Commercial PA Criteria

Effective: June 2014

Prior Authorization: Otezla

Products Affected: Otezla (apremilast) oral tablets

Medication Description: Otezla (apremilast), a phosphodiesterase 4 inhibitor, is indicated in adults for the treatment of active psoriatic arthritis. Apremilast is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels.

Covered Uses:

1. **Behcet's disease**, in adults with oral ulcers.
2. **Plaque psoriasis**, adults who are candidates for phototherapy or systemic therapy.
3. **Plaque psoriasis**, in pediatric patients ≥ 6 years of age and ≥ 20 kg with moderate to severe disease who are candidates for phototherapy or systemic therapy.
4. **Psoriatic arthritis**, in adults with active disease.

Exclusion Criteria:

1. Concurrent use with a biologic DMARD or Targeted Synthetic DMARD
2. Ankylosing Spondylitis
3. Rheumatoid Arthritis

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

- Behcet's disease, plaque psoriasis, psoriatic arthritis: 18 years of age or older
- Plaque Psoriasis: ≥ 6 years of age and ≥ 20 kg

Prescriber Restrictions:

- Psoriatic Arthritis: Must be prescribed by, or in consultation with, a rheumatologist or dermatologist.
- Plaque Psoriasis: Must be prescribed by, or in consultation with, a Dermatologist.
- Behçet's Disease: Must be prescribed by, or in consultation with, a rheumatologist, dermatologist, or physician who specializes in the treatment of Behcet's Disease.

Coverage Duration:

Initial: 4 months
Continuation: 1 year

Other Criteria:

1. **Behcet's Disease.** Approve for the duration noted if the patient meets ONE of the following criteria (A **OR** B):
   A. Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, **AND** iv):
      i. Patient is ≥ 18 years of age; **AND**

ii. Patient has oral ulcers or other mucocutaneous involvement; **AND**
iii. Patient has tried at least ONE other systemic therapy; **AND**
Note: Examples of systemic therapies include colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors (e.g., an adalimumab product [Humira, biosimilars], an etanercept product [Enbrel, biosimilars], Cimzia [certolizumab pegol subcutaneous injection], Simponi [golimumab subcutaneous injection], Simponi Aria [golimumab intravenous infusion], or an infliximab product [Remicade, biosimilars]).
iv. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

B. Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets ALL of the following (i, ii, **AND** iii):
i. Patient has been established on therapy for at least 4 months; **AND**
Note: A patient who has received < 4 months of therapy or who is restarting therapy should be considered under criterion A (Initial Therapy).
ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla); **AND**
Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); ulcer depth, number, and/or lesion size.
iii. Compared with baseline (prior to initiating Otezla), patient experienced an improvement in at least one symptom, such as decreased pain, or improved visual acuity (if ophthalmic manifestations).

2. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A **OR** B):
A. Initial Therapy. Approve for 4 months if the patient meets ALL of the following criteria (i, ii, **AND** iii):
i. Patient is ≥ 6 years of age; **AND**
ii. Patient meets ONE of the following conditions (a **OR** b):
a. Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; **OR**
Note: Examples of traditional systemic agents for psoriasis include methotrexate, cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
b. Patient has a contraindication to methotrexate, as determined by the prescriber; **AND**
iii. The medication is prescribed by or in consultation with a dermatologist.

B. Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets ALL of the following (i, ii, **AND** iii):
i. Patient has been established on therapy for at least 4 months; **AND**
Note: A patient who has received < 4 months of therapy or who is restarting therapy with the requested drug should be considered under criterion A (Initial Therapy).
ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; **AND**

iii. Compared with baseline (prior to receiving the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

3. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A **OR** B):

A. Initial Therapy. Approve for 6 months if the patient meets BOTH of following (i **AND** ii)
   i. Patient is ≥ 18 years of age; **AND**
   ii. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.

B. Patient is Currently Receiving Otezla. Approve for 1 year if the patient meets BOTH of the following (i **AND** ii):
   i. Patient has been established on the requested drug for at least 6 months; **AND**
   Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
   ii. Patient meets at least ONE of the following (a **OR** b):
      a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Otezla); **OR**
      Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortuium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
      b. Compared with baseline (prior to initiating Otezla), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

References:

1. Otezla® tablets [prescribing information]. Summit, NJ: Celgene; April 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/2014
2	Update	Update	Coverage Duration	07/01/2019
3	Update	CCI adopted EH template CCI P&T Review History:6/14, 10/14, 11/15, 11/16, 11/17, 11/18 CCI Revision Record: 9/14, 11/14, 12/14, 2/16, 11/16, 5/17, 12/18	All	7/3/2019
4	Update	Added indication for Oral Ulcers associated with Behcet's Disease	Covered Uses, Prescriber Restrictions, Other Criteria	8/27/2019

5	Update	Removed required trial of preferred products: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR for PsA diagnosis	Other Criteria	8/1/2020
6	Update	Psoriatic Arthritis: updated "Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND** Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine) TO "Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **OR** Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine)"	Other Criteria	9/6/2023
7	Update	Psoriatic Arthritis: Removed: • Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **OR** • Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); **AND** Plaque Psoriasis Removed: • Patient has chronic (greater than or equal to 1 year) plaque psoriasis; AND • Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; AND Behcet's Disease Removed: • Patient has at least two active oral ulcers; **AND** • Patient has been previously treated with at least one nonbiologic Behçet's Disease medication (i.e. corticosteroids, immunosuppressants, azathioprine, cyclosporine, cyclophosphamide, colchicine, mouthwashes that contain corticosteroids and other agents to reduce the pain of mouth sores); **AND** • Patient is not currently receiving another biologic or systemic treatment for Behçet's Disease; **AND** • Differential diagnoses have been ruled out by the prescribing physician. Added: • Patient has oral ulcers or other mucocutaneous involvement **AND** • Patient has tried at least ONE other systemic therapy; AND • The medication is prescribed by or in consultation with a rheumatologist or dermatologist. Removal of: Conneticare does not consider needle-phobia to be a clinical reason to use Otezla over injectable medications.	Other Criteria	11/15/2023
8	Update	Plaque Psoriasis: Expanded age requirement from ≥ 18 to ≥ 6 years of age.	Age Restrictions	12/16/2024