

Clinical Policy: Apremilast (Otezla)

Reference Number: CP.PHAR.245

Effective Date: 08/16

Last Review Date 08/17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation[®] 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 \geq 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 \geq 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 \geq 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 \geq 18 years;
4. Member meets one of the following (a or b):
 - a. Failure of MTX for \geq 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
 - b. If intolerance or contraindication to MTX, failure of sulfasalazine, leflunomide, or cyclosporine trialed for \geq 3 consecutive months unless contraindicated or clinically significant adverse effect are experienced;
5. Failure of etanercept (*Enbrel is preferred*) and adalimumab (*Humira is preferred*), each used for \geq 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 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 Centene benefit or member has previously met initial approval criteria;
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 Centene benefit and documentation supports positive response to therapy.

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

2. Refer to 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 CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PsO: plaque psoriasis

PsA: psoriatic arthritis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsA, PsO	<p>Titrate to reduce risk of gastrointestinal symptoms:</p> <p>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</p> <p>Severe Renal Impairment: 30 mg once daily Titrate using only morning schedule and skip afternoon dose.</p>	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
<p>Policy split from CP.PHAR.85.Psoriasis Treatment. Added prescriber specialty, max dose and contraindications per PI. Added requirement for trial and failure of PDL Enbrel and Humira, unless contraindicated; Removed question related to concurrent use with another biologic-not in contraindications section per PI. Modified prior treatment trial for PSA to require trial of MTX and added requirement for the following agents as an alternative if MTX cannot be used: leflunomide, cyclosporine, sulfasalazine, azathioprine. Plaque Psoriasis: removed duration of trial for topical and phototherapy; added requirement for trial and failure of one oral systemic agent (e.g., MTX, cyclosporine or acitretin), unless contraindicated to such therapies; re-auth: modified specific efficacy criteria related to Psoriasis Area and Severity Index (PASI)-75 to general efficacy statement. Re-auth: combined into “All Indications”, added max dose and reasons to discontinue per PI.</p>	06/16	08/16

Converted to new template. Trial requirement modified to require the concomitant use of oral and topical or phototherapy.	08/17	08/17
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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