OVERVIEW
Otezla® (apremilast) tablets
Prior Approval Criteria
July 2016

Otezla® (apremilast) tablets is an inhibitor of phosphodiesterase 4 (PDE4), and is indicated for the treatment of adult patients with active psoriatic arthritis or plaque psoriasis.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Otezla. Otezla also follows the Inflammatory Condition Care Value Step Therapy Policy for Psoriatic arthritis and Plaque Psoriasis. Patients that have not been on Otezla for at least 4 months should follow initial therapy requirements for Psoriatic arthritis and Plaque Psoriasis.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Otezla is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Psoriatic arthritis, approve for 4 months.
   A) Initial Therapy.
      1. The patient is ≥18 years; AND
      2. Otezla will not be used in combination with a targeted synthetic DMARD (e.g., Xeljanz) or a biologic DMARD (e.g., Actemra (IV, SC), Kineret, Orencia (IV, SC), Rituxan, or TNF antagonists [Cimzia, Enbrel, Humira, Remicade, or Simponi (Aria, SC)]); AND
      3. The patient has moderate to severe psoriatic arthritis and at least one of the follow (a or b):
         a) Used in combination with methotrexate; OR
         b) Inadequately controlled disease activity and continued disease progression despite treatment with methotrexate for at least three months, or at least two other non-biologic DMARDs (e.g., leflunomide, sulfasalazine) after a trial of at least three months each, unless contraindicated or intolerant; AND
      4. Otezla is prescribed by or in consultation with a rheumatologist or dermatologist;
   B) Patients Currently Receiving Otezla, approve for 1 year.
      1. Patient must be currently established on Otezla for ≥ 120 days; AND
      2. The patient has had a clinical response as determined by the prescriber.

2. Plaque Psoriasis, approve for 4 months.
   A) Initial Therapy.
      1. The patient has tried at least one of the following agents for at least 3 months for plaque psoriasis: an oral therapy for psoriasis (e.g., MTX, cyclosporine, Soriatane® [acitretin tablets]); oral methoxsalen plus ultraviolet A light (PUVA); or a biologic agent (e.g., Humira, Remicade, or Stelara' [ustekinumab for SC injection]); OR
2. The patient experienced an intolerance to a trial of at least one oral therapy for plaque psoriasis (e.g., MTX, cyclosporine, Soriatane); OR
3. The patient has a contraindication to one oral agent for psoriasis such as MTX, as determined by the prescribing physician; AND
4. Otezla is prescribed by or in consultation with a dermatologist; AND
5. Will not be used in combination with a targeted synthetic DMARD (e.g., Xeljanz) or a biologic DMARD (e.g., Actemra (IV, SC), Kineret, Ocrevus (IV, SC), Rituxan, or TNF antagonists [Cimzia, Enbrel, Humira, Remicade, or Simponi (Aria, SC), Cosentyx])

B) Patients Currently Receiving Otezla, approve for 1 year.

1. Patient must be currently established on Otezla for ≥ 120 days; AND
2. The patient has had a clinical response as determined by the prescriber.

Other Uses With Supportive Evidence

3. Behcet’s Disease. Approve for 1 year if the patient meets the following criteria (A and B):
   A) The patient meets ONE of the following criteria (i or ii):
      i. The patient has tried at least ONE biologic (e.g., Enbrel [etanercept SC injection], Humira [adalimumab SC injection], or Remicade [infliximab IV infusion]); OR
      ii. The patient meets one of the following conditions or relative contraindications to use of a TNF blocker (a, b, c, d, or e):
         a) The patient has a history of one of the following: hepatitis B, hepatitis C, demyelinating disease, or malignancy; OR
         b) The patient has heart failure; OR
         c) The patient is on chronic systemic corticosteroid therapy (e.g., prednisone, dexamethasone); OR
         d) The patient has a chronic infection or is at high risk of infection (e.g., human immunodeficiency virus [HIV], malignancy, neutropenia, diabetes), as determined by the prescribing physician, OR
         e) The patient has a history of recurrent infections, as determined by the prescribing physician; AND
   B) Otezla is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

4. Patient has been Established on Otezla for ≥ 120 days. For conditions that do not have criteria for Patients Currently Receiving Otezla but are indications or conditions addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications and Other Uses with Supportive Evidence), approve Otezla for 1 year if the patient is currently taking Otezla for ≥ 120 days.

Approval Duration:
Initial Approval = 4 months for Psoriatic arthritis and Plaque Psoriasis, 365 days (1 year) for Behcet’s.
Re-authorization = 365 days (1 year)

References


