Effective Date: 2/2020
Reviewed: 12/2019, 8/2020,12/2020, 5/2021, 1/2022, 12/2022, 8/2023, 2/2024 Scope: Medicaid

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.

A. FDA-Approved Indications
   1. Plaque psoriasis
   2. Active psoriatic arthritis
   3. Oral ulcers associated with Behçet's disease

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INTIAL AND RENEWAL CRITERIA

For all indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Otezla will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Stelara (ustekinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)

III. DOCUMENTATION

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

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis

Authorization of 12 months may be granted for treatment of plaque psoriasis for members who are 18 years of age or older when all of the following criteria are met:

1. Otezla is prescribed by, or in consultation with, a specialist in dermatology.
2. At least 10% of BSA is affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Member with mild plaque psoriasis has had at least a 3 month trial to two conventional therapies, from 2 different drug classes, such as
   a. Topical corticosteroids (e.g., hydrocortisone, triamcinolone, betamethasone, fluocinonide, etc.)
   b. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
   c. Vitamin D analogs (e.g., calcipotriene)
   d. UVB Phototherapy; OR
4. Member with moderate to severe plaque psoriasis meets the following criteria:
   a. Member meets one of the following:
      i. Member has had an inadequate response to at least a 3 month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin; OR
      ii. Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced; AND
   b. Member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream within the last 12 months or if the member is switching from a biologic for psoriasis treatment, they are not required to trial Zoryve before Otelza; OR
   c. The member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses. Contraindications, adverse effects and/or intolerance must be documented.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA) for members who are 18 years of age or older when all of the following criteria are met:

1. Otezla is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. Documented moderate to severe active disease and member meets either of the following criteria:
   a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated

b. If member has peripheral arthritis, member has experienced an inadequate response to at least a 3 month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine

3. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

C. Behcet's syndrome

Authorization of 12 months may be granted for the treatment of oral ulcers associated with Behçet's syndrome when the member has had an inadequate response to at least one nonbiologic medication for Behçet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine).

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who achieve or maintain positive clinical response after at least 4 months of therapy with Otezla as evidenced by low disease activity or improvement in signs and symptoms of the condition.

VI. QUANTITY LIMIT

1. Otezla 30mg tablet – 2 tablets per day
2. Otezla Starter Therapy Pack – 55 tablets per 28 days

Indication	Dose
Plaque psoriasis, Psoriatic arthritis & Oral ulcers associated with Behçet's disease	Titrate dose over 5 days as follows: Day 1: 10mg every morning Day 2: 10mg twice a day Day 3: 10mg every morning & 20mg every evening Day 4: 20mg twice daily Day 5: 20mg every morning & 30mg every evening Day 6 & after: 30 mg twice daily

VII. REFERENCES

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; February 2021.
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.