Clinical Policy: Apremilast (Otezla)

Reference Number: PA.CP.PHAR.245
Effective Date: 08/16
Last Review Date 08/17
Line of Business: Medicaid

Revision Log

Description
Apremilast (Otezla®) is an inhibitor of phosphodiesterase 4.

FDA Approved Indication(s)
Otezla is indicated for the treatment of:

- Adult patients with active psoriatic arthritis (PsA)
- Patients with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Otezla is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of PsO and at least one of the following:
   a. Greater than 5% of body surface area is affected;
   b. Palms, soles, face and neck, body folds, or genitalia is involved;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least one oral systemic therapy for plaque psoriasis (e.g., methotrexate, cyclosporine, acitretin, or thioguanine) in combination with phototherapy or topical therapy (e.g., corticosteroids, calcipotriene, tazarotene) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. Otezla will not be used concurrently with a biologic agent;
7. Dose does not exceed 60 mg per day.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of active PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;

4. Member meets one of the following (a or b):
    a. For Axial Disease
        i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs or
        ii. A documented contraindication or intolerance to NSAIDs
    b. For Peripheral Disease:
        i. A documented history of therapeutic failure of a six (6) week trial of two (2) NSAIDs AND
        ii. A documented history of therapeutic failure of a three (3) or more month trial of methotrexate OR an alternate DEMARD OR
        iii. A documented contraindication or intolerance to NSAIDs, methotrexate, or an alternate DMARD.
5. Failure of etanercept *(Enbrel is preferred)* and adalimumab *(Humira is preferred)*, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for etanercept and adalimumab*
6. Dose does not exceed 60 mg per day.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed 60 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
PDE4: phosphodiesterase 4
PsO: plaque psoriasis
PsA: psoriatic arthritis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsA, PsO	Titrate to reduce risk of gastrointestinal symptoms: Day 1: 10 mg in morning Day 2: 10 mg in morning and 10 mg in evening Day 3: 10 mg in morning and 20 mg in evening Day 4: 20 mg in morning and 20 mg in evening Day 5: 20 mg in morning and 30 mg in evening Day 6 and thereafter: 30 mg twice daily Severe Renal Impairment: 30 mg once daily Titrate using only morning schedule and skip afternoon dose.	30 mg twice daily

VI. Product Availability

Tablets: 10 mg, 20 mg, 30 mg

VII. References

1. Otezla Prescribing Information. Summit, NJ: Celgene Corporation; June 2017. Available at http://www.otezla.com/. Accessed August 03, 2017.
2. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58(5):826-50.
3. 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 Annals of the Rheumatic Diseases Published Online First: 07 December 2015. doi: 10.1136/annrheumdis-2015-208337

Reviews, Revisions, and Approvals	Date	Approval Date