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, 8/2026 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
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND Otezla or Otezla XR will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (Hadlima), 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., tofacitinib(Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)

III. CRITERIA FOR INITIAL APPROVAL

A. Plaque psoriasis

Authorization of 12 months may be granted for treatment of plaque psoriasis for members when all of the following criteria are met:
1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND
3. If member is less than 18 years of age, documentation has been submitted 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

4. If member is adult with documentation of mild plaque psoriasis, member meets the following criteria:
    a. Documentation that the member had an inadequate treatment response, intolerance, or contraindication to two of the following therapies (as monotherapy or in combination with a topical corticosteroid) within the last 12 months.
        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.
5. If member (either adult or pediatric) has documentation of moderate to severe plaque psoriasis (i.e., BSA affected is at least 10% OR crucial body areas affected (e.g., face, hands, feet, genitals, scalp) OR inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene)) , member must meet the following criteria:
    a. Documentation has been submitted of any of the following:
        i. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine, or acitretin); OR Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA; OR
        ii. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
    b. Documentation has been submitted that the member meets all of the following:
        i. Member meets either of the following criteria:
            1. If member is 18 years of age or older, member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; OR
            2. If member is under 18 years of age, member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA) when ALL of the following criteria are met:

1. Member is 6 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology or dermatology; AND
3. Member has documented active disease; AND
4. Documentation has been submitted indicating one of the following criteria:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.); OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease; AND
5. If member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; OR
6. If member is under 18 years of age, member must meet both of the following criteria:

a. Documentation has been submitted 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; AND
b. Documentation has been submitted that member has had an inadequate response, intolerance, or contraindication at least a 6-month trial of ustekinumab biosimilar 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 following criteria is met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND
3. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication 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. DOSING

Indication	Dose
Adult Psoriatic Arthritis, Plaque Psoriasis, or Behcet's Disease	30 mg Otezla twice daily or Otezla XR 75 mg once daily (after initial titration)
Pediatric Psoriatic Arthritis or Moderate to Severe Plaque Psoriasis (≥6 years, ≥50 kg)	30 mg Otezla twice daily or Otezla XR 75 mg once daily (after initial titration)
Pediatric Psoriatic Arthritis or Moderate to Severe Plaque Psoriasis (≥6 years, 20 kg to <50 kg)	20 mg Otezla twice daily (after initial titration)

VII. REFERENCES

1. Otezla/Otezla XR[package insert]. Thousand Oaks, CA: Amgen Inc.; August 2025.
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.