Effective Date: 2/2020
Reviewed: 12/2019, 8/2020,12/2020, 5/2021, 1/2022, 12/2022, 8/2023, 2/2024, 1/2025, 5/2025, 3/2026
Scope: Medicaid

OTEZLA and OTEZLA XR (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. Adult patients with plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
2. Pediatric patients* 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
3. Adults and pediatric patients* 6 years of age and older with active psoriatic arthritis
4. Adult patients with oral ulcers associated with Behcet's disease

**In the pediatric population, Otezla is indicated for patients weighing at least 20 kg, and Otezla XR is indicated for patients weighing at least 50 kg*

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 or Otezla XR will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira/Hadlima (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma and Yesintek, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)
- Otezla or Otezla XR is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.

III. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis

Authorization of 12 months may be granted for treatment of plaque psoriasis for members who are 6 years of age or older when all of the following criteria are met:
1. Documentation of affected area(s) and the percentage of affected body surface area. Pediatric members must also have at least 10% of BSA affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. If member is less than 18 years of age, documentation that member weighs at least 20 kg if the request is for Otezla OR documentation the member weighs at least 50 kg if the request is for Otezla XR.

3. If member is adult with documentation of mild plaque psoriasis, member meets the following criteria:
    a. Documentation that the member experienced an inadequate treatment response or intolerance from two of the following therapies (as monotherapy or in combination with a topical corticosteroid) within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
        i. Topical calcineurin inhibitors (e.g., tacrolimus ointment, pimecrolimus cream)
        ii. Topical vitamin D analogs (e.g., calcipotriene 0.005% ointment, cream, solution)
        iii. Topical retinoid (e.g., tazarotene cream 0.1%)
        iv. Phototherapy
    b. Documentation that the member experienced an inadequate treatment response or intolerance from Zoryve (roflumilast) cream 0.3% within the last 12 months. Contraindications, adverse effects and/or intolerance must be documented.
        i. If the member is switching from a biologic for psoriasis treatment or has concomitant psoriatic arthritis, they are not required to trial Zoryve before Otezla/Otezla XR.
4. If member has documentation of moderate to severe plaque psoriasis (i.e., at least 10% of BSA affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected), member meets the following criteria:
    a. Documentation that the member meets either of the following:
        ii. 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
        iii. Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
    c. Documentation that the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses. Contraindications, adverse effects and/or intolerance must be documented.
        i. If member is 18 years of age or older, documentation that the member has also had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA) for members who are 6 years of age or older when ALL of the following criteria are met:

1. For members under 18 years of age both of the following:
    a. Documentation that member weighs at least 20 kg if the request is for Otezla OR documentation the member weighs at least 50 kg if the request is for Otezla XR.
    b. Documentation that member has had at least a 6-month trial of ustekinumab biosimilar
2. If member is 18 years of age or older, documentation that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab and to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.
3. Documentation member has enthesitis.

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 documentation of having an inadequate response to at least one nonbiologic medication for Behçet's disease (e.g., colchicine, systemic glucocorticoids, azathioprine).

IV. CONTINUATION OF THERAPY

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

V. QUANTITY LIMIT

1. Otezla 20mg and 30mg tablet – 2 tablets per day
2. Otezla Starter Therapy Pack – 55 tablets per 28 days
3. Otezla XR Starter Therapy Pack – 41 tablets per 28 days
4. Otezla XR 75 mg tablet- 1 tablet per day

VI. REFERENCES

1. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
3. 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):1445-1486.
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. Coates LC, Soriano ER, Corp N, et al. Group for research and assessment of psoriasis and psoriatic arthritis (GRAPPA): updated treatment recommendation for psoriatic arthritis. *Nature Rev Rheumatol.* 2022;18:465-479. May;68(5):1060-71.