

SPECIALTY GUIDELINE MANAGEMENT

OTEZLA (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. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Moderate to severe plaque psoriasis**

1. Authorization of 24 months may be granted for members who have received Otezla or any biologic disease-modifying antirheumatic drug (DMARD) indicated for the treatment of moderate to severe plaque psoriasis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Otezla.
2. Authorization of 24 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:
 1. At least 5% of BSA is affected OR crucial body areas (i.e., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
 2. Member meets any of the following criteria:
 - a. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
 - b. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix A).

B. **Active psoriatic arthritis (PsA)**

1. Authorization of 24 months may be granted for members who have received Otezla in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Otezla.
2. Authorization of 24 months may be granted for treatment of active psoriatic arthritis when any of the following criteria is met:
 1. Member has had an inadequate response to at least a 3-month trial of at least one prior biologic DMARD indicated for PsA (see Appendix B).
 2. Member has experienced an intolerance or adverse event to a trial of at least one prior biologic DMARD indicated for PsA.
 3. All biologic DMARDs indicated for PsA are not appropriate for the member (e.g., due to comorbidities or a history of infections contraindicating any biologic DMARD).

III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Otezla as evidenced by low disease activity or improvement in signs and symptoms of the condition.

IV. APPENDICES

Appendix A: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Appendix B: Biologic DMARDs Indicated for Psoriatic Arthritis

1. Cimzia® (certolizumab pegol)
2. Cosentyx® (secukinumab)
3. Enbrel® (etanercept)
4. Humira® (adalimumab)
5. Remicade® (infliximab)
6. Simponi® (golimumab)
7. Stelara® (ustekinumab)

V. REFERENCES

1. Otezla [package insert]. Summit, NJ: Celgene Corporation; December 2015.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol*. 2009;61:451-485.
3. 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.
4. 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. *Ann Rheum Dis*. 2016;75(3):499-510.