older and ONE of the following criteria is met:
    - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
    - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one first line therapy agent (e.g., medium or higher potency topical corticosteroid)

Psoriasis
Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when ONE of the following criteria are met:

- The request is for tacrolimus 0.03% ointment
- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older

Vitiligo
Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when ONE of the following criteria are met:

- The request is for tacrolimus 0.03% ointment

- The request is for tacrolimus 0.1% ointment and the following criteria is met:
  - The patient is 16 years of age or older

CONTINUATION OF THERAPY

Atopic Dermatitis
Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis (eczema) when the following criteria is met:

- 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)] and ONE of the following criteria is met:
  - The request is for tacrolimus 0.03% ointment
  - The request is for tacrolimus 0.1% ointment and the following criteria is met:
    - The patient is 16 years of age or older

Psoriasis
Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.) and ONE of the following criteria is met:
  - The request is for tacrolimus 0.03% ointment
  - The request is for tacrolimus 0.1% ointment and the following criteria is met:
    - The patient is 16 years of age or older

Vitiligo
Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation) and ONE of the following criteria is met:
  - The request is for tacrolimus 0.03% ointment
  - The request is for tacrolimus 0.1% ointment and the following criteria is met:
    - The patient is 16 years of age or older

DURATION OF APPROVAL (DOA)

- 492-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Less than 2 years of age: DOA: 3 months
- 1255-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 36 months
  - Less than 2 years of age: DOA: 3 months

REFERENCES

1. Tacrolimus Ointment [package insert]. Melville, NY: Fougera PHARMACEUTICALS INC.; November 2023.
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7. Eleftheriadou V, Atkar R, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. *The British Journal of Dermatology*. 2022;186(1):18-29.
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Reference number(s)
1808-A

SPECIALTY GUIDELINE MANAGEMENT

AUBAGIO (teriflunomide)
teriflunomide

POLICY

I. 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
Indicated for the treatment of patients with 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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER

A. Members will not use the requested medication concomitantly with other disease modifying multiple sclerosis agents (Note: Ampyra and Nuedexta are not disease modifying).

B. Authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

VI. REFERENCES

1. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; June 2024.
2. Teriflunomide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2024.

Reference number(s)
976-A

Initial Prior Authorization
Azmiro, Depo-Testosterone
Testosterone Products – Injectable

Products Referenced by this Document

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

Brand Name	Generic Name	Dosage Form
Azmiro	testosterone cypionate	injection
Depo-Testosterone	testosterone cypionate	injection

Indications

FDA-approved Indications

Azmiro

Azmiro is indicated for testosterone replacement therapy in males in conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchiectomy, Klinefelter's syndrome, or toxic damage from alcohol or heavy metals, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors,

trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use

- Safety and efficacy of Azmiro in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of Azmiro in pediatric patients below the age of 12 years have not been established.

Depo-Testosterone Injection

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

Gender dysphoria[3-4,6-8] (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).
- 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, the patient meets ALL of the following criteria:
    - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider.

- The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism).
- 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 initial authorization criteria.

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).
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 976-A: DOA: 12 months

References

1. Azmiro [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; May 2024.
2. Depo-Testosterone [package insert]. New York, NY: Pharmacia & Upjohn Co; September 2018.

3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed January 11, 2024.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/11/2024).
5. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.
6. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022;23(S1):S1-S258.
7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
8. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2021;137:e75-88.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS – ORAL**
BRAND NAME (generic)	**JATENZO (testosterone undecanoate oral)** **KYZATREX (testosterone undecanoate oral)** **TLANDO (testosterone undecanoate oral)**
Status: CVS Caremark® Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Jatenzo, Kyzatrex, Tlando

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.
- 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

Gender dysphoria[6,8-10] (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)
- 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, the patient meets ALL of the following criteria:
  - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider
  - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater

Primary or Hypogonadotropic Hypogonadism
Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:
- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
- 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 initial authorization criteria.

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)
- 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: Antares Pharma, Inc.; March 2022.
4. Testopel (testosterone pellets) [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2018.
5. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed January 26, 2024.
6. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/26/2024).
7. 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.
8. 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.
9. 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.
10. 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.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS – INJECTABLE**
BRAND NAME (generic)	**DELATESTRYL (testosterone enanthate injection)** **XYOSTED (testosterone enanthate injection)**
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Testosterone Enanthate Injection

Males

Testosterone Enanthate Injection (generic Delatestryl), USP is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testosterone Enanthate Injection (generic Delatestryl) in men with age-related hypogonadism have not been established.

Delayed puberty - Testosterone Enanthate Injection (generic Delatestryl), USP 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), USP 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 pre-menopausal 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 of age have not been established.

Compendial Uses
Gender Dysphoria[4,7-9] (also known as transgender and gender diverse (TGD) persons)

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The requested drug is NOT being prescribed for "age-related hypogonadism" (also referred to as "late-onset hypogonadism")

AND
- The requested drug is being prescribed for primary or hypogonadotropic hypogonadism

AND
- The request is NOT for continuation of therapy

AND
- 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

OR
- The request is for continuation of therapy

AND
- 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

OR
- 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

AND
- The patient's comorbid conditions are reasonably controlled

AND
- The patient has been educated on any contraindications and side effects to therapy

AND
- Before the start of therapy, the patient has been informed of fertility preservation options

AND
- If the patient is less than 18 years of age,

AND
- 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

AND
- The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater

OR
- The request is for intramuscular testosterone enanthate injection (generic Delatestryl)

AND
- 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

OR

- 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

OR

- The requested drug is being prescribed for delayed puberty

REFERENCES

1. Testosterone Enanthate Injection [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA Inc.; January 2021.
2. Xyosted [package insert]. Ewing, NJ: Antares Pharma, Inc; November 2019.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2023; Accessed January 26, 2023.
4. Lexicomp Online, Lexi-Drugs Online, Hudson, Ohio: UpToDate, Inc.; 2023; Accessed January 26, 2023.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 26, 2023
6. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2018;103(5):1715-1744.
7. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*. 2022;23(S1):S1-S258.
8. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.
9. Health Care for Transgender and Gender Diverse Individuals. ACOG Committee Opinion No. 823. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2021;137:e75-88.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS – TOPICAL/NASAL**
BRAND NAME (generic)	**ANDRODERM (testosterone transdermal patch)** **ANDROGEL (testosterone topical gel)** **FORTESTA (testosterone topical gel)** **NATESTO (testosterone nasal gel)** **TESTIM (testosterone topical gel)** **(testosterone topical solution)** **VOGELXO (testosterone topical gel)**
Status: CVS Caremark® Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Androderm, Androgel, Fortesta, Natesto, Testim, testosterone topical gel, testosterone topical solution, Vogelxo

Topical and nasal testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use:

- Safety and efficacy of topical and nasal testosterone products in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

- Safety and efficacy of topical and nasal testosterone products in males less than 18 years old have not been established.
- Topical testosterone products may have different doses, strengths or application instructions that may result in different systemic exposure.

Compendial Uses
Gender dysphoria[10,12-14] (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)
- 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, the patient meets ALL of the following criteria:
  - The requested drug is being prescribed by, or in consultation with, a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist), that has collaborated care with a mental health provider
  - The patient has reached, or has previously reached, Tanner stage 2 of puberty or greater

Primary or Hypogonadotropic Hypogonadism
Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:
- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)
- 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 initial authorization criteria.

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)
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values

DURATION OF APPROVAL (DOA)
- 1370-A: DOA: 12 months

REFERENCES
1. Androderm [package insert]. Madison, NJ: Allergan USA, Inc.; May 2020.
2. Androgel 1.62% [package insert]. Morristown, NJ: Ascend Therapeutics US, LLC; November 2020.

3. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; January 2022.
4. Natesto Nasal Gel [package insert]. Mississauga, ON: Acerus Pharmaceutical Corporation; December 2021.
5. Testim [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2021.
6. Testosterone Gel 1% [package insert]. Durham, NC: Encube Ethicals, Inc.; September 2023.
7. Testosterone Topical Solution [package insert]. Upper Saddle River, NJ: Dash Pharmaceuticals LLC; August 2023.
8. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; April 2020.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed January 26, 2024.
10. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/26/2024).
11. 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.
12. 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.
13. 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.
14. 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.

Reference number(s)
5104-A

SPECIALTY GUIDELINE MANAGEMENT

TEZSPIRE (tezepelumab-ekko)

POLICY

I. 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
Tezspire is indicated for 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
B. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

III. PRESCRIBER SPECIALTIES

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

IV. CRITERIA FOR INITIAL APPROVAL

A. 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.

B. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   1. Member is 12 years of age or older.
   2. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      ii. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
      iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)

3. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
   i. High-dose inhaled corticosteroid
   ii. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
4. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

V. CONTINUATION OF THERAPY

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

A. Member is 12 years of age or older.
B. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   1. A reduction in the frequency and/or severity of symptoms and exacerbations
   2. A reduction in the daily maintenance oral corticosteroid dose
C. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

VI. 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.

VII. REFERENCES

1. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06-WMS.pdf. Accessed March 8, 2024.
3. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA.* 2020;324(22): 2301-2317.
4. Wechsler ME, Colice G, Griffiths JM, et al. SOURCE: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of tezepelumab in reducing oral corticosteroid used in adults with oral corticosteroid dependent asthma. *Respir Res.* 2020;21(1):264.

Reference number(s)
1846-A

SPECIALTY GUIDELINE MANAGEMENT

TYSABRI (natalizumab)
TYRUKO (natalizumab-sztn)

POLICY

I. 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

A. 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.
B. 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.

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

II. DOCUMENTATION

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

Crohn's disease (CD):

A. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.
B. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. PRESCRIBER SPECIALTIES

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

A. Crohn's disease: gastroenterologist
B. Multiple sclerosis: neurologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Crohn's disease (CD)
Authorization of 12 months may be granted to 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.

B. Relapsing forms of multiple sclerosis (MS)
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.

C. Clinically isolated syndrome (CIS)
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.

V. CONTINUATION OF THERAPY

A. Crohn's disease (CD)

1. 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.

2. 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:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

B. Relapsing forms of multiple sclerosis (MS) or clinically isolated syndrome (CIS)
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.

VI. 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).

VII. DOSAGE AND ADMINISTRATION

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

VIII. REFERENCES

1. Tysabri [package insert]. Cambridge, MA: Biogen Inc; April 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.

Reference number(s)
3395-A

SPECIALTY GUIDELINE MANAGEMENT

VUMERITY (diroximel fumarate)

POLICY

I. 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
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.

II. PRESCRIBER SPECIALTIES

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

III. CRITERIA FOR INITIAL APPROVAL

A. Relapsing forms of multiple sclerosis
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).

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

IV. 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.

V. OTHER CRITERIA

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

VI. REFERENCES

1. Vumerity [package insert]. Cambridge, MA: Biogen; February 2023.

Reference number(s)
1656-A

SPECIALTY GUIDELINE MANAGEMENT

XOLAIR (omalizumab)

POLICY

I. 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.

A. FDA-Approved Indications

1. Allergic asthma
   Xolair is indicated for 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: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.

2. Chronic rhinosinusitis with nasal polyps (CRSwNP)
   Xolair is 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.

3. IgE-mediated food allergy
   Xolair is 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.

   Xolair is to be used in conjunction with food-allergen avoidance.

   Limitations of use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

4. Chronic spontaneous urticaria (CSU)
   Xolair is 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: Xolair is not indicated for treatment of other forms of urticaria.

B. Compendial Uses

1. Immune checkpoint inhibitor-related toxicities
2. Systemic mastocytosis

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

II. DOCUMENTATION

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

A. Asthma:
   1. Initial Requests:
      i. Chart notes or medical record documentation showing pre-treatment IgE level.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
   2. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. CRSwNP:
   1. Initial Requests:
      i. Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
      ii. 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.
   2. Continuation Requests: Chart notes or medical record documentation supporting positive response to therapy.

C. IgE-mediated food allergy:
   1. Initial Requests: Chart notes, medical record documentation, or laboratory tests showing the following (if applicable):
      i. Pre-treatment allergen-specific IgE level
      ii. Skin-prick test wheal diameter
      iii. Pre-treatment serum IgE level
      iv. Positive result of a physician controlled oral food challenge
      v. History of a systemic reaction to a food
   2. Continuation Requests: Chart notes or medical record documentation supporting positive response to therapy (e.g., decrease in hypersensitivity to food-allergen).

D. CSU:
   1. Initial Requests: Chart notes, medical record documentation, or claims history supporting previous medications tried showing an inadequate treatment response to up-dosing of a second-generation H1 antihistamine.
   2. Continuation Requests: Chart notes or medical record documentation supporting positive response to therapy.

E. Immune checkpoint inhibitor-related toxicity (initial requests): Chart notes or medical record documentation showing pre-treatment IgE level.

F. Systemic mastocytosis (initial requests):
   1. Chart notes or medical record documentation supporting diagnosis of systemic mastocytosis.
   2. Chart notes, medical record documentation, or claims history of prerequisite therapies (if applicable).

III. PRESCRIBER SPECIALTIES

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

A. Asthma: allergist/immunologist or pulmonologist
B. CRSwNP: allergist/immunologist or otolaryngologist
C. IgE-mediated food allergy: allergist/immunologist
D. Chronic spontaneous urticaria: allergist/immunologist or dermatologist
E. Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist or oncologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. 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.

2. Authorization of 6 months may be granted for treatment of moderate-to-severe asthma when all of the following criteria are met:
   i. Member is 6 years of age or older.
   ii. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
   iii. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.
   iv. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      b. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
      c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
   v. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
      a. Medium-to-high-dose inhaled corticosteroid
      b. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   vi. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. 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.

2. Authorization of 6 months may be granted for treatment of CRSwNP when all of the following criteria are met:
   i. Member is 18 years of age or older.
   ii. Member has bilateral nasal polyps and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated.
   iii. Member has one of the following:
      a. 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
      b. Meltzer Clinical Score of 2 or higher in both nostrils
      c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
   iv. Member has symptoms of nasal blockage, congestion or obstruction plus one of the following additional symptoms:
      a. Rhinorrhea (anterior/posterior)
      b. Reduction or loss of smell
      c. Facial pain or pressure
   v. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

C. IgE-mediated food allergy

Authorization of 6 months may be granted for the reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

1. Member is 1 year of age or older.
2. IgE-mediated food allergy has been confirmed by either of the following:

   i. Pre-treatment allergen-specific IgE level greater than or equal to 6 IU/mL
   ii. Skin-prick test (SPC) with wheal diameter greater than or equal to 4 mm
3. Member has either of the following:
   i. A positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms)
   ii. History of a systemic reaction to a food
4. Member has a pre-treatment serum IgE level greater than or equal to 30 IU/mL.
5. Member will continue to follow a food-allergen avoidance diet.

D. Chronic spontaneous urticaria

Authorization of 6 months may be granted for treatment of chronic spontaneous urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA^{2}LEN/EDF/WAO guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
4. Member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks.

E. Immune checkpoint inhibitor-related toxicity

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

1. The member has a refractory case of immune-therapy related severe (G3) pruritus.
2. The member has elevated IgE levels.

F. Systemic mastocytosis

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

1. 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).
2. The requested medication will be used in any of the following treatment settings:
   i. Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when the member has tried both of the following:
      a. H1 blockers and H2 blockers
      b. Corticosteroids
   ii. Used for prevention of recurrent unprovoked anaphylaxis
   iii. Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test
   iv. Used to improve tolerability of venom immunotherapy

V. CONTINUATION OF THERAPY

A. Asthma

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

1. Member is 6 years of age or older.
2. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose

3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair.

B. Chronic rhinosinusitis with nasal polyps (CRSwNP)
Authorization of 12 months may be granted for continuation of treatment of CRSwNP when all of the following criteria are met:
1. Member is 18 years of age or older.
2. 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).
3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

C. IgE-mediated food allergy
Authorization of 12 months may be granted for the reduction of IgE-mediated food allergy reactions when all of the following criteria are met:
1. Member is 1 year of age or older.
2. Member has achieved or maintained a positive clinical response to therapy as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen.
3. Member will continue to maintain a food-allergen avoidance diet.

D. Chronic spontaneous urticaria
Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria when all of the following criteria are met:
1. Member is 12 years of age or older.
2. Member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

E. Immune checkpoint inhibitor-related toxicities and systemic mastocytosis
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

VI. 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.

VII. APPENDIX

2022 WHO Diagnostic Criteria for Systemic Mastocytosis
A. 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
B. Minor Criteria
   1. Greater than 25% of all mast cells are atypical cells (type 1 or type II) on bone marrow smears or are spindle-shaped in dense and diffuse mast cell infiltrates in bone marrow or other extracutaneous organ(s)

2. Activating *KIT* point mutation(s) at codon 816 or in other critical regions of *KIT* in the bone marrow or other extracutaneous organ(s)
3. Mast cells in bone marrow, blood, or other extracutaneous organs aberrantly express one or more of the following antigens: CD2, CD25, CD30
4. Baseline serum tryptase concentration greater than 20 ng/mL in the absence of a myeloid associated hematologic neoplasm (AHN). In the case of a known hereditary alpha-tryptasemia (HαT), the tryptase level should be adjusted.

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Reference number(s)
3747-A

SPECIALTY GUIDELINE MANAGEMENT

ZEPOSIA (ozanimod)

POLICY

I. 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

A. Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
B. Treatment of moderately to severely active ulcerative colitis (UC) in adults.

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

II. DOCUMENTATION

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

A. Ulcerative colitis (UC)
Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

III. PRESCRIBER SPECIALTIES

The medication must be prescribed by or in consultation with one of the following:
A. Ulcerative colitis: gastroenterologist
B. Multiple sclerosis: neurologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Relapsing Forms of Multiple Sclerosis
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).

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

C. Ulcerative Colitis

Authorization of 12 months may be granted for adult members for treatment of moderately to severely active ulcerative colitis.

V. CONTINUATION OF THERAPY

A. 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.

B. Ulcerative Colitis

1. 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 ulcerative colitis and who achieve or maintain remission.

2. 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 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:
   i. Stool frequency
   ii. Rectal bleeding
   iii. Urgency of defecation
   iv. C-reactive protein (CRP)
   v. Fecal calprotectin (FC)
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

VI. OTHER

A. For all indications: Zeposia will not be used 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).
B. For multiple sclerosis: authorization may be granted for pediatric members less than 18 years of age when benefits outweigh risks.

VII. DOSAGE AND ADMINISTRATION

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

VIII. REFERENCES

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Reference number(s)
2380-A

SPECIALTY GUIDELINE MANAGEMENT

RECLAST (zoledronic acid)
zoledronic acid

POLICY

I. 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

A. Treatment and prevention of osteoporosis in postmenopausal women
B. Treatment to increase bone mass in men with osteoporosis
C. Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
D. 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.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Supporting chart notes or medical record indicating a history of fractures, T-score, and FRAX fracture probability as applicable to Section III.

III. CRITERIA FOR INITIAL APPROVAL

A. Postmenopausal osteoporosis, treatment and prevention

Authorization of 12 months may be granted to postmenopausal members for treatment or prevention of osteoporosis when ANY of the following criteria are met:

1. Member has a history of fragility fractures
2. Member has a pre-treatment T-score less than or equal to -2.5
3. Member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1)

B. Osteoporosis in men

Authorization of 12 months may be granted to male members with osteoporosis when ANY of the following criteria are met:

1. Member has a history of an osteoporotic vertebral or hip fracture
2. Member has a pre-treatment T-score less than or equal to -2.5

3. 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)

C. Glucocorticoid-induced osteoporosis

Authorization of 12 months may be granted for members with glucocorticoid-induced osteoporosis when BOTH of the following criteria are met:

1. 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
2. Member meets ANY of the following criteria:
   i. Member has a history of a fragility fracture
   ii. Member has a pre-treatment T-score of less than or equal to -2.5
   iii. 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)

D. Paget's disease of bone

Authorization of 1 month (one dose [5 mg]) may be granted for treatment of Paget's disease of bone.

IV. CONTINUATION OF THERAPY

A. Paget's disease of bone

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

B. 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:

1. Member has received less than 24 months of therapy and has not experienced clinically significant adverse events during therapy
2. Member has received 24 months of therapy or more and meets both of the following:
   i. Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
   ii. Member has not experienced any adverse effects

V. APPENDIX

FRAX Fracture Risk Assessment Tool

- 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://www.sheffield.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.

VI. REFERENCES

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