I. Medication Description

Otezla, a phosphodiesterase 4 (PDE4) inhibitor, is indicated for treatment of adult patients with psoriatic arthritis (PsA) and plaque psoriasis. Otezla is an oral small-molecule inhibitor of PDE4 specific for cyclic adenosine monophosphate (cAMP). Inhibition of PDE4 results in increased intracellular cAMP levels. The specific mechanism by which Otezla exerts its effect in PsA and psoriasis is not well defined.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Otezla is provided for adult members for the following conditions when the listed criteria are met:

- Oral ulcers associated with Behçet’s Disease:
  - Prescribed by a rheumatologist or dermatologist **AND**
  - Member has a diagnosis of Behçet’s Disease **AND**
  - Member has at least 2 oral ulcers **AND**
  - Member has a history of recurring oral ulcers (defined as at least three occurrences within a 12 month period) **AND**
  - Member has failed to adequately respond to treatment with at least one non-biologic medication for the treatment of oral ulcers associated with Behçet’s Disease (for example, topical/systemic corticosteroids, topical sucralfate, oral colchicine, etc.) **AND**
  - Medication will not be used in combination with other systemic therapies for Behçet’s Disease.

- Plaque psoriasis (moderate to severe disease):
  - Prescribed by a rheumatologist or dermatologist **AND**
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

- Psoriatic arthritis (active disease):
  - Prescribed by a rheumatologist or dermatologist **AND**
If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated).

IV. Quantity Limitations

- 1 titration pack is covered in the first month to accommodate induction dosing
- Up to 60 tablets per 30 days are covered to accommodate maintenance dosing

V. Coverage Duration

- For the treatment of oral ulcers associated with Behçet’s Disease, initial coverage is available for 3 months and may be renewed in 12-month increments
- For all other indications, coverage is available for 12 months and may be renewed in 12-month increments

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Clinical response or remission of disease is maintained with continued use AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as:
- 30mg tablets
- Two-week starter pack including
  - 4 x 10mg tablets
  - 4 x 20mg tablets
  - 5 x 30mg tablets (with an additional 14 x 30mg tablets)
- Twenty eight-day starter pack including
  - 4 x 10mg tablets
  - 4 x 20mg tablets
  - 47 x 30mg tablets

VIII. Summary of Policy Changes

- 9/15/14: new policy
- 10/6/14: included new indication for psoriasis
- 3/15/15: addition of coverage criteria for new indication of psoriasis
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/17: step therapy rules updated on the pharmacy benefit
- 5/1/17: step therapy criteria added
- 1/1/18: no policy changes
- 2/15/19: added Xeljanz/XR as preferred products for PsA
- 8/15/19: updated coverage criteria for PsA
- 11/15/19: added coverage criteria for treatment of oral ulcers associated with Behçet’s disease
- 1/30/20: no policy changes
- 8/1/20: removed step with biologics for the treatment of PsA

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.