Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Otezla® (apremilast) and Otezla XR™ (apremilast) extended-release

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Otezla (apremilast) is a phosphodiesterase 4 inhibitor indicated for:

Disease State	
Behcet's Disease	X
Plaque Psoriasis	X
Psoriatic Arthritis	X

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Otezla for Members when **ALL** of the following criteria are met:

Behcet's Disease

Initial Authorization Criteria

1. Documented diagnosis of oral ulcers associated with Behcet's Disease

AND

2. Documentation of presence of active oral ulcers

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of oral ulcers associated with Behcet's Disease

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Plaque Psoriasis – Adults

Initial Authorization Criteria

1. Documented diagnosis of plaque psoriasis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a dermatologist

AND

4. Documentation of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to **one (1)** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: corticosteroid, vitamin D analog, tazarotene, calcineurin inhibitor *(Note: document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of plaque psoriasis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in body surface area affected by plaque psoriasis from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of plaque psoriasis such as itching, redness, flaking, scaling, burning, cracking, or pain

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Plaque Psoriasis – Pediatrics

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1)** of the following:
    a. Greater than or equal to 3% body surface area involvement
    b. Severe scalp psoriasis
    c. Palmoplantar, facial, or genital involvement

AND

3. Documentation of **both** of the following:
    a. Patient is 6 to 17 years of age or older
    b. Patient's weight is at least 20 kg if using Otezla or at least 50 kg if using Otezla XR

AND

4. Prescribed by a dermatologist

AND

5. Documentation of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to **one (1)** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: corticosteroid, vitamin D analog, tazarotene, calcineurin inhibitor *(Note: document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderate to severe plaque psoriasis

AND

3. Documentation of **both** of the following
    a. Patient is 6 to 17 years of age
    b. Patient's weight is at least 20 kg if using Otezla or at least 50 kg if using Otezla XR

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in body surface area affected by plaque psoriasis from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of plaque psoriasis such as itching, redness, flaking, scaling, burning, cracking, or pain

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Documentation of **one (1)** of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 6 to 17 years of age
        ii. Patient's weight is at least 20 kg if using Otezla or at least 50 kg if using Otezla XR

AND

4. Prescribed by a dermatologist or rheumatologist

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

3. Patient of **one (1)** of the following:
    a. Patient is at least 18 years of age or older
    b. Both of the following:
        i. Patient is 6 to 17 years of age
        ii. Patient's weight is at least 20 kg if using Otezla or at least 50 kg if using Otezla XR

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Documentation of a patient being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
3. For Behcet's Disease authorizations will be provided in 12-month intervals. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
4. For plaque psoriasis and psoriatic arthritis, initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals. A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria
5. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

Codes

None

References

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2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
3. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. Ann Rheum Dis 2018; 77:808.
4. 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.
5. 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;80:1029-72.
6. Otezla (apremilast) [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2025.
7. Singh JA, Guyatt G, Ogdie A, et al. "Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis," Arthritis Rheumatol. 2019 Jan;71(1):5-32. DOI: 10.1002/art.40726. Epub 2018 Nov 30.
8. Smith E, Yazici Y. Treatment of Behçet's syndrome. In: Curtis M, ed. UpToDate. Waltham, Mass.: UpToDate, August 2019.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes
- September 10, 2024: Updated age requirements for plaque psoriasis based on the expanded indication (eff 10/1/24).
- September 9, 2025: No changes.
- October 14, 2025: Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. For plaque psoriasis and psoriatic arthritis, initial approvals limited to 6 months with annual reauthorization coverage criteria added, added disease severity requirements for psoriatic arthritis and pediatric plaque psoriasis, added minimum duration requirements for topical prerequisites for plaque psoriasis. For Behcet's disease, approvals limited to 12 months with reauthorization coverage criteria added (eff 1/1/26).

- December 9, 2025: Added Otezla XR to the Medical Necessity Guideline, updated the name of the Medical Necessity Guideline to Otezla and Otezla XR, and updated weight requirements for pediatric use of psoriatic arthritis and plaque psoriasis to be in line with package labeling (eff 1/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.