Pharmacy Medical Necessity Guidelines: Otezla® (apremilast)

Effective: January 1, 2018

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<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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Pharmacy (RX) or Medical (MED) Benefit

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<th>Department to Review</th>
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This Pharmacy Medical Necessity Guidelines applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:

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<tr>
<th>RXUM</th>
<th>617-673-0988</th>
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OVERVIEW

FDA-APPROVED INDICATIONS
Otezla (apremilast) is an oral phosphodiesterase 4 inhibitor indicated for treatment of adult patients with active psoriatic arthritis and patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

PHARMACY COVERAGE GUIDELINES
The plan may authorize coverage of Otezla (apremilast) for Members, when the following criteria are met and limitations do not apply:

**Psoriatic Arthritis**
1. The Member has a documented definitive diagnosis of psoriatic arthritis
   AND
2. The Member is 18 years of age or older
   AND
3. The prescription is written by a rheumatologist
   AND
4. The Member has a documented inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months
   AND
5. The Member has a documented inadequate response or inability to take both Enbrel and Humira

**Plaque Psoriasis**
1. The Member has a documented definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis
   AND
2. The Member is 18 years of age or older
   AND
3. The Member has failed to respond to, or has been unable to tolerate phototherapy and ONE of the following therapeutically-similar medications:
   - Soriatane (acitretin)
   - Methotrexate
   - Cyclosporine
   AND
4. The Member has a documented inadequate response or inability to take both Enbrel and Humira

Note: Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient’s tolerance.
LIMITATIONS

1. Samples, free goods or similar offerings of Otezla (apremilast) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Members new to the plan and stable on Otezla (apremilast) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., cyclosporine, methotrexate).
3. Coverage for Otezla (apremilast) will be limited to a 28-day supply as follows
   - Otezla Starter Pack – one starter package containing 27 tablets will initially be authorized for a 14-day supply, followed by
   - Otezla 30 mg tablets – 56 tablets per 28 days.

CODES

None

REFERENCES


**APPROVAL HISTORY**
- September 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee
- December 9, 2014: Added criteria for newly approved indication for plaque psoriasis.
- November 10, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Added exception language for Members new to the plan and stable on Otezla prior to enrollment.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Actemra (tocilizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
- December 12, 2017: Effective January 1, 2018, removed criteria allowing members new to the plan stable on Otezla (apremilast) to be authorized due to new state requirements. Added the following limitation: Members new to the plan and stable on Otezla (apremilast) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., cyclosporine, methotrexate).

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary.
depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.