

# SPECIALTY GUIDELINE MANAGEMENT

## OTEZLA (apremilast)

### 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<sup>1</sup>

1. Moderate to severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy
2. Adults with active psoriatic arthritis
3. Adults with oral ulcers associated with Behcet's disease

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

#### II. DOCUMENTATION

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

- A. Plaque psoriasis
  1. Initial requests:
    - i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
    - 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: For continuation requests: Chart notes or medical record documentation supporting positive clinical response.
- C. 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. CRITERIA FOR INITIAL APPROVAL

##### **A. Moderate to severe plaque psoriasis (PsO)<sup>1-3,5</sup>**

1. Authorization of 12 months may be granted for members who have previously received a biologic 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 when all of the following criteria are met:
  - i. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - ii. 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. Active psoriatic arthritis (PsA)<sup>1,4,6,7</sup>**

Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

**C. Behcet's disease<sup>1,8</sup>**

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Behcet's disease.
2. Authorization of 12 months may be granted for the treatment of oral ulcers associated with Behcet's disease when the member has had an inadequate response to at least one nonbiologic medication for Behcet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine).

#### IV. CONTINUATION OF THERAPY

**A. Moderate to severe plaque psoriasis (PsO)<sup>1-3,5</sup>**

Authorization of 12 months may be granted for all members (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)

**B. Active psoriatic arthritis (PsA)<sup>1,4,6,7</sup>**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain 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

**C. Behcet's disease<sup>1,8</sup>**

Authorization of 12 months may be granted for all members (including new members) who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

#### V. OTHER

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

## VI. DOSAGE AND ADMINISTRATION

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

## VII. 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. 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 (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

## VIII. REFERENCES

1. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009;61:451-485.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137-174.
4. Coates LC, Kavanaugh A, Mease PJ, et al. Group for research and assessment of psoriasis and psoriatic arthritis 2015 treatment recommendation for psoriatic arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
5. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Dermatology Programs. April 2015.
6. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheum*. 2018;71:5-32
8. Hatemi G, Christensen R, Bodaghi, et al. 2018 update of the EULAR recommendations for the management of Behcet's syndrome. *Ann Rheum Dis*. 2018.; 77: 808-818.