# COUNTYCARE HEALTH PLAN
# PRIOR AUTHORIZATION GUIDELINES

Administered by

January 1, 2024

| Reference number |
| --- |
| 1959-A |

# SPECIALTY GUIDELINE MANAGEMENT

## ACTEMRA (tocilizumab)
## TOFIDENCE (tocilizumab-bavi)

**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.
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)

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), 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
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), including response to therapy.
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.

## 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, and giant cell arteritis: 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 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. 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 both of the following criteria are met:
i. Member has active systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis).
ii. Member has had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs) or systemic glucocorticoids.

**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 the following:
1. Temporal artery biopsy or cross-sectional imaging; or
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 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 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.

**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.

## 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.

**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. All other diagnoses**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## 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 clinical reasons to avoid pharmacologic treatment with methotrexate[19]**

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[18]**

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

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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 adult patients 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**
Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 18 years of age or older when all of the following criteria are met:
A. 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.
B. Member meets one of the following:
   1. Member has had an inadequate treatment response with one of the following in the past year:
      i. A medium potency to super-high potency topical corticosteroid (see Appendix)
      ii. A topical calcineurin inhibitor

2. 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 18 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 Adbry concomitantly with any other biologic drug or targeted synthetic drug.

## 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% |
| **Potency** | **Drug** | **Dosage form** | **Strength** |
| 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% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| | 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

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# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**
**(generic)**

**AFREZZA**
**(insulin human inhalation powder)**

***Status: CVS Caremark® Criteria***
***Type: Initial Prior Authorization***

**POLICY**

**FDA-APPROVED INDICATIONS**
Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.
Limitations of Use:

- Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus.
- Afrezza is not recommended for the treatment of diabetic ketoacidosis.
- The safety and efficacy of Afrezza in patients who smoke have not been established. The use of Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

**COVERAGE CRITERIA**
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has been evaluated with spirometry ($FEV_1$) to rule out any potential lung disease
  [Note: Afrezza is contraindicated in patients with chronic lung disease and not recommended in patients who smoke or who have recently stopped smoking.]
  **AND**
  - The patient has NOT been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The requested drug is being prescribed for an adult with type 1 diabetes mellitus **AND**
      - The patient has experienced an intolerance or has a contraindication to an injectable rapid-acting insulin
      **AND**
      - The requested drug will be used in combination with long-acting insulin

    **OR**
    - The requested drug is being prescribed for an adult with type 2 diabetes mellitus **AND**
      - The patient has experienced an intolerance or has a contraindication to an injectable rapid-acting insulin OR is unable to administer injectable insulin
      **AND**
      - The patient has experienced an inadequate treatment response, intolerance or has a contraindication to metformin

  **OR**
  - The patient has been receiving a stable maintenance dose of the requested drug for at least 3 months **AND**
    - The patient has demonstrated a reduction in A1C since starting this therapy

Duration of Approval (DOA):

- 1238-A: DOA: 36 months

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# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**
**(generic)**

**AMPHETAMINES:**

**ADZENYS (ALL PRODUCTS)**
**(amphetamine)**

**DYANAVEL (ALL PRODUCTS)**
**(amphetamine)**

**EVEKEO (ALL PRODUCTS)**
**(amphetamine)**

**AMPHETAMINE-DEXTROAMPHETAMINES:**

**ADDERALL (ALL PRODUCTS)**
**(amphetamine-dextroamphetamine)**

**MYDAYIS (ALL PRODUCTS)**
**(amphetamine-dextroamphetamine)**

**DEXTROAMPHETAMINES:**

**DEXEDRINE (ALL PRODUCTS)**
**(dextroamphetamine)**

**(dextroamphetamine) (ALL PRODUCTS)**

**PROCENTRA (ALL PRODUCTS)**
**(dextroamphetamine)**

**XELSTRYM (ALL PRODUCTS)**
**(dextroamphetamine)**

**ZENZEDI (ALL PRODUCTS)**
**(dextroamphetamine)**

**LISDEXAMFETAMINES:**

**VYVANSE (ALL PRODUCTS)**
**(lisdexamfetamine)**

**METHAMPHETAMINES:**

**DESOXYN (ALL PRODUCTS)**
**(methamphetamine)**

## POLICY

## FDA-APPROVED INDICATIONS

**Adderall**
Adderall is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

**Adderall XR**
Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Adzenys ER, Adzenys XR-ODT, Dyanavel XR**
These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

**Desoxyn**
Attention Deficit Disorder with Hyperactivity: Desoxyn tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

**Dexedrine Spansule**
Dexedrine is indicated in:
Narcolepsy
Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome.

**Dextroamphetamine, ProCentra, Zenzedi**
These products are indicated for:
Narcolepsy
Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

**Evekeo**
Evekeo is indicated for:
Narcolepsy
Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.
Exogenous Obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drug.

**Evekeo ODT**
Evekeo ODT is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

**Mydayis**

Mydayis is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.
Limitations of Use
Pediatric patients 12 years and younger experienced higher plasma exposure than patients 13 years and older at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

**Vyvanse**
Vyvanse is indicated for the treatment of:
- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
- Moderate to Severe Binge-Eating Disorder (BED) in adults

Limitations of Use
Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.

**Xelstrym**
Xelstrym is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.
Limitations of Use
Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

Compendial Uses
Narcolepsy[16-18,23]

## COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)
  **AND**
  - The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires) **AND**
    - The patient is 6 years of age or older
      **OR**
    - The patient is 5 years of age or younger
      **AND**
      - The patient continues to have ADHD/ADD (Attention-Deficit/Hyperactivity Disorder or Attention Deficit Disorder) symptoms despite participating in evidence-based behavioral therapy (e.g., parent training in behavior management (PTBM), behavioral classroom interventions)

  **OR**
  - The request is for continuation of therapy
    **AND**
  - The patient achieved or maintained improvement in their signs and symptoms of ADHD/ADD (Attention-Deficit/Hyperactivity Disorder or Attention Deficit Disorder) from baseline
    **AND**
  - The patient's need for continued therapy has been assessed within the previous year

**OR**
- The patient has a diagnosis of narcolepsy
  **AND**
  - The requested drug is being prescribed by, or in consultation with, a sleep specialist
    **AND**
  - The diagnosis has been confirmed by a sleep study

  **OR**

- The request is for continuation of therapy
  **AND**
- The patient achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline

**OR**

- The request is for Vyvanse for the treatment of moderate to severe binge eating disorder (BED)
  **AND**
  - The request is for initial therapy
  **OR**
  - The request is for continuation of therapy
    **AND**
  - The patient achieved or maintained improvement in symptoms of BED from baseline
    **AND**
  - The patient's need for continued therapy has been assessed within the previous year

Duration of Approval (DOA):

- 14-A: Initial therapy DOA: 36 months; Continuation of therapy DOA: 36 months
- 1261-A: Initial therapy DOA: 12 months; Continuation of therapy DOA: 12 months

## REFERENCES


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11. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2020.
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| Reference number(s) |
| --- |
| 1891-A |

# SPECIALTY GUIDELINE MANAGEMENT

## AVASTIN (bevacizumab)
## ALYMSYS (bevacizumab-maly)
## 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, 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, 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, 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, Mvasi, Vegzelma or Zirabev, is indicated for the treatment of recurrent glioblastoma in adults.
4. Metastatic Renal Cell Carcinoma (mRCC)
   Avastin, Alymsys, 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, 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, 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. Glioma (WHO Grade 1)
   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
3. Malignant Pleural Mesothelioma, Malignant 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. Ophthalmic Disorders
    a. Diabetic Macular Edema
    b. Neovascular (wet) Age-Related Macular Degeneration (AMD)
    c. Macular Edema following Retinal Vein Occlusion (RVO)
    d. Proliferative Diabetic Retinopathy
    e. Choroidal Neovascularization (CNV)
    f. Neovascular Glaucoma; adjunct
    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. Glioma (WHO Grade 1)
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

**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, advanced, 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 recurrent or 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 malignant pleural mesothelioma, malignant peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when any of the following criteria are met:
   a. As first-line therapy for unresectable disease 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 malignant 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 unresectable locally advanced, recurrent, or metastatic vulvar carcinoma, including squamous cell carcinoma and adenocarcinoma.

**O. Hepatocellular Carcinoma**

Authorization of 12 months may be granted for treatment of unresectable or metastatic hepatocellular carcinoma, when the requested medication will be used as initial treatment in combination with atezolizumab.

## III. CONTINUATION OF THERAPY

**A. Ophthalmic Disorders**

For ophthalmic disorders, authorization of 12 months may be granted for continued treatment of an indication outlined in Section II for members who have 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.

## IV. REFERENCES

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| Reference number(s) |
| --- |
| 1891-A |

| Reference number(s) |
| --- |
| 3881-A |

# SPECIALTY GUIDELINE MANAGEMENT

## BAFIERTAM (monomethyl fumerate)

### 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 (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).

**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; May 2021.

| 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, current plasma HIV-1 RNA level (viral load).

#### 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 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 greater than or equal to 200 copies per mL.

## V. REFERENCES

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# 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***
***Type: Initial 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.

## COVERAGE CRITERIA

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

- The requested drug is being prescribed for the preventive treatment of migraine in an adult patient
  **AND**
  - The request is for Aimovig, Ajovy, Emgality 120 mg, or Vyepti
  **AND**
  - The requested drug will not be used concurrently with another CGRP receptor antagonist

**AND**

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

  **AND**

  - The patient experienced an inadequate treatment response with an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)

  **OR**

  - The patient experienced an intolerance to, or the patient has a contraindication that would prohibit an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)

**OR**

- The patient has received at least 3 months of treatment with the requested drug

  **AND**

  - The patient had a reduction in migraine days per month from baseline

**OR**

- The request is for Emgality 100mg for the treatment of episodic cluster headaches in an adult patient

  **AND**

  - The requested drug will not be used concurrently with another CGRP receptor antagonist

    **AND**

    - The patient has NOT received at least 3 weeks treatment with the requested drug

      **AND**

      - The patient experienced an inadequate treatment response to any of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)

      **OR**

      - The patient experienced an intolerance to, or the patient has a contraindication to any of the following: A) sumatriptan (nasal or subcutaneous), B) zolmitriptan (nasal or oral)

    **OR**

    - The patient received at least 3 weeks treatment with the requested drug

      **AND**

      - 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) | 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 |

**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): Initial therapy DOA: 12 months; Continuation of therapy 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)**<br>**QULIPTA (atogepant)**<br>**UBRELVY (ubrogepant)**<br>**ZAVZPRET (zavegepant)** |

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

**POLICY**

**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, metoprolol, propranolol, timolol, atenolol, nadolol, 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, metoprolol, propranolol, timolol, atenolol, nadolol, 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**

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

- The request is for Nurtec ODT, Ubrelvy, or Zavzpret being prescribed for the acute treatment of migraine in an adult patient
  **AND**
  - The requested drug will not be used concurrently with another CGRP receptor antagonist
    **AND**
    - The patient experienced an inadequate treatment response or an intolerance to two triptan 5-HT1 receptor agonists
    **OR**
    - The patient has a contraindication that would prohibit a trial of triptan 5-HT1 receptor agonists

**OR**

- The request is for Nurtec ODT being prescribed for the preventive treatment of episodic migraine in an adult patient

**OR**

- The request is for Qulipta being prescribed for the preventive treatment of migraine in an adult patient
  **AND**
  - The requested drug will not be used concurrently with another CGRP receptor antagonist
    **AND**
    - The patient has NOT received at least 3 months of treatment with the requested drug
      **AND**
      - The patient experienced an inadequate treatment response with an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)
      **OR**
      - The patient experienced an intolerance to, or the patient has a contraindication that would prohibit an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)
    **OR**
    - The patient has received at least 3 months of treatment with the requested drug
      **AND**
      - 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

## REFERENCES


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| 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
Cibinqo is 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**
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:
A. 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.
B. Member meets one of the following:
   1. Member has had an inadequate treatment response with one of the following in the past year:
      i. A medium potency to super-high potency topical corticosteroid (see Appendix)
      ii. A topical calcineurin inhibitor

2. 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).

C. Member has had an inadequate response to treatment with a systemic drug product (e.g., oral cyclosporine, azathioprine, methotrexate, mycophenolate mofetil) or a biologic (e.g., Dupixent, Adbry) 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

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.

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% |
| | Clobetasol propionate | Cream | 0.025% |
| | Desoximetasone | Cream, Ointment, Spray | 0.25% |
| | | Gel | 0.05% |
| | Diflorasone diacetate | Ointment, Cream (emollient) | 0.05% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| | Fluocinonide | Cream, Ointment, Gel, Solution | 0.05% |
| | Halcinonide | Cream, Ointment | 0.1% |
| | Halobetasol propionate | Lotion | 0.01% |
| **Potency** | **Drug** | **Dosage form** | **Strength** |
| 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% |
| | Triamcinolone acetonide | Cream, lotion | 0.025% |
| | Hydrocortisone (base, greater than or equal to 2%) | Cream, Ointment, Solution | 2.5% |
| | | Lotion | 2% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| VII. Least potent (group 7) | 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

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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.

FDA-Approved Indications

A. 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.
B. Treatment of adults with moderately to severely active rheumatoid arthritis.
C. Treatment of adult patients with active psoriatic arthritis.
D. Treatment of adults with active ankylosing spondylitis.
E. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
F. Treatment of adults with moderate-to-severe plaque psoriasis 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. 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. Ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and 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)

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

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.

## III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis, ankylosing spondylitis, or non-radiographic axial spondyloarthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Crohn's disease: gastroenterologist
D. Plaque psoriasis: dermatologist

## IV. CRITERIA FOR INITIAL APPROVAL

**B. 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 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).

**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), 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 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.

**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).

## 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

**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 active ankylosing spondylitis or active 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)

**D. 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)

**E. 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)

## 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.

## 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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| Reference number(s) |
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| 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)

## V. REFERENCES

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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. Member's chart notes or medical record showing pretreatment blood eosinophil count, 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.

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 resulting in hospitalization or emergency medical care visit.
   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:

1. Member is 18 years of age or older.
2. 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.
3. 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.

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# PRIOR AUTHORIZATION CRITERIA

**DRUG CLASS** **COMPOUNDED DRUG PRODUCTS**

***Status: CVS Caremark® Criteria***
***Type: Initial Prior Authorization***

**POLICY**

**COVERAGE CRITERIA**

Compounded drug products will be covered with prior authorization when the following criteria are met:

- The request is for any of the following: A) intravenous (IV) injection or infusion, B) anti-infective for injectable use, C) total parenteral nutrition (TPN), D) leuprolide acetate for infertility in a patient unable to utilize the FDA-approved commercially available product (1mg per 0.2mL kit), E) pyrimethamine, F) sirolimus for tuberous sclerosis where other dermatological treatments (e.g., laser therapy, surgery, dermabrasion) are inappropriate
  Note: Examples of anti-infectives may include antibacterials, antivirals, antifungals

**OR**

- The request is for tacrolimus (Prograf) or everolimus (Zortress) for a patient receiving a transplant

**OR**

- Each of the active ingredients in the compound are FDA-approved drugs
  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

  **AND**

  - Each of the active ingredients in the compound are FDA-approved for the indication for which the compound is being prescribed

  **AND**

  - 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

  **AND**

  - The dosage or concentration of each active ingredient in the compound is equal to or below the FDA-approved dosage or concentration

  **AND**

  - The request is not for a topical compound or a topical compound kit for use on skin (e.g., cream, gel, lotion, ointment)

  **AND**

  - 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

  **AND**

  - 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)

  **AND**

  - 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)

  **AND**

  - There is a current supply shortage of the commercially manufactured product

  **OR**

  - The patient has a medical need for a dosage form or dosage strength that is not available commercially or manufactured

  **OR**

- The patient had an intolerance or contraindication to the commercially manufactured product (examples may include allergen or adverse effects due to inactive ingredients)

**OR**

- 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**


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# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **CONTINUOUS GLUCOSE MONITORS** |
| **BRAND NAME (generic)** | **DEXCOM (ALL PRODUCTS)**<br>**EVERSENSE (ALL PRODUCTS)**<br>**FREESTYLE LIBRE (ALL PRODUCTS)**<br>**GUARDIAN (ALL PRODUCTS)** |
| ***Status: CVS Caremark® Criteria*** | |
| ***Type: Initial Prior Authorization*** | |

**POLICY**

**COVERAGE CRITERIA**

The requested continuous glucose monitor and associated accessories will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of diabetes mellitus
  **AND**
  - The patient is using an intensive insulin regimen [Note: An intensive insulin regimen is defined as multiple daily injections (i.e., 3 or more injections per day) or insulin pump therapy]
    **AND**
    - The request is NOT for continuation of therapy
      **AND**
      - The patient is less than 18 years of age
        **OR**
      - The patient is not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness)

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

  **OR**
- The patient has a diagnosis of glycogen storage disease

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| 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 the treatment of active enthesitis-related arthritis.

2. Authorization of 12 months may be granted for members 4 years of age or older for the 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

**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)

**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 [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. 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

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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 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 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.; February 2023.
2. dimethyl fumarate [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2023.

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **DISPOSABLE INSULIN PUMPS** |
| **BRAND NAME (generic)** | **OMNIPOD (ALL RX PRODUCTS)** |
| | **V-GO (ALL PRODUCTS)** |

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

**POLICY**

**COVERAGE CRITERIA**
The requested medical device will be covered with prior authorization when the following criteria are met:

- The request is for Omnipod GO
  **AND**
  - The patient has a diagnosis of type 2 diabetes mellitus
  **AND**
  - The patient does NOT require bolus or mealtime insulin
  **AND**
  - The patient has completed a comprehensive diabetes education program
  **AND**
  - The patient has documented frequency of glucose self-testing at least once daily OR the patient has been using a continuous glucose monitor (CGM)
  **AND**
  - The patient has a hypersensitivity to an ingredient in ALL available basal insulin (e.g., long-acting insulin, intermediate-acting insulin)

**OR**

- The request is for other Omnipod products (e.g., Omnipod DASH, Omnipod 5) or V-Go
  **AND**
  - The request is NOT for continuation of therapy
    **AND**
    - The patient is managing their diabetes with multiple daily insulin injections (i.e., at least 3 injections per day) with frequent self-adjustments of the insulin dose for at least 6 months
    **AND**
    - The patient has documented frequency of glucose self-testing an average of at least 4 times per day for the past two months OR the patient has been using a continuous glucose monitor (CGM) for the past two months
    **AND**
    - The patient has completed a comprehensive diabetes education program
    **AND**
    - The patient has experienced any of the following while on multiple daily injections of insulin (i.e., more than 3 injections per day): A) elevated glycosylated hemoglobin level (e.g., HbA1c greater than 7 percent), B) history of recurrent hypoglycemia (e.g., blood glucose levels less than 70 mg/dL), C) wide fluctuations in blood glucose before mealtime, D) "dawn" phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, E) history of severe glycemic excursions
    **AND**

- If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

**OR**

- The patient is currently established on therapy with an insulin pump

  **AND**

  - 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)

  **AND**

  - If additional quantities of Omnipod pods are being requested, then the patient requires more than 200 units of insulin within a 72-hour period

Quantity Limits apply.
Omnipod GO: 10 pods per 25 days* or 30 pods per 75 days*
Oher 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


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| Reference number(s) |
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| 1690-A |

# SPECIALTY GUIDELINE MANAGEMENT

## DUPIXENT (dupilumab)

### 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. Dupixent is indicated for the 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.

2. Dupixent is indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

   *Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus*

3. Dupixent is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

4. Dupixent is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

5. Dupixent is indicated for the treatment of adult patients with prurigo nodularis (PN).

B. Compendial Uses
Immune checkpoint inhibitor-related toxicities

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. Atopic dermatitis**

1. For initial requests:
   i. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
   ii. 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 therapies are not advisable for the member.
2. 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.

**B. Asthma**

1. For initial requests:
   i. Member's chart or medical record showing pretreatment blood eosinophil count (where 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.

**C. Chronic rhinosinusitis with nasal polyposis**

1. For initial requests:
   i. Member's chart or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., 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. 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.

**D. Eosinophilic esophagitis**

1. For initial requests:
   i. Member's chart or medical record showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. 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.

**E. Prurigo Nodularis**

1. For initial requests:
   i. Member's chart or medical record of symptoms (e.g., pruritus, nodular lesions).
   ii. Member's chart, medical record, or claims history of prerequisite therapies including response to therapy. 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. PRESCRIBER SPECIALTIES

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

A. Atopic dermatitis: dermatologist or allergist/immunologist
B. Asthma: allergist/immunologist or pulmonologist
C. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist
D. Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
E. Prurigo nodularis: dermatologist or allergist/immunologist

## IV. CRITERIA FOR INITIAL APPROVAL

**A. Atopic dermatitis**

Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 6 months 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 A)
      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, potency not appropriate for member's age).

**B. 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.

2. 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:
   i. 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 resulting in hospitalization or emergency medical care visit.
      c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
   ii. Member meets either of the following criteria:
      a. 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:
         1. Medium-to-high-dose inhaled corticosteroid
         2. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
      b. Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses*:
         1. High-dose inhaled corticosteroid
         2. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
         3. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
         *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).[6]
   iii. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

**C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)**

1. Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Nucala, Xolair) indicated for CRSwNP.

2. Authorization of 6 months may be granted for treatment of CRSwNP in members 18 years of age or older when all of the following criteria are met:
   i. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated

ii. The 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
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.

**D. Eosinophilic esophagitis (EoE)**

Authorization of 6 months may be granted for treatment of EoE in members 12 years of age or older, weighing at least 40 kg, when all of the following criteria are met:

1. Member has history of an average of at least 2 episodes of dysphagia (with intake of solids) per week.
2. Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field.
3. Member has had an inadequate treatment response to both of the following:
   i. Proton pump inhibitor
   ii. Systemic corticosteroid or oral topical corticosteroid therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation] swallowed), unless contraindicated or not tolerated.

**E. 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:

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

**F. Immune checkpoint inhibitor-related toxicity**

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when member has a refractory case of immune-therapy related severe (G3) pruritus.

## V. CONTINUATION OF THERAPY

### A. 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).

### B. 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 all of the following criteria are met:

1. 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
2. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

### C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis in members 18 years of age or older when all of the following are met:

1. Member has achieved or maintained positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain, or reduction in corticosteroid use).
2. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

### D. Eosinophilic Esophagitis

Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 12 years of age or older, weighing at least 40 kg, when member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of eosinophilic esophagitis (e.g., dysphagia, heartburn, chest pain, emesis).

### E. 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 one of the following:

1. Low disease activity (i.e., clear or almost clear skin).
2. Reduction in pruritis intensity and improvement in extent and severity of nodular lesions.

### F. Immune checkpoint inhibitor-related toxicities

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. APPENDICES

**Appendix A: Table. Relative potency of select topical corticosteroid products[9]**

| 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** |
| 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% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| | | 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% |

**Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine**

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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# 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

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

- The requested drug is being prescribed for psoriasis on the face, genitals, or skin folds
  **AND**
  - The request is NOT for continuation of therapy
  **OR**
  - The request is for continuation of therapy
    **AND**
    - The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.)

**OR**

- The requested drug is being prescribed for vitiligo on the head or neck
  **AND**
  - The request is NOT for continuation of therapy
  **OR**
  - The request is for continuation of therapy
    **AND**
    - The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)

**OR**

- The requested drug is being prescribed for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (eczema)
  **AND**
  - The request is NOT for continuation of therapy
    **AND**

- The patient is less than 2 years of age

**OR**

- The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)

**OR**

- 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)

**OR**

- The request is for continuation of therapy

**AND**

- 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)]

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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 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
   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 immunotherapy-related inflammatory arthritis (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. Stevens-Johnson syndrome or toxic epidermal necrolysis: oncologist, hematologist, or dermatologist
F. Immunotherapy-related inflammatory arthritis: 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 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. Articular juvenile idiopathic arthritis (JIA)**

1. Authorization of 12 months may be granted for members 2 years of age and 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 and older for the 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 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.

**E. Plaque psoriasis (PsO)**

1. Authorization of 12 months may be granted for members 4 years of age or older who have previously 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 treatment of moderate to severe plaque psoriasis in members 4 years of age or older 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 the 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 C).

**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 any of the following criteria is met:
   i. Member has experienced an inadequate response to at least a 3-month trial of one of the following despite adequate dosing or maximally tolerated dose:
      a. Sulfasalazine (i.e., titrated to 1000 mg twice daily)
      b. Methotrexate (i.e., titrated to at least 15 mg/week)
   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 experienced an inadequate response to an oral antibiotic for at least 90 days.
   ii. Member has an intolerance or contraindication to oral antibiotics.

**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 experienced 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 nonbiologic medication for Behcet's disease (e.g., apremilast, colchicine, systemic glucocorticoids, azathioprine).

**J. Immune checkpoint inhibitor toxicity**

1. Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor 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 toxicity when the member has severe immunotherapy-related inflammatory arthritis and has experienced an inadequate response, 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. Articular juvenile idiopathic arthritis (JIA)**

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 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

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

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis 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 when there is improvement in any of the following from baseline:

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

**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 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 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. Graft versus host disease and immune checkpoint inhibitor toxicity**

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

**I. 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 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 [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.

## 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 Contraindications to Methotrexate or Leflunomide**
1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

**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

**Appendix C: 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. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

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# 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 (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

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: 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 either of the following criteria is met:
1. Member has had an inadequate response, intolerance, or contraindication to systemic corticosteroids or infliximab.
2. Member has moderate or severe diarrhea or colitis.

## 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. 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

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| 2137-A, 2676-A |

# SPECIALTY GUIDELINE MANAGEMENT

## EPCLUSA (sofosbuvir and velpatasvir)

**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
Epclusa is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection:
A. without cirrhosis or with compensated cirrhosis
B. with decompensated cirrhosis for use in combination with ribavirin

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 prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### III. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, without ribavirin**

**1. Genotype 1, 2, 3, 4, 5 or 6 infection**

i. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with peginterferon alfa (PEG-IFN) and ribavirin (RBV) with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).
ii. Authorization of up to 12 weeks may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without ribavirin and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
iii. Authorization of up to 12 weeks may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

**2. Unknown genotype/genotype could not be determined**

Authorization of up to 12 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis who are treatment-naïve and do not have any of the following characteristics:
i. HIV in those on a tenofovir disoproxil fumarate (TDF)-containing regimen with an eGFR less than 60 ml/min
ii. HBsAG positive

iii. Current pregnancy
iv. Known or suspected hepatocellular carcinoma
v. Prior liver transplantation

Note: Genotype testing is required for members with any of the characteristics listed.

3. **Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)**
Authorization of up to 24 weeks total may be granted for members with genotype 1, 2, 3, 4, 5 or 6 infection who have decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Section VI).

4. **Recurrent HCV infection post liver transplantation**
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.

5. **Kidney transplant recipients**
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have HCV genotype 1, 2, 3, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

6. **Organ recipient from HCV-viremic donor**
Authorization of up to 12 weeks total may be granted for members who have received a liver or non-liver organ transplant from an HCV-viremic donor.

**B. Hepatitis C virus infection, in combination with ribavirin**

1. **Genotype 3 infection**
Authorization of up to 12 weeks total may be granted for treatment naïve members with compensated cirrhosis who have the Y93H substitution associated with velpatasvir resistance.

2. **Decompensated cirrhosis (CTP class B or C)**
i. Authorization of up to 12 weeks total may be granted for members with genotype 1, 2, 3, 4, 5 or 6 infection and decompensated cirrhosis.
ii. Authorization of up to 24 weeks total may be granted for members with genotype 1, 2, 3, 4, 5 or 6 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir- or NS5A inhibitor-based regimen.

3. **Recurrent HCV infection post liver transplantation**
i. Authorization of up to 12 weeks total may be granted for treatment-naïve members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.
ii. Authorization of up to 24 weeks total may be granted for treatment experienced members with decompensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.

**C. HCV and HIV coinfection**
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A or B above are met.

## IV. CONTINUATION OF THERAPY

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

## V. OTHER

A. Member must be 3 years of age or older.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    1. Treatment status (i.e., treatment-naïve or retreatment)
    2. For initial treatment: confirmation of member readiness
    3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
    4. Hepatitis B screening results
    5. Metavir/Fibrosis score

## VI. APPENDIX: RIBAVIRIN INELIGIBILITY

RBV ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

## VII. REFERENCES

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 24, 2022. Accessed December 1, 2022.

| Reference number(s) |
| --- |
| 2609-A |

# SPECIALTY GUIDELINE MANAGEMENT

## EPIDIOLEX (cannabidiol)

**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
Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC) in patients 1 year of age and older.

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

### II. CRITERIA FOR INITIAL APPROVAL

**A. Seizures associated with Lennox-Gastaut syndrome or Dravet syndrome**
Authorization of 12 months may be granted for treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in members 1 year of age and older.

**B. Seizures associated with Tuberous Sclerosis Complex**
Authorization of 12 months may be granted for treatment of seizures associated with tuberous sclerosis complex in members 1 year of age and older.

### III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of treatment in members (including new members) 1 year of age or older requesting reauthorization for an indication listed in Section II when the member has achieved or maintained a positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiating Epidiolex.

### IV. REFERENCE

1. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; January 2023.

# 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**
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for mild to moderate atopic dermatitis

**AND**

- The patient is 3 months of age or older

**AND**

- The request is NOT for continuation of therapy
  **AND**
  - The patient is less than 2 years of age
  **OR**
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
    **AND**
    - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor
  **OR**
  - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid

**OR**

- The request is for continuation of therapy
  **AND**
  - 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**

- 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.*

**REFERENCES**


1. Eucrisa [package insert]. New York, NY: Pfizer Inc.; April 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed February 21, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: February/21/2023).
4. Eichenfield LF, Tom WL, et. al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol.* 2014;71:116-32.
5. Paller AS, Tom WL, et. al. Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. *J Am Acad Dermatol.* 2016 Jul 1175(3)494-503.e4.
6. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. November 16, 2022. Available at: https://chemm.hhs.gov/burns.htm. Accessed March 1, 2023.
7. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014; 70:338-51.

| 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 the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

*Limitations of Use:*
- Not for treatment of other eosinophilic conditions
- 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. For initial requests:
   1. Member's chart notes or medical record showing pretreatment blood eosinophil count, 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 members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma.

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 meets either of the following criteria:
   i. Member has a baseline blood eosinophil count of at least 150 cells per microliter
   ii. 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:
   i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
   ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
   iii. 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:
   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)
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 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. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
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. 2022 update. Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed March 1, 2023.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 1, 2023.

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) |
| --- |
| 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 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 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. REFERENCE

1. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2022.
2. Fingolimod [package insert]. Weston, FL: Apotex Corporation; February 2023.
3. Tascenso ODT [package insert]. San Jose, CA: Handa Neuroscience, LLC; December 2022.

| 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 the 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.; February 2023.
2. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; April 2022.
3. Glatiramer acetate 20mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022.
4. Glatiramer acetate 40mg/mL [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; May 2022.
5. IBM Micromedex [database online]. Ann Arbor, MI: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. March 22, 2023.
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 March 22, 2023.
7. The Multiple Sclerosis Coalition. *The use of disease-modifying therapies in multiple sclerosis: principles and current evidence.* http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed May 01, 2019.

| Reference number(s) |
| --- |
| 2134-A, 2677-A |

# SPECIALTY GUIDELINE MANAGEMENT

## HARVONI (ledipasvir and sofosbuvir)

### 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
Harvoni is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV):

A. genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
B. genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin
C. genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

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

### II. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### III. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, without ribavirin**

**1. Genotype 1 infection**

i. Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis who have any of the following: HIV co-infection, or are less than 18 years of age, or have pre-treatment HCV RNA greater than or equal to 6 million IU/mL.
iii. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis who have pre-treatment HCV RNA below 6 million IU/mL and are HIV-uninfected.
iv. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor (telaprevir, boceprevir, or simeprevir).
v. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

**2. Genotype 4 or 5**

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

3. **Genotype 6 infection**
   Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria are met:
   i. Member is treatment-naïve and does not have genotype 6e subtype
   ii. Member has failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor

4. **Decompensated cirrhosis (CTP class B or C)**
   Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5 or 6 infection and documented anemia (baseline Hgb below 10 g/dL) or RBV ineligibility (see Section VI).

5. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis and recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation.

6. **Kidney transplant recipients**
   Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have HCV genotype 1, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

**B. Hepatitis C virus infection, in combination with ribavirin**

1. **Genotype 1 infection**
   Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

2. **Genotype 4 infection**
   Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

3. **Decompensated cirrhosis (CTP class B or C)**
   i. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5 or 6 infection.
   ii. Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5 or 6 infection who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV, sofosbuvir plus PEG-IFN and RBV, sofosbuvir plus simeprevir with or without RBV).

4. **Recurrent HCV infection post liver transplantation**
   i. Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation and decompensated cirrhosis.
   ii. Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 4, 5 or 6 infection post liver transplantation and decompensated cirrhosis.
   iii. Authorization of up to 12 weeks total may be granted for treatment-naïve members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis.
   iv. Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor.

**C. HCV and HIV coinfection**

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A or B above are met.

## IV. CONTINUATION OF THERAPY

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

## V. OTHER

A. The member must be 3 years of age or older.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
   1. Treatment status (i.e., treatment-naïve or retreatment)
   2. For initial treatment: confirmation of member readiness
   3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
   4. Hepatitis B screening results
   5. Metavir/Fibrosis score

## VI. APPENDIX: RIBAVIRIN INELIGIBILITY

RBV ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

## VII. REFERENCES

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences; March 2020.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 5, 2021. Accessed August 9, 2022.

| 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)

**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 advanced, recurrent, or metastatic uterine serous carcinoma
5. HER2-amplified/positive and RAS and BRAF wild-type colorectal cancer
6. HER2-positive salivary gland tumor
7. HER2-positive hepatobiliary 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 Gastroesophageal Junction Cancer

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

### C. Uterine Serous Carcinoma

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

### D. Colorectal Cancer

Authorization of 12 months may be granted for treatment of unresectable, 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 HER2-positive salivary gland tumors.

### F. Hepatobiliary Cancers

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

## 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

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
2. Kanjinti [package insert]. Thousand Oaks, CA: Amgen, Inc.; October 2022.
3. Ogivri [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2021.
4. Trazimera [package insert]. Cork, Ireland: Pfizer Ireland Pharmaceuticals; November 2020.
5. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; May 2019.
6. Ontruzant [package insert]. Incheon, Republic of Korea: Samsung Bioepis Co.; June 2021.
7. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 27, 2023.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 7, 2022.
9. Thorpe LM, Schrock AB, Erlich RL, et al. Significant and durable clinical benefit from trastuzumab in 2 patients with HER2-amplified salivary gland cancer and a review of the literature. Head Neck. 2017;39(3): E40-E44.
10. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; https://www.clinicalkey.com/pharmacology [available with subscription]. Accessed December 7, 2022.
11. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 1.2023. Accessed January 27, 2023. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf
12. Tukysa [package insert]. Bothell, WA: Seagen, Inc.; January 2023.

| 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.

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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)
## YUFLYMA (adalimumab-aaty)
## YUSIMRY (adalimumab-aqvh)
## adalimumab
## adalimumab-aacf
## adalimumab-adaz
## adalimumab-adbm
## adalimumab-fkjp

**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

**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)

**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 |
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| 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 children 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 [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.

## VII. REFERENCES

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| 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 [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.

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

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| Reference number |
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| 2182-A |

# SPECIALTY GUIDELINE MANAGEMENT

## REMICADE (infliximab)
## AVSOLA (infliximab-axxq)
## INFLECTRA (infliximab-dyyb)
## RENFLEXIS (infliximab-abda)
## 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. Adult patients with moderately to severely active Crohn's disease (CD) and fistulizing CD who have had an inadequate response to conventional therapy
2. 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
3. Moderately to severely active ulcerative colitis (UC) in patients 6 years of age or older who have had an inadequate response to conventional therapy
4. Adult patients with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate
5. Adult patients with active ankylosing spondylitis (AS)
6. Adult patients with active psoriatic arthritis (PsA)
7. Adult patients with chronic severe plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate

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 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, and uveitis
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 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:[60] rheumatologist or dermatologist
D. Plaque psoriasis and pyoderma gangrenosum: dermatologist
E. Sarcoidosis: dermatologist or pulmonologist
F. Uveitis: ophthalmologist or rheumatologist
G. Immune checkpoint inhibitor toxicity and acute graft versus host disease: oncologist or hematologist

## IV. CRITERIA FOR INITIAL APPROVAL

**A. 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.

**B. Ulcerative colitis (UC)**
Authorization of 12 months may be granted for members 6 years of age or older for treatment of moderately to severely active UC.

**C. 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).

**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 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.

**E. 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.

**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 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**

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., apremilast, colchicine, systemic glucocorticoids, azathioprine).

**H. Hidradenitis suppurativa**

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 experienced an inadequate response to an oral antibiotic for at least 90 days.

ii. Member has an intolerance or contraindication to oral antibiotics.

**I. 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 experienced 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).

**J. Sarcoidosis**

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

**K. Takayasu's arteritis**

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

**L. Uveitis**

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

**M. 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 experienced an inadequate response to at least a 3-month trial of one of the following despite adequate dosing or maximally tolerated dose:
      a. Sulfasalazine (i.e., titrated to 1000 mg twice daily)
      b. Methotrexate (i.e., titrated to at least 15 mg/week)
   ii. Member has an intolerance or contraindication to methotrexate (see Appendix) and sulfasalazine (e.g., porphyria, intestinal or urinary obstruction).

**N. Immune checkpoint inhibitor toxicity**

1. Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor toxicity when either of the following criteria is met:
   i. Member has experienced an inadequate response, intolerance, or contraindication to corticosteroids.
   ii. Member has moderate or severe diarrhea or colitis.

2. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor toxicity when the member has severe inflammatory arthritis and has experienced an inadequate response, intolerance, or contraindication to corticosteroids.

**O. 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.

## 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 (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)

**B. Ulcerative colitis (UC)**

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 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 (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)**
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)**
Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for active ankylosing spondylitis or active 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)

**E. 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

**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. 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. Uveitis**

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 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**

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 toxicity and acute graft versus host disease**

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

**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 [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.

## 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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# 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 for both initial approval and continuation of therapy prior authorization reviews (where applicable): Documentation of score of items 1 to 7 of the Abnormal Involuntary Movement Scale (AIMS).

### III. CRITERIA FOR INITIAL APPROVAL

**A. Tardive dyskinesia**
Authorization of 6 months may be granted for treatment of tardive dyskinesia when the baseline AIMS score for items 1 to 7 is obtained.

**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

**A. Tardive dyskinesia**
Authorization of 12 months may be granted for treatment of tardive dyskinesia when the member's tardive dyskinesia symptoms have improved as indicated by a decreased AIMS score (items 1 to 7) from baseline.

**B. Chorea associated with Huntington's disease**
Authorization of 12 months may be granted for treatment of chorea associated with Huntington's disease when the disease has improved or stabilized.

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# 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. Adult T-cell leukemia/lymphoma (ATLL)
2. Renal cell carcinoma
3. Chronic myeloid leukemia (CML)
4. 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. Adult T-cell leukemia/lymphoma (ATLL)**
Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma (ATLL) when the requested medication is used in combination with zidovudine.

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

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

**E. 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.

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

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

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

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

**J. 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.

**K. 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.

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| Reference number(s) |
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| 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

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| 4129-A |

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| 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.

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.

### 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).

**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).

## 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)

## 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. APPENDIX: 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

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| 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
   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).
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 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 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).

iii. 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.

**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, urticarial hypocomplementemic vasculitis, acquired C1 inhibitor deficiency, and cryoglobulinemia.

**J. Management of gout and pseudogout flares**
Authorization of 6 months may be granted for management of flares for gout or pseudogout (also known as calcium pyrophosphate deposition disease) when either of the following criteria is met:
1. Member has had an inadequate response or intolerance to maximum tolerated doses of non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and oral and injectable corticosteroids.
2. Member has a contraindication to NSAIDs and colchicine and has a clinical reason to avoid repeated courses of 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, or 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 chest pain
2. Pericardial 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 [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.

## 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

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| Reference number(s) |
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| 1639-A |

# SPECIALTY GUIDELINE MANAGEMENT

## KISQALI (ribociclib)

### 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. Kisqali is indicated in combination with an aromatase inhibitor 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.

2. Kisqali is indicated in combination with fulvestrant for the treatment of postmenopausal women or in men with (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.

B. Compendial Uses
Breast cancer: Recurrent HR-positive, HER2-negative disease.

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

### II. DOCUMENTATION

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

### III. CRITERIA FOR INITIAL APPROVAL

**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.

### 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.

## V. REFERENCES

1. Kisqali [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 8, 2022.

| Reference number(s) |
| --- |
| 2104-A |

# SPECIALTY GUIDELINE MANAGEMENT

## KISQALI FEMARA CO-PACK (ribociclib tablets; letrozole tablets)

**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
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.

B. Compendial Uses
Breast cancer: Therapy for recurrent HR-positive, HER2-negative disease

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

### II. DOCUMENTATION

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

### III. CRITERIA FOR INITIAL APPROVAL

**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.

### 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.

### V. REFERENCES


1. Kisqali Femara Co-Pack [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2022.
2. Ribociclib. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 10, 2022.

| 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; January 2023.

| 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. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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 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:
   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. 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.

**C. 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.

**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 in 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)

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.

## IV. CONTINUATION OF THERAPY

**A. Ovarian cancer**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

**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

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
2. Leuprolide acetate depot 22.5mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2018.
3. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 6, 2023.
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# 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 70-70mg 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 70-70mg 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% 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% 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% 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% 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% 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% gel or Lidocaine-collagen-aloe vera 2% 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% 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<br>Lidocaine-tetracaine 7-7% cream | 60 gm / 25 days | Does Not Apply* |
| Synera 70-70mg patch<br>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.*

**REFERENCES**


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14. Medical Devices. Available at: https://www.fda.gov/medical-devices. Accessed September 2022.

# 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 70-70mg 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% 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% 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% 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% 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% 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% gel or Lidocaine-collagen-aloe vera 2% 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% 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<br>Lidocaine-tetracaine 7-7% cream | 60 gm / 25 days | Does Not Apply* |
| Synera 70-70mg patch<br>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.*

**REFERENCES**


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2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-aloe vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
4. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; February 2020.
6. Lidocaine HCl 4% topical solution [package insert]. Buena, NJ: Teligent Pharma, Inc; November 2019.
7. Lidocaine 5% ointment [package insert]. Bridgewater, NJ: Alembic Pharmaceuticals, Inc.; September 2020.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Parsippany, NJ: Actavis Pharma, Inc; July 2019.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
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| Reference number(s) |
| --- |
| 1970-A, 6049-A |

# SPECIALTY GUIDELINE MANAGEMENT

## LUPRON DEPOT 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 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot 3.75 mg monthly and Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily are also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Use of norethindrone acetate in combination with Lupron Depot 3.75 mg and Lupron Depot 11.25 mg is referred to as add-back therapy, and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of Lupron Depot 3.75 mg and Lupron Depot 11.25 mg.

2. Uterine Leiomyomata (Fibroids)
When used concomitantly with iron therapy, Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. 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. Recurrent 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, or
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 salivary gland tumors 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

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria in addition to the following diagnosis-specific criteria (if applicable).

**A. Endometriosis**

Authorization of up to 6 months (for a lifetime maximum of 12 months total) may be granted for retreatment of endometriosis when all 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, or
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

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| 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. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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. Intracranial tumor has been evaluated by appropriate lab tests and diagnostic imaging (e.g., 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

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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; February 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) |
| --- |
| 2242-A, 2678-A |

# SPECIALTY GUIDELINE MANAGEMENT

## MAVYRET (glecaprevir and pibrentasvir)

**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
Mavyret is indicated for the treatment of adult and pediatric patients 3 years and older with:

A. Chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)
B. HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

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

### II. EXCLUSIONS

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### IV. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, without ribavirin**

**1. Genotype 1 infection**

i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
iii. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir or telaprevir in combination with peginterferon and ribavirin, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.

iv. Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without ribavirin (RBV) and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
v. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
vi. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

**2. Genotype 3 infection**

i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
iii. Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir or telaprevir in combination with peginterferon and ribavirin, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
iv. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
v. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon) without sofosbuvir/NS5A inhibitor experience (e.g., sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) or prior exposure to a NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

**3. Genotype 4 infection**

i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
ii. Authorization of up to 12 weeks total may be granted for treatment naïve members with compensated cirrhosis and HIV coinfection.
iii. Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
iv. Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir or telaprevir in combination with peginterferon and ribavirin, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
v. Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
vi. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
vii. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir/ledipasvir [Harvoni],

sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

4. **Genotype 2, 5, or 6 infection**
   i. Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis or with compensated cirrhosis.
   ii. Authorization of up to 16 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
   iii. Authorization of up to 12 weeks total may be granted for members less than 18 years of age without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir or telaprevir in combination with peginterferon and ribavirin, simeprevir with sofosbuvir) and who have not received an NS5A inhibitor.
   iv. Authorization of up to 8 weeks total may be granted for members without cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
   v. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with an interferon-based regimen with or without RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
   vi. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and ribavirin with or without interferon, sofosbuvir/ledipasvir [Harvoni], sofosbuvir/velpatasvir [Epclusa]) and who have not had prior exposure to an NS5A inhibitor plus NS3/4A protease inhibitor regimen (e.g., elbasvir/grazoprevir [Zepatier]).

5. **Unknown genotype/genotype could not be determined**
   Authorization of up to 8 weeks total may be granted for members with unknown or undetermined genotype without cirrhosis who are treatment-naïve and do not have any of the following characteristics:
   i. HIV in those on a tenofovir disoproxil fumarate (TDF)-containing regimen with an eGFR less than 60 ml/min
   ii. HBsAG positive
   iii. Current pregnancy
   iv. Known or suspected hepatocellular carcinoma
   v. Prior liver transplantation

   Note: Genotype testing is required for members with any of the characteristics listed.

6. **Recurrent HCV infection post liver transplantation**
   i. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis and recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection post liver transplantation.
   ii. Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 1 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
   iii. Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 3 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
   iv. Authorization of up to 16 weeks total may be granted for members with recurrent HCV genotype 3 infection post liver transplantation without cirrhosis or with compensated cirrhosis who failed prior

treatment with sofosbuvir (Sovaldi) and RBV with or without PEG-IFN and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

7. **Kidney transplant recipients**
   i. Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who have HCV genotype 1, 2, 3, 4, 5 or 6 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.
   ii. Authorization of up to 16 weeks total may be granted for members with HCV genotype 1 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with an NS5A inhibitor (excluding glecaprevir/pibrentasvir) and who have not received an NS3/4A protease inhibitor.
   iii. Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with PEG-IFN and RBV and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.
   iv. Authorization of up to 16 weeks total may be granted for members with HCV genotype 3 infection without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir (Sovaldi) and RBV with or without PEG-IFN and who have not received an NS3/4A protease inhibitor or NS5A inhibitor.

8. **Organ recipient from HCV-viremic donor**
   i. Authorization of up to 12 weeks total may be granted for members who have received a liver transplant from an HCV-viremic donor.
   ii. Authorization of up to 8 weeks total may be granted for members who have received a non-liver organ transplant from an HCV-viremic donor when treatment is initiated in the first week after transplant.
   iii. Authorization of up to 12 weeks total may be granted for members who have received a non-liver organ transplant from an HCV-viremic donor when treatment is initiated more than one week after transplant.

**B. Hepatitis C virus infection, in combination with Sovaldi and ribavirin**
**Genotype 1, 2, 3, 4, 5, or 6 infection**

1. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with glecaprevir/pibrentasvir (Mavyret). An additional 8 weeks may be granted following failure with sofosbuvir (Sovaldi) and Mavyret.
2. Authorization of up to 16 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who failed prior treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi). Authorization of up to 24 weeks may be granted for members with extremely difficult cases (e.g., genotype 3 with cirrhosis).

**C. HCV and HIV Coinfection**

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Sections A or B above are met.

## V. CONTINUATION OF THERAPY

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

## VI. OTHER

A. Member must be 3 years of age or older.

B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
   1. Treatment status (i.e., treatment-naïve or retreatment)
   2. For initial treatment: confirmation of member readiness
   3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
   4. Hepatitis B screening results
   5. Metavir/Fibrosis score

## VII. REFERENCES

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; September 2021.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 24, 2022. Accessed December 1, 2022.

| 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; June 2022.

| Reference number(s) |
| --- |
| 1931-A |

# SPECIALTY GUIDELINE MANAGEMENT

## NEULASTA (pegfilgrastim)
## FULPHILA (pegfilgrastim-jmdb)
## FYLNETRA (pegfilgrastim-pbbk)
## NYVEPRIA (pegfilgrastim-apgf)
## STIMUFEND (pegfilgrastim-fpgk)
## UDENYCA (pegfilgrastim-cbqv)
## ZIEXTENZO (pegfilgrastim-bmez)

**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

**Neulasta**

1. 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.
2. 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**[2]

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**

1. 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.
2. 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.

**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.

B. Compendial Use
   1. Stem cell transplantation-related indications
   2. Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
   3. Hematopoietic Subsyndrome of Acute Radiation Syndrome
   4. Hairy cell leukemia, neutropenic fever

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

## II. DOCUMENTATION

**Primary Prophylaxis of Febrile Neutropenia**

A. Documentation must be provided of the member's diagnosis and chemotherapeutic regimen.
B. 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.

## III. CRITERIA FOR INITIAL APPROVAL

**A. 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 (1, 2, 3, and 4):
   1. The requested medication will not be used in combination with other colony stimulating factors within any chemotherapy cycle.
   2. The member will not receive chemotherapy at the same time as they receive radiation therapy.
   3. The requested medication will not be administered with weekly chemotherapy regimens.
   4. One of the following criteria is met (i or ii):

i. 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:
   a. Myelosuppressive anti-cancer therapy that is expected to result in 20% or higher incidence of febrile neutropenia (FN) *(See Appendix A)*.
   b. 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).*
   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)*.

ii. 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).

**B. Other indications**

Authorization of 6 months may be granted for members with any of the following indications:

1. Stem cell transplantation-related indications
2. Hematopoietic Subsyndrome of Acute Radiation Syndrome
   Treatment for radiation-induced myelosuppression following a radiological/nuclear incident
3. Hairy cell leukemia
   Members with hairy cell leukemia with neutropenic fever following chemotherapy

## IV. CONTINUATION OF THERAPY

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

## V. APPENDIX

A. APPENDIX A: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 20% or Higher*†

1. Acute Lymphoblastic Leukemia:
   Select ALL regimens as directed by treatment protocol (see NCCN guidelines ALL)
2. Bladder Cancer:
   i. Dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
   ii. CBDCa/Pac (carboplatin, paclitaxel)
3. Bone Cancer
   i. VAI (vincristine, doxorubicin or dactinomycin, ifosfamide)
   ii. VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide
   iii. Cisplatin/doxorubicin
   iv. VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin)
   v. VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
4. Breast Cancer:
   i. Docetaxel + trastuzumab
   ii. Dose-dense AC (doxorubicin, cyclophosphamide) + paclitaxel (or dose dense paclitaxel)

iii. TAC (docetaxel, doxorubicin, cyclophosphamide)
iv. AT (doxorubicin, docetaxel)
v. Doc (docetaxel)
vi. TC (docetaxel, cyclophosphamide)
vii. TCH (docetaxel, carboplatin, trastuzumab)

5. Colorectal Cancer:
   FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
6. Esophageal and Gastric Cancers:
   Docetaxel/cisplatin/fluorouracil
7. Head and Neck Squamous Cell Carcinoma
   TPF (docetaxel, cisplatin, 5-fluorouracil)
8. Hodgkin Lymphoma:
   i. Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine)
   ii. Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
9. Kidney Cancer:
   Doxorubicin/gemcitabine
10. Non-Hodgkin's Lymphoma:
    i. CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin
    ii. Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)
    iii. ICE (ifosfamide, carboplatin, etoposide)
    iv. Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) ± rituximab
    v. MINE (mesna, ifosfamide, mitoxantrone, etoposide)
    vi. DHAP (dexamethasone, cisplatin, cytarabine)
    vii. ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine (Ara-C))
    viii. HyperCVAD ± rituximab (cyclophosphamide, vincristine, doxorubicin, dexamethasone ± rituximab)
    ix. VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
11. Melanoma:
    Dacarbazine-based combination with IL-2, interferon alpha (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
12. Multiple Myeloma:
    i. VTD-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide + bortezomib)
    ii. DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide)
13. Ovarian Cancer:
    i. Topotecan
    ii. Docetaxel
14. Soft Tissue Sarcoma:
    i. MAID (mesna, doxorubicin, ifosfamide, dacarbazine)
    ii. Doxorubicin
    iii. Ifosfamide/doxorubicin
15. Small Cell Lung Cancer:
    i. Top (topotecan)
    ii. CAV (cyclophosphamide, doxorubicin, vincristine)
16. Testicular Cancer:
    i. VeIP (vinblastine, ifosfamide, cisplatin)
    ii. VIP (etoposide, ifosfamide, cisplatin)
    iii. TIP (paclitaxel, ifosfamide, cisplatin)
17. Gestational Trophoblastic Neoplasia:
    i. EMA/CO (etoposide, methotrexate, dactinomycin/cyclophosphamide, vincristine)
    ii. EMA/EP (etoposide, methotrexate, dactinomycin/etoposide, cisplatin)

iii. EP/EMA (etoposide, cisplatin/etoposide, methotrexate, dactinomycin)
iv. TP/TE (paclitaxel, cisplatin/paclitaxel, etoposide)
v. BEP (bleomycin, etoposide, cisplatin)
vi. VIP (etoposide, ifosfamide, cisplatin)
vii. ICE (ifosfamide, carboplatin, etoposide)

18. Wilms Tumor:
    i. Regimen M (vincristine, dactinomycin, doxorubicin, cyclophosphamide, etoposide)
    ii. Regimen I (vincristine, doxorubicin, cyclophosphamide, etoposide)

*Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)
† This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

B. APPENDIX B: Selected Chemotherapy Regimens with an Incidence of Febrile Neutropenia of 10% to 19%*†

1. Occult Primary – Adenocarcinoma:
   Gemcitabine/docetaxel
2. Breast Cancer:
   i. Docetaxel
   ii. CMF classic (cyclophosphamide, methotrexate, fluorouracil)
   iii. CA (doxorubicin, cyclophosphamide) (60 mg/m2) (hospitalized)
   iv. AC (doxorubicin, cyclophosphamide) + sequential docetaxel (taxane portion only)
   v. AC + sequential docetaxel + trastuzumab
   vi. A (doxorubicin) (75 mg/m2)
   vii. AC (doxorubicin, cyclophosphamide)
   viii. CapDoc (capecitabine, docetaxel)
   ix. Paclitaxel every 21 days
3. Cervical Cancer:
   i. Irinotecan
   ii. Cisplatin/topotecan
   iii. Paclitaxel/cisplatin
   iv. Topotecan
4. Colorectal Cancer:
   i. FL (fluorouracil, leucovorin)
   ii. CPT-11 (irinotecan) (350 mg/m2 q 3 wk)
   iii. FOLFOX (fluorouracil, leucovorin, oxaliplatin)
   iv. FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
5. Esophageal and Gastric Cancers:
   i. Irinotecan/cisplatin
   ii. Epirubicin/cisplatin/5-fluorouracil
   iii. Epirubicin/cisplatin/capecitabine
6. Non-Hodgkin's Lymphomas:
   i. EPOCH-IT chemotherapy
   ii. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin)
   iii. GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) + rituximab
   iv. FMR (fludarabine, mitoxantrone, rituximab)
   v. CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin
   vi. CHOP + rituximab (cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab) including regimens with pegylated liposomal doxorubicin

vii. Bendamustine
7. Non-Small Cell Lung Cancer:
   i. Cisplatin/paclitaxel
   ii. Cisplatin/vinorelbine
   iii. Cisplatin/docetaxel
   iv. Cisplatin/etoposide
   v. Carboplatin/paclitaxel
   vi. Docetaxel
8. Ovarian Cancer:
   Carboplatin/docetaxel
9. Pancreatic Cancer:
   FOLFIRINOX (fluorouracil, leucovorin, oxaliplatin, irinotecan)
10. Prostate Cancer:
    Cabazitaxel
11. Small Cell Lung Cancer:
    Etoposide/carboplatin
12. Testicular Cancer:
    i. BEP (bleomycin, etoposide, cisplatin)
    ii. Etoposide/cisplatin
13. Uterine Sarcoma:
    Docetaxel

*Applies to chemotherapy regimens with or without monoclonal antibodies (e.g., trastuzumab, rituximab)
† This list is not comprehensive; there are other agents/regimens that have an intermediate/high risk for development of febrile neutropenia.

C. APPENDIX C: Patient Risk Factors*
   1. Active infections, open wounds, or recent surgery
   2. Age greater than or equal to 65 years
   3. Bone marrow involvement by tumor producing cytopenias
   4. Previous chemotherapy or radiation therapy
   5. Poor nutritional status
   6. Poor performance status
   7. Previous episodes of FN
   8. Other serious co-morbidities, including renal dysfunction, liver dysfunction, HIV infection, cardiovascular disease
   9. Persistent neutropenia

*This list is not all-inclusive.

## VI. REFERENCES

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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***

## POLICY

## FDA-APPROVED INDICATIONS

**Nexletol**
Nexletol is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Limitations of Use
The effect of Nexletol on cardiovascular morbidity and mortality has not been determined.

**Nexlizet**
Nexlizet is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Limitations of Use
The effect of Nexlizet on cardiovascular morbidity and mortality has not been determined.

## COVERAGE CRITERIA

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

- The requested drug is being prescribed for the treatment of an adult patient with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease

**AND**

- The request is NOT for continuation of therapy **AND**
  - The requested drug is being prescribed as an adjunct to maximally tolerated statin therapy

  **AND**
  - The patient requires additional lowering of low-density lipoprotein cholesterol (LDL-C)

**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

## REFERENCES


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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 patients with severe asthma aged 6 years and older, 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 adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).

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. Member's chart notes or medical record showing pretreatment blood eosinophil count, 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. Member's chart notes or medical record showing pretreatment blood eosinophil count.
      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 EGPA control.

C. HES:
1. For initial requests:
   i. FIP1L1-PDGFRA fusion gene test results.
   ii. Member's chart notes or medical record showing pretreatment blood eosinophil count.
2. For continuation requests: Chart notes or medical record documentation supporting improvement in HES control.

D. CRSwNP:
1. For initial requests:
   i. Member's chart notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyps score (NPS) (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. 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. 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 polyposis: allergist/immunologist or otolaryngologist

## 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, Cinqair) indicated for asthma.

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 resulting in hospitalization or emergency medical care visit.
      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 eosinophilic granulomatosis with polyangiitis 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 an 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[8,9]:
   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 corticosteroids 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 does not have either of the following:
   i. HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)
   ii. FIP1L1-PDGFRA kinase-positive HES
3. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
4. Member will not use the requested medication as monotherapy.
5. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
6. Member has had HES for at least 6 months.
7. Member has experienced at least two HES flares within the past 12 months.

**D. Chronic rhinosinusitis with nasal polyps**

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.

2. Authorization of 6 months may be granted for treatment of chronic rhinosinusitis with nasal polyps 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. The 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.

## V. 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 eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has 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 in the 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

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis 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, sinonasal 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.

## 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

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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.
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| 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 [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, 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

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# 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**
The requested drug will be covered with prior authorization when 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

**AND**

- 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

  **AND**

  - The request is for an adult or pediatric patient 12 years of age or older

  **AND**

    - The request is NOT for continuation of therapy

      **AND**

      - The patient's disease is not adequately controlled with other topical prescription therapies (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor)

      **OR**

      - Other topical prescription therapies are not advisable (e.g., medium or higher potency topical corticosteroid, topical calcineurin inhibitor)

  **OR**

    - The request is for continuation of therapy

      **AND**

      - 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**

  - The requested drug will NOT be applied to affected areas of greater than 20% body surface area (BSA)

**AND**

- 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.*
***For new starts, the mail limit will be the same as the retail limit.* ***The intent is for prescriptions of the requested drug to be filled one month at a time for new starts, even if filled at mail order; there should be no 3-month supplies filled for new starts.*** *The duration of 21 days is used for a 28-day fill period to allow time for refill processing.*

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.; 2023. https://online.lexi.com. Accessed February 21, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: February/21/2023).
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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.
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7. U.S. Department of Health & Human Services. Burn Triage and Treatment – Thermal Injuries. Chemical Hazards Emergency Medical Management. November 16, 2022. Available at: https://chemm.hhs.gov/burns.htm. Accessed April 6, 2022.

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **ORAL FENTANYL PRODUCTS** |
| **BRAND NAME (generic)** | **ACTIQ (fentanyl citrate oral transmucosal lozenge)**<br>**FENTORA (fentanyl citrate buccal tablet)**<br>**SUBSYS (fentanyl sublingual spray)** |

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

**POLICY**

**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**

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

- The requested drug is indicated for the treatment of breakthrough CANCER-related pain only. The requested drug is being prescribed for the management of breakthrough pain in a CANCER patient with underlying CANCER pain. The prescriber must submit chart notes or other documentation supporting a diagnosis of cancer-related pain and list the type of cancer.
  [Note: For drug coverage approval, ICD diagnosis code provided MUST support the CANCER-RELATED DIAGNOSIS.]

**AND**

- Chart notes or other documentation supporting a diagnosis of cancer-related pain have been submitted to CVS Health

**AND**

- The patient is currently receiving, and will continue to receive, around-the-clock opioid therapy for underlying CANCER pain

**AND**

- The requested drug is intended only for use in opioid tolerant patients. The patient can safely take the requested dose based on their history of opioid use.
  [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.]

**AND**

- If additional quantities are being requested, then:
  - The patient's dose of a concomitant long-acting analgesic is being increased

  **OR**

  - 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

  [Note: Ensure that the patient can safely take the requested dose based on their history of opioid use.]

Quantity Limits apply.

**QUANTITY FOR APPROVAL**

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*

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.*

**REFERENCES**


1. Actiq [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
2. Fentora [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2021.
3. Subsys [package insert]. Northbrook, IL: West Therapeutic Development LLC.; April 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed December 9, 2022.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed December 9, 2022.

6. Adult Cancer Pain. NCCN Guidelines version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 15, 2022.

 

| Reference number |
| --- |
| 2127-A |

# SPECIALTY GUIDELINE MANAGEMENT

## ORENCIA (abatacept)

### 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
2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
3. Active psoriatic arthritis (PsA) in patients 2 years of age and older
4. 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

B. Compendial Uses
1. Oligoarticular juvenile idiopathic arthritis
2. Chronic graft versus host disease
3. 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. 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. 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.

D. Chronic graft versus host disease and 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.

## III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Rheumatoid arthritis and articular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Prophylaxis of acute graft versus host disease (aGVHD), chronic GVHD, and immune checkpoint inhibitor-related toxicity: 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 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. 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. Has 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.
   ii. Member has severe disease.

**D. 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:

1. Member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.
2. The requested medication will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate.

**E. 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:

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

**F. 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 either of the following:
1. Member has experienced an inadequate response to systemic 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 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 (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. Skin and/or nail involvement

### D. Prophylaxis of acute graft versus host disease, chronic 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.

## 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 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

## IX. REFERENCES

1. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb; October 2023.
2. Smolen JS, Landewé R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis.* 2020;*79*:685-699.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
4. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.
5. Ringold S, Angeles-Han S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *American College of Rheumatology*. 2019;1-18.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum.* 2018;71:5-32.
7. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on June 12, 2023 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
8. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 12, 2023.

9. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum*. 2010;62(9):2569-81.
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11. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
12. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569.
13. Gossec L, Baraliakos X, Kerschbaumer A. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79(6):700-712.
14. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
15. 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***

**POLICY**

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

- The requested drug is being prescribed for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a premenopausal patient

**AND**

- 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: 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

Duration of Approval Limits apply.
Total cumulative duration: 24 months

**REFERENCES**

1. Myfembree [package insert]. Brisbane, CA: Myovant Sciences, Inc.; September 2022.
2. Oriahnn [package insert]. North Chicago, IL: AbbVie Inc.; August 2021.
3. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed November 22, 2022.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed November 22, 2022.

| 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 $\beta^+$-thalassemia (HbS$\beta^+$) genotype.
B. Member has homozygous hemoglobin S (HbSS) or sickle $\beta^0$-thalassemia (HbS$\beta^0$) 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 |


1. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics, Inc.; October 2022.
2. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. *N Engl J Med.* 2019 Aug 8;381(6):509-519.

| Reference number(s) |
| --- |
| 2574-A |

# SPECIALTY GUIDELINE MANAGEMENT

## PCSK9i
## PRALUENT (alirocumab), REPATHA (evolocumab)

**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. Members with established atherosclerotic cardiovascular disease.
B. Members with an untreated LDL-C of greater than or equal to 190 mg/dL.
C. Members with familial hypercholesterolemia.

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

### II. CRITERIA FOR INITIAL APPROVAL

**A. Clinical atherosclerotic cardiovascular disease (ASCVD)**

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

1. Member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event.
2. Member has a current LDL-C level greater than or equal to 70 mg/dL.
3. Member is receiving maximally tolerated statin therapy or is statin intolerant.

**B. Primary hyperlipidemia**

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

1. Member had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 mg/dL.
2. Member has a current LDL-C level greater than or equal to 100 mg/dL.
3. Member is receiving maximally tolerated statin therapy or is statin intolerant.

**C. Familial hypercholesterolemia**

Authorization of 12 months may be granted for treatment of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH) when all of the following criteria are met:

1. Member meets one of the following criteria:
   a. Member is 18 years of age or older and had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 mg/dL.
   b. Member is less than 18 years of age and had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 160 mg/dL.
2. Member has a current LDL-C level greater than or equal to 100 mg/dL.
3. Member is receiving maximally tolerated statin therapy or is statin intolerant.

## III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who are continuing therapy with a PCSK9i.

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| Reference number(s) |
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| 2139-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
   Pegasys, as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) and compensated liver disease. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC and compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs.
2. Chronic Hepatitis B
   Pegasys is indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation. Pegasys is indicated for the treatment of HBeAG-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

B. Compendial Uses
1. Myeloproliferative neoplasm (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 neoplasm**
Authorization of 12 months may be granted for treatment of myeloproliferative neoplasm (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, etc.).

**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, etc.).

**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
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; February 2022.

| Reference number(s) |
| --- |
| 4179-A |

# ENHANCED SPECIALTY GUIDELINE MANAGEMENT

## Treatment of Plaque Psoriasis

**Abrilada, adalimumab, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Avsola, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, infliximab, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, 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-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Avsola, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, infliximab, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, 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.






CVS caremark®

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** |
| 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% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| | 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% |

**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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# STEP THERAPY CRITERIA

**BRAND NAME**
**(generic)**

**REYVOW**
**(lasmiditan)**

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

**POLICY**

**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.

| 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 |

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

- The requested drug is being prescribed for the acute treatment of migraine with or without aura in an adult patient

**AND**

- The patient has experienced an inadequate treatment response or an intolerance to TWO triptan 5-HT1agonists

**OR**

- The patient has a contraindication that would prohibit a trial of triptan 5-HT1 agonists

**AND**

- If additional quantities are being requested, medication overuse headache has been considered and ruled out
  **AND**
  - The patient is currently using migraine prophylactic therapy
    [Note: Examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]
    **OR**
  - 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, amitriptyline, venlafaxine.]

Quantity Limits apply.
Reyvow 50 mg: 4 tablets per 25 days*, 12 tablets per 75 days*,
Reyvow 100 mg: 8 tablets per 25 days*, 24 tablets per 75 days*

Post Limit, If additional quantities are being requested,
Reyvow 50 mg: 8 tablets per 25 days*, 24 tablets per 75 days*,
Reyvow 100 mg: 16 tablets per 25 days*, 48 tablets per 75 days*
**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

Duration of Approval (DOA):

- 3373-E: DOA: 12 months

## REFERENCES


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| Reference number |
| --- |
| 1987-D |

# ENHANCED SPECIALTY GUIDELINE MANAGEMENT

## Treatment of Rheumatoid Arthritis

**Abrilada, Actemra, adalimumab, adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, infliximab, Kevzara, Kineret, Orencia, Remicade, Renflexis, Simponi, Simponi Aria, Tofidence, 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-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, infliximab, Kevzara, Kineret, Orencia, Remicade, Renflexis, Simponi, Simponi Aria, Tofidence, 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.

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

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, 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

## IX. REFERENCES

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12. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthrit Care Res*. 2021;0:1-16.
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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 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.

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), and non-radiographic axial spondyloarthritis (nr-axSpA)
    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, and non-radiographic axial spondyloarthritis: 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 adult members for treatment of active psoriatic arthritis 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, Otezla) indicated for active psoriatic arthritis.

### C. Atopic dermatitis

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) or a biologic (e.g., Dupixent, Adbry) 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.

## 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 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

**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)

**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)

## 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, 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% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| | 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** |
| 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% |
| | Triamcinolone acetonide | Cream, lotion | 0.025% |
| | | Cream, Ointment, Solution | 2.5% |

| Potency | Drug | Dosage form | Strength |
| --- | --- | --- | --- |
| VII. Least potent (group 7) | Hydrocortisone (base, greater than or equal to 2%) | 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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# SPECIALTY GUIDELINE MANAGEMENT

## Adempas (riociguat)
## 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**

**1 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 diseases
- 1.4.2 HIV infection
- 1.4.3 Portal hypertension
- 1.4.4 Congenital heart diseases
- 1.4.5 Schistosomiasis

1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/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 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 obstruction**

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 tumours of the testis
Other tumours
4.2.3 Non-malignant tumours
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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| Reference number(s) |
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| 1704-A |

# SPECIALTY GUIDELINE MANAGEMENT

## RITUXAN (rituximab)
## RUXIENCE (rituximab-pvvr)
## TRUXIMA (rituximab-abbs)
## RIABNI (rituximab-arrx)

### Treatment of Rheumatoid Arthritis and Other 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, Ruxience, Truxima, and Riabni are indicated for:
1. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older* in combination with glucocorticoids (*pediatric indication applies to Rituxan only).
2. 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.
3. Non-Hodgkin's lymphoma (NHL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)
4. Chronic lymphocytic leukemia (CLL)
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)

Rituxan is also indicated for:
1. Pemphigus Vulgaris (PV)
Rituxan is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.
2. Mature B-cell acute leukemia (B-AL)
(Not addressed in this policy - Refer to Rituxan-Ruxience-Truxima-Riabni Oncology SGM)

B. Compendial Uses
1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. Neuromyelitis optica (i.e. neuromyelitis optica spectrum disorder, NMOSD, Devic disease)
4. Autoimmune blistering disease
5. Cryoglobulinemia
6. Solid organ transplant
7. Opsoclonus-myoclonus ataxia
8. Systemic lupus erythematosus
9. Myasthenia gravis, refractory
10. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-Oncology 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:

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. Sjögren's syndrome, cryoglobulinemia, opsoclonus-myoclonus-ataxia, and systemic lupus erythematosus (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

## III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. RA, GPA (Wegener's granulomatosis), MPA, Churg-Strauss, pauci-immune glomerulonephritis, SLE: rheumatologist, immunologist, nephrologist
B. Sjogren's syndrome: rheumatologist, ophthalmologist, immunologist
C. Multiple sclerosis, NMOSD, myasthenia gravis, opsoclonus-myoclonus-ataxia: neurologist, immunologist
D. Autoimmune blistering disease: dermatologist, immunologist
E. Cryoglobulinemia: hematologist, rheumatologist, neurologist, nephrologist
F. Solid organ transplant: immunologist, transplant specialist

## IV. EXCLUSIONS

A. Coverage will not be provided for requests for the treatment of rheumatoid arthritis (RA) when planned date of administration is less than 16 weeks since date of last dose received.
B. Member will not receive Rituxan, Ruxience, Truxima, or Riabni with other biologics for RA.
C. Member will not receive Rituxan, Ruxience, Truxima, or Riabni with other multiple sclerosis (MS) drugs excluding Ampyra.
D. Member will not use Rituxan, Ruxience, Truxima, or Riabni concomitantly with other biologics for the treatment of neuromyelitis optica.

## V. CRITERIA FOR INITIAL APPROVAL

### A. Rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX) or leflunomide unless the member has a contraindication (see VII. Appendix) or intolerance to MTX or leflunomide and either of the following criteria are met:

i. The member has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis; or
ii. The member has received at least two full doses of Rituxan, Ruxience, Truxima, or Riabni for the treatment of RA, where the most recent dose was given within 6 months of the request.

2. Authorization of 12 months may be granted for treatment of adults with moderately to severely active RA in combination with MTX or leflunomide unless the member has a contraindication (see VII. Appendix) or intolerance to MTX or leflunomide when all of the following criteria are met:
   i. The member meets either of the following criteria:
      a. The 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. The 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. The member meets either of the following criteria:
      a. The member has experienced an inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to at least 15 mg/week); or
      b. The member had an intolerable adverse effect or contraindication to MTX (see VII. Appendix), and an inadequate response to another conventional drug (e.g., hydroxychloroquine, leflunomide, sulfasalazine).

**B. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauci-immune glomerulonephritis**
Authorization of 12 months may be granted for treatment of GPA, MPA, Churg-Strauss, or pauci-immune glomerulonephritis.

**C. Sjögren's syndrome**
Authorization of 12 months may be granted for treatment of Sjögren's syndrome when corticosteroids and other immunosuppressive agents were ineffective.

**D. Multiple sclerosis**
Authorization of 12 months may be granted for treatment of relapsing remitting multiple sclerosis (MS).

**E. Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic Disease)**
Authorization of 12 months may be granted for treatment of neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease).

**F. Autoimmune blistering disease**
Authorization of 12 months may be granted for treatment of autoimmune blistering disease (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus).

**G. Cryoglobulinemia**
Authorization of 12 months may be granted for treatment of cryoglobulinemia when corticosteroids and other immunosuppressive agents were ineffective.

**H. Solid organ transplant**
Authorization of 3 months may be granted for treatment of solid organ transplant and prevention of antibody mediated rejection in solid organ transplant.

**I. Opsoclonus-myoclonus-ataxia**
Authorization of 12 months may be granted for treatment of opsoclonus-myoclonus-ataxia associated with neuroblastoma when the member is refractory to steroids and chemotherapy.

**J. Systemic Lupus Erythematosus**
Authorization of 12 months may be granted for the treatment of systemic lupus erythematosus that is refractory to immunosuppressive therapy.

**K. Myasthenia Gravis**
Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

## VI. CONTINUATION OF THERAPY

**A. Rheumatoid arthritis**
Authorization of 12 months may be granted for continued treatment in all adult members (including new members) requesting reauthorization who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with Rituxan, Ruxience, Truxima, or Riabni as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

**B. Multiple Sclerosis**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for relapsing remitting multiple sclerosis (MS) who are experiencing disease stability or improvement while receiving Rituxan, Ruxience, Truxima, or Riabni.

**C. Other indications**
Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and are receiving benefit from therapy.

## VII. APPENDIX

**Examples of contraindications to methotrexate and leflunomide**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

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| Reference number(s) |
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| 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. Pulmonary arterial hypertension (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 patients or pulmonary vascular resistance index (PVRI) ≥ 3 Wood units x $m^2$ in pediatric patients

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. 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 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 diseases
  1.4.2 Human Immunodeficiency Virus (HIV) infection
  1.4.3 Portal hypertension
  1.4.4 Congenital heart diseases
  1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/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 obstruction**

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 tumours of the testis
  - Other tumours
- 4.2.3 Non-malignant tumours
  - 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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| Reference number(s) |
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# 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

**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)

**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 [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. 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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# 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

**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)

**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. OTHE

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 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 |
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| 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

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)
   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: 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 or predominantly axial disease.
   ii. Member has severe disease.

### C. Crohn's disease (CD)

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

## 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. Axial disease
6. Skin and/or nail involvement

**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)

## 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.

## 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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| Reference number |
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| 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 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 [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.

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 (examples include 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.
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| Reference number(s) |
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| 2141-A, 2680-A |

# SPECIALTY GUIDELINE MANAGEMENT

## SOVALDI (sofosbuvir)

## 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
Sovaldi is indicated for the treatment of:
1. Adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen
   a. Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin
   b. Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.
2. Chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

B. Compendial Uses
Hepatitis C genotype 5 or 6 infection (refer to Mavyret SGM)

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 prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### III. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, in combination with peginterferon alfa (PEG-IFN) and ribavirin (RBV)[1]**
**1. Genotype 1 infection**
Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

**2. Genotype 4 infection**
Authorization of up to 12 weeks total may be granted for adult members who are treatment-naïve.

**B. Hepatitis C virus infection, in combination with ribavirin**
**1. Genotype 1 infection**
Authorization of up to 24 weeks total may be granted for adult members who have documented interferon (IFN) ineligibility (see Section VI).

**2. Genotype 2 infection**
Authorization of up to 12 weeks total may be granted for members 3 years of age and older who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.

3. **Genotype 3 infection**
   Authorization of up to 24 weeks total may be granted for members 3 years of age and older who are treatment-naïve or failed prior treatment with PEG-IFN and RBV.
4. **Members with hepatocellular carcinoma awaiting liver transplantation**
   Authorization of up to 48 weeks total or until liver transplantation, whichever occurs first, may be granted for adult members with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma who meet the MILAN criteria, defined as the following:
   i. Tumor size 5 cm or less in diameter with single hepatocellular carcinomas OR 3 tumor nodules or less, each 3 cm or less in diameter with multiple tumors AND
   ii. No extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor

**C. Hepatitis C virus infection, in combination with Mavyret (with ribavirin)**
Authorization of up to 24 weeks total (as applicable) may be granted for members 3 years of age or older who are prescribed Sovaldi in combination with Mavyret (with ribavirin) who meet the criteria for approval for the requested regimen. Refer to the Mavyret SGM for the specific criteria for approval and approval durations.

**D. HCV and HIV coinfection**
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A, B, or C above are met.

## IV. CONTINUATION OF THERAPY

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

## V. OTHER

A. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
B. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
   1. Treatment status (i.e., treatment-naïve or retreatment)
   2. For initial treatment: confirmation of member readiness
   3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
   4. Hepatitis B screening results
   5. Metavir/Fibrosis score

## VI. APPENDIX: INTERFERON INELIGIBLITY

IFN ineligible is defined as one or more of the below:

- Intolerance to IFN
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG-IFN or any of its components
- Major uncontrolled depressive illness
- A baseline neutrophil count < 1,500/mcL
- A baseline platelet count < 90,000/mcL
- A baseline hemoglobin < 10 g/dL
- History of pre-existing cardiac disease

## VII. REFERENCES

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
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| Reference number |
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| 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. Submission of one of the following is required for approval:
    1. Specific and detailed chart 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(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 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 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; December 2022.
2. Teriflunomide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2023.

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **TESTOSTERONE PRODUCTS - INJECTABLE** |
| **BRAND NAME (generic)** | **DEPO-TESTOSTERONE (testosterone cypionate injection)** |

***Status: CVS Caremark Criteria***
***Type: Initial Prior Authorization***

**POLICY**

**FDA-APPROVED INDICATIONS**
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 conditions such as 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.

**Limitations of Use**
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.

**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

**REFERENCES**


1. Depo-Testosterone [package insert]. New York, NY: Pharmacia and Upjohn Company; September 2018.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2023; Accessed January 3, 2023.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 3, 2023.

4. 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.

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **TESTOSTERONE PRODUCTS – ORAL** |
| **BRAND NAME (generic)** | **JATENZO (testosterone undecanoate oral)**<br>**KYZATREX (testosterone undecanoate oral)**<br>**TLANDO (testosterone undecanoate oral)** |
| ***Status: CVS Caremark Criteria*** | |
| ***Type: Initial Prior Authorization*** | |

**POLICY**

**FDA-APPROVED INDICATIONS**

**Jatenzo, Kyzatrex, Tlando**

Testosterone Undecanoate 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 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[5,7-9] (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

**REFERENCES**


1. Jatenzo [package insert]. Northbrook, IL: Clarus Therapeutics, Inc.; March 2019.
2. Kyzatrex [package insert]. Raleigh, NC: Marius Pharmaceuticals; September 2022.
3. Tlando [package insert]. Ewing, NJ: Pharma, Inc.; March 2022.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2023; Accessed January 3, 2023.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 3, 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. 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. 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. 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)**<br>**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), USP 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.

## 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 request is for intramuscular testosterone enanthate injection (generic Delatestryl)
  - 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.

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **DRUG CLASS** | **TESTOSTERONE PRODUCTS – TOPICAL/NASAL** |
| **BRAND NAME (generic)** | **ANDRODERM (testosterone transdermal patch)**<br><br>**ANDROGEL (testosterone topical gel)**<br><br>**FORTESTA (testosterone topical gel)**<br><br>**NATESTO (testosterone nasal gel)**<br><br>**TESTIM (testosterone topical gel)**<br><br>**(testosterone topical solution)**<br><br>**VOGELXO (testosterone topical gel)** |

***Status: CVS Caremark Criteria***
***Type: Initial Prior Authorization***

**POLICY**

**FDA-APPROVED INDICATIONS**

**Androderm, Androgel, Fortesta, Natesto, Testim, 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 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[11,12-14] (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

## REFERENCES


1. Androderm [package insert]. Madison, NJ: Allergan USA, Inc.; May 2020.
2. Androgel 1% [package insert]. North Chicago, IL: Abbvie Inc; May 2019.
3. Androgel 1.62% [package insert]. North Chicago, IL: Abbvie Inc; November 2020.
4. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; January 2022.
5. Natesto [package insert]. Mississauga, ON: Acerus Pharmaceutical Corporation; December 2021.
6. Testim [package insert]. Malvern, PA: Endo Pharmaceuticals.; August 2021.
7. Testosterone Topical Solution [package insert]. Warren, NJ: Cipla USA, Inc.; December 2022.
8. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; April 2020.
9. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2023; Accessed January 3, 2023.
10. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed January 3, 2023.

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. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.
13. 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
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.

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 resulting in hospitalization or emergency medical care visit.
      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 beta2-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.; February 2023.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 update. Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed March 1, 2023.
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) |
| --- |
| 2143-A, 2682-A |

# SPECIALTY GUIDELINE MANAGEMENT

## VIEKIRA PAK
## (ombitasvir/paritaprevir/ritonavir/dasabuvir)

**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
Viekira Pak is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV):
A. genotype 1b without cirrhosis or with compensated cirrhosis
B. genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin (RBV)

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

### II. EXCLUSIONS

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### IV. CRITERIA FOR INITIAL APPROVAL

**A. Chronic hepatitis C virus infection, in combination with ribavirin**
Note: Members with mixed genotype 1 infection or unknown genotype 1 subtype should follow the criteria for approval for genotype 1a infection.

**1. Genotype 1a infection**
i. Authorization of up to 12 weeks total may be granted for members without cirrhosis who are either of the following:
   a. Treatment-naïve
   b. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV
ii. Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who are either of the following:
   a. Treatment-naïve
   b. Failed prior treatment with PEG-IFN and RBV

2. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 24 weeks total may be granted for members with recurrent HCV infection post liver transplantation who meet all of the following criteria:
   i. Genotype 1 infection (irrespective of subtype)
   ii. Metavir fibrosis score of 2 or lower

**B. Chronic hepatitis C virus infection, without ribavirin**
**Genotype 1b infection**
Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are either of the following:
1. Treatment-naïve
2. Failed prior treatment with PEG-IFN and RBV

**C. HCV and HIV coinfection**
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in section A or B above are met.

## V. CONTINUATION OF THERAPY

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

## VI. OTHER

A. This medication will be approved for use in adult members only.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
   1. Treatment status (i.e., treatment-naïve or retreatment)
   2. For initial treatment: confirmation of member readiness
   3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
   4. Hepatitis B screening results
   5. Metavir/Fibrosis score

## VII. REFERENCES

1. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.

| Reference number(s) |
| --- |
| 2176-A, 2683-A |

# SPECIALTY GUIDELINE MANAGEMENT

## VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)

**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
Vosevi is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have:

A. Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor
B. Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor
   Additional benefit of Vosevi over sofosbuvir/velpatasvir was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

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

### II. EXCLUSIONS

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### IV. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, without ribavirin**
**1. Genotype 1a, 1b, and 2 infection**
i. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with a sofosbuvir-containing regimen.
ii. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with an HCV NS5A inhibitor-containing regimen (except glecaprevir/pibrentasvir [Mavyret]).
iii. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

2. **Genotype 3 infection**
   i. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen), including glecaprevir/pibrentasvir [Mavyret]).
   ii. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who are treatment-naïve and have the Y93H substitution associated with velpatasvir resistance.

3. **Genotype 4, 5, or 6 infection**
   i. Authorization of up to 12 weeks total may be granted for members who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen except glecaprevir/pibrentasvir [Mavyret]).
   ii. Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).

4. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

5. **Kidney transplant recipients**
   Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

**B. Hepatitis C virus infection, in combination with ribavirin**

1. **Genotype 3 infection**
   Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen), including glecaprevir/pibrentasvir [Mavyret]).

2. **Direct-acting antiviral treatment failure**
   **Genotype 1, 2, 3, 4, 5, or 6 infection**
   i. Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed initial treatment with glecaprevir/pibrentasvir (Mavyret).
   ii. Authorization of up to 24 weeks total may be granted for members with or without compensated cirrhosis who failed initial treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi).

3. **Recurrent HCV infection post liver transplantation**
   Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 2, 3, 4, 5 or 6 infection who failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

4. **Kidney transplant recipients**
   Authorization of up to 12 weeks total may be granted for members who have genotype 1, 2, 3, 4, 5 or 6 infection and failed prior treatment with any direct-acting antiviral regimen (e.g., NS5A- or sofosbuvir-containing regimen).

**C. HCV and HIV Coinfection**

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A or B above are met.

## V. CONTINUATION OF THERAPY

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

## VI. OTHER

A. This medication will be approved for use in adult members only.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    1. Treatment status (i.e., treatment-naïve or retreatment)
    2. For initial treatment: confirmation of member readiness
    3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
    4. Hepatitis B screening results
    5. Metavir/Fibrosis score

## VII. REFERENCES

1. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 5, 2021. Accessed August 9, 2022.

| 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 (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).

**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 2022.

| 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 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.

   3. 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.

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. Member's chart notes or medical record showing pre-treatment IgE level
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried
   2. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. CSU:

1. Initial Requests: Member's chart notes or medical record documentation, or claims history supporting previous medications tried showing an inadequate treatment response to a second-generation H1 antihistamine
2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

C. CRSwNP:
1. Initial Requests:
   i. Member's chart notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., 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. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

D. Immune checkpoint inhibitor-related toxicity (initial requests): Member's chart or medical record showing pre-treatment IgE level

E. 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. Chronic spontaneous urticaria: allergist/immunologist or dermatologist
C. CRSwNP: allergist/immunologist or otolaryngologist

## 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.

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 resulting in hospitalization or emergency medical care visit.
      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 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 $H_1$ 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.

**C. 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., Nucala, Dupixent) indicated for chronic rhinosinusitis with nasal polyps (CRSwNP).

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.

**D. Immune checkpoint inhibitor-related toxicity**

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when both of the following are met:

1. The member has a refractory case of immune-therapy related severe (G3) pruritus
2. The member has elevated IgE levels

**E. Systemic mastocytosis**

Authorization of 12 months may be granted for the treatment of systemic mastocytosis when both of the following 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 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 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 response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

### C. 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 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, sinonasal 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.

### D. 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

2017 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. In biopsy sections of bone marrow or other extracutaneous organs, greater than 25% of mast cells in the infiltrate are spindle-shaped or have atypical morphology, or greater than 25% of all mast cells in bone marrow aspirate smears are immature or atypical
2. Detection of an activating point mutation at codon 816 of *KIT* in the bone marrow, blood, or another extracutaneous organ
3. Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers
4. Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

## VIII. REFERENCES

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2. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Asthma Management Guidelines: Focused Updates 2020. Bethesda, MD: National Heart Lung and Blood Institute; December 2020. Available at https://www.nhlbi.nih.gov/sites/default/files/publications/AsthmaManagementGuidelinesReport-2-4-21.pdf. Accessed March 1, 2023.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 update. Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed March 1, 2023.
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| Reference number(s) |
| --- |
| 2596-A |

# SPECIALTY GUIDELINE MANAGEMENT

## YONSA (fine-particle abiraterone 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.

A. FDA-Approved Indication
Yonsa is indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).

B. Compendial Use
Prostate Cancer

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

### II. EXCLUSIONS

Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

### III. CRITERIA FOR INITIAL APPROVAL

**Metastatic castration-resistant prostate cancer**
Authorization of 12 months may be granted for treatment of metastatic castration-resistant prostate cancer when the member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH agonist or degarelix.

### 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.

### V. REFERENCES


1. Yonsa [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.
2. The NCCN Drugs & Biologics Compendium™ © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 6, 2023.

| Reference number(s) |
| --- |
| 2145-A, 2684-A |

# SPECIALTY GUIDELINE MANAGEMENT

## ZEPATIER (elbasvir and grazoprevir)

### 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
Zepatier is indicated for the treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.

Zepatier is indicated for use with ribavirin in certain patient populations.

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

### II. EXCLUSIONS

Coverage will not be provided for members with decompensated cirrhosis/moderate or severe hepatic impairment (Child Turcotte Pugh Class B or C).

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology, or transplant.

### IV. CRITERIA FOR INITIAL APPROVAL

**A. Hepatitis C virus infection, in combination with ribavirin (RBV)**

**1. Genotype 1a infection**

i. Authorization of up to 16 weeks total may be granted for members with baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Section VII) who are either of the following:
   a. Treatment-naïve
   b. Failed prior treatment with peginterferon alfa (PEG-IFN) and RBV with or without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

ii. Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Section VII) who have failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

**2. Genotype 1b infection**

Authorization of up to 12 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV with an HCV protease inhibitor (boceprevir, simeprevir or telaprevir).

**3. Genotype 4 infection**
Authorization of up to 16 weeks total may be granted for members who failed prior treatment with PEG-IFN and RBV.

**B. Hepatitis C virus infection, without RBV**

**1. Genotype 1a infection**
Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms who are either of the following:
i. Treatment-naïve
ii. Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

**2. Genotype 1b infection**
Authorization of up to 12 weeks total may be granted for members who are either of the following:
i. Treatment-naïve
ii. Failed prior treatment with PEG-IFN and RBV without an HCV protease inhibitor (boceprevir, simeprevir or telaprevir)

**3. Genotype 4 infection**
Authorization of up to 12 weeks total may be granted for members who are treatment-naïve.

**4. Kidney transplant recipients**
Authorization of up to 12 weeks total may be granted for members without baseline NS5A resistance-associated substitutions (RASs)/polymorphisms (see Section VII) who have HCV genotype 1 or 4 infection and are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

**C. HCV and HIV coinfection**
Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of the requested regimen in Section A or B above are met.

## V. CONTINUATION OF THERAPY

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

## VI. OTHER

A. Member must be 12 years of age or older or weigh at least 30 kg.
B. Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
C. The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
1. Treatment status (i.e., treatment-naïve or retreatment)
2. For initial treatment: confirmation of member readiness
3. For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
4. Hepatitis B screening results
5. Metavir/Fibrosis score

## VII. APPENDIX: NS5A RESISTANCE-ASSOCIATED SUBSTITUTIONS (POLYMORPHISMS)

NS5A resistance-associated substitutions (polymorphisms) at amino acid positions M28, Q30, L31 or Y93. Examples include M28A/T, Q30H/R, L31M/V, and Y93C/H/N.

## VIII. REFERENCES

1. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.
2. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made October 5, 2021. Accessed August 9, 2022.

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# 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 (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

1. Zeposia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; April 2023.
2. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25.
3. Rubin DT, Ananthakrishnan AN, et al. 2019 ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114:384-413.

4. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. *Gastroenterology*. 2020; 158:1450-1461.

| Reference number(s) |
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| 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

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 A)

**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:
   a. Member has a history of a fragility fracture
   b. Member has a pre-treatment T-score of less than or equal to -2.5
   c. 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 A)

**D. Paget's disease of bone**
Authorization of 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 one 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:
   a. Member has experienced clinical benefit (i.e., improvement or stabilization in T-score since the previous bone mass measurement)
   b. Member has not experienced any adverse effects

## V. APPENDIX

Appendix A. WHO Fracture Risk Assessment Tool
- High FRAX fracture probability: 10-year major osteoporotic 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
1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.
2. Zoledronic acid injection [package insert]. Schaumburg, IL: Sagent Pharmaceuticals, Inc.; August 2021.
3. Bisphosphonates. *Drug Facts and Comparisons.* Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health Inc; March 21, 2019. Accessed October 10, 2022.
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5. Jeremiah MP, Unwin BK, Greenwald MH, et al. Diagnosis and management of osteoporosis. *Am Fam Physician*. 2015;92(4):261-268.
6. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis 2020. *Endocr Pract*. 2020;26 (Suppl 1):1-46.
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8. National Institute for Health and Care Excellence. Osteoporosis Overview. Last updated October 13, 2021. Available at: http://pathways.nice.org.uk/pathways/osteoporosis. Accessed October 13, 2021.
9. Treatment to prevent osteoporotic fractures: an update. Department of Health and Human Services, Agency for Healthcare Research and Quality. 2012; Publication No. 12-EHC023-EF. Available at www.effectivehealthcare.ahrq.gov/lbd.cfm.
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14. Ensrud KE, Crandall CJ. Osteoporosis. *Ann Intern Med*. 2017;167(03):ITC17–ITC32.