Commercial/Healthcare Exchange 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. Efficacy was established in 3 randomized clinical trials (n=1493). Apremilast treatment resulted in significantly more patients achieving an American College of Rheumatology (ACR) 20 response at week 16 in 3 studies (38%, 32%, and 41%) compared with placebo (19%, 19%, and 18%). Number of tender and swollen joints, pain assessment, and Health Assessment Questionnaire Disability Index were also all improved at week 16. Diarrhea, nausea, and headache were the most commonly reported adverse reactions in the trials. Patients should be monitored for depression and decreases in weight.
Apremilast is also indicated to treat moderate to severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy. Apremilast compared with placebo showed improvement of 75% or greater from baseline in Psoriasis Area and Severity Index-75 (PASI-75) at 16 weeks in the PSOR-1 study (33.1% vs 5.3%) and the PSOR-2 study (28.8% vs 5.8%). Static Physician Global Assessment (sPGA) score of clear or almost clear at 16 weeks was also improved in PSOR-1 (21.7% vs 3.9%) and PSOR-2 (20.4% vs 4.4%).

Covered Uses:

1. Adult patients with active psoriatic arthritis.
2. Moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy.
3. Adult patients with oral ulcers associated with Behçet's Disease.

Exclusion Criteria: Concurrent use with a biologic DMARD or Targeted Synthetic DMARD.

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restrictions:
Psoriatic Arthritis: Must be prescribed by, or in consultation with, a rheumatologist or dermatologist.
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: 3 years

Other Criteria:

Initiation

Psoriatic Arthritis

*Note: Otezla is a preferred product for the diagnosis of Psoriatic Arthritis and does not require the use of Humira first

A. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
B. 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**
C. Otezla is prescribed by or in consultation with a rheumatologist or a dermatologist

Plaque Psoriasis

*Note: Otezla is a preferred product for the diagnosis of Psoriasis and does not require the use of Humira first

A. Patient has chronic (greater than or equal to 1 year) plaque psoriasis; **AND**
B. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; **AND**
C. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed;* **AND**
D. Otezla is prescribed by or in consultation with a dermatologist.

Behcet's Disease

A. Patient has a diagnosis of Behçet's Disease; **AND**
B. Patient has at least two active oral ulcers; **AND**
C. 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**
D. Patient is not currently receiving another biologic or systemic treatment for Behçet's Disease; **AND**
E. Differential diagnoses have been ruled out by the prescribing physician.

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a 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.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Otezla over methotrexate.
*ConnectiCare does not consider needle-phobia to be a clinical reason to use Otezla over injectable medications.

References:

1. OTEZLA(R) oral tablets, apremilast oral tablets. Celgene Corporation (per FDA), Summit, NJ, 2017.

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: Continuation Update to 3 years	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