Otezla (apremilast)
Effective 12/1/2019

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<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☑ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
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**Specialty Limitations**
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Contact Information**

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>All Plans</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
</tr>
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<tbody>
<tr>
<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<tr>
<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
</tr>
<tr>
<td>Medical Specialty Medications (NLX)</td>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
<td>Fax: 844-851-0882</td>
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**Exceptions**
N/A

**Overview**
Apremilast inhibits phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) which results in increased intracellular cAMP levels and regulation of numerous inflammatory mediators (e.g. decreased expression of nitric oxide synthase, TNF-α, and interleukin [IL]-23, as well as increased IL-10).

**FDA-Approved Indications**
1. Moderate to severe plaque psoriasis
2. Active psoriatic arthritis
3. Treatment of oral ulcers associated with Behcet’s Disease

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

**Coverage Guidelines**

**Moderate to severe plaque psoriasis**
Authorization may be granted for members who have previously received Otezla or any biologic disease-modifying antirheumatic drug (DMARD) indicated for the treatment of moderate to severe plaque psoriasis, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**
Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:
1. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.

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2. Member meets any of the following criteria:
   a. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
      i. 1 topical agent + 1 systemic agent (methotrexate, cyclosporine, acitretin)
      ii. 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
      iii. 1 systemic agent + 1 phototherapy (e.g., UVB, PUVA)
      iv. 2 systemic agents
3. Member has a clinical reason to avoid ALL conventional therapies (topical agents, phototherapy, and systemic agents). (see Appendix A).
4. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

**Active psoriatic arthritis (PsA)**

1. Authorization may be granted for members who have previously received Otezla or any biologic disease-modifying antirheumatic drug (DMARD) indicated for the treatment of moderate to severe plaque psoriasis, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs
   OR
2. Authorization may be granted for treatment of active PsA when all the following criteria are met:
   a. One of the following:
      i. Member has had an inadequate response to at least a 3-month trial of at least one TNF inhibitor indicated for PsA (see Appendix B).
      ii. Member has experienced an intolerance to a trial of at least one TNF inhibitor indicated for PsA.
      iii. All TNF inhibitors indicated for PsA are not appropriate for the member
   OR
   b. One of the following:
      i. Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
      ii. Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or has a contraindication to sulfasalazine.

**Oral ulcers associated with Behcet’s Disease**

1. Authorization may be granted for members who have previously received Otezla for the treatment oral ulcers associated with Bechet’s Disease, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs
   OR
2. Authorization may be granted for treatment of oral ulcers associated with Bechet’s Disease when the member has experienced an inadequate response or intolerance to topical or oral steroids and colchicine.
   OR
3. The member has a contraindication to topical and oral steroids and colchicine

**Continuation of Therapy**

Members must 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.
Appendices

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)

B. Examples of TNF Inhibitors Indicated for PsA
   1. Cimzia
   2. Enbrel
   3. Humira
   4. Remicade
   5. Simoni

Limitations
1. Initial and reauthorizations are issued for 24 months
2. The following quantity limits apply:

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<th>For all diagnoses</th>
<th>#60 tablets per 30 days</th>
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References
1. Otezla [package insert]. Summit, NJ: Celgene Corporation; APRPL007 07/19

Review History
Reviewed: 02/23/15; 02/22/16 P&T Mtg
Revised: 02/27/17 (adopted SGM & Step); 2/26/18 P&T Mtg; 02/20/19; 9/18/19 (Added oral ulcers associated with Behcet’s Disease as an indication)

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