Pharmacy Medical Necessity Guidelines: Enbrel® (etanercept)

Effective: June 12, 2018

Prior Authorization Required √ Type of Review – Care Management
Not Covered Type of Review – Clinical Review √
Pharmacy (RX) or Medical (MED) Benefit RX Department to Review RXUM

This Pharmacy Medical Necessity Guideline 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:
RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- **Ankylosing Spondylitis**
  Enbrel (etanercept) is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

- **Plaque Psoriasis**
  Enbrel (etanercept) is indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

- **Polyarticular Juvenile Idiopathic Arthritis**
  Enbrel (etanercept) is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.

- **Psoriatic Arthritis**
  Enbrel (etanercept) is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel can be used with or without methotrexate (MTX).

- **Rheumatoid Arthritis**
  Enbrel (etanercept) is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with MTX or used alone.

**COVERAGE GUIDELINES**
The plan may authorize coverage of Enbrel (etanercept) for Members when the following criteria are met:

**Ankylosing Spondylitis**
1. The Member has a documented diagnosis of ankylosing spondylitis
   **AND**
2. The prescription is written by a rheumatologist
   **OR**
3. The Member has tried and failed treatment with another biological agent for the treatment of ankylosing spondylitis
   **OR**
4. The Member is new to the plan and has been stable on Enbrel prior to enrollment
**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 4 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:
   a) Soriatane (acitretin)
   b) Methotrexate
   c) Cyclosporine OR
4. The Member has tried and failed treatment with another biological agent for the treatment of plaque psoriasis OR
5. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Polyarticular Juvenile Idiopathic Arthritis**
1. The Member has a documented diagnosis of polyarticular juvenile idiopathic arthritis AND
2. The prescription is written by a rheumatologist AND
3. The Member is 2 years of age or older AND
4. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate the DMARD methotrexate OR
5. The Member has tried and failed treatment with another biological agent for the treatment of polyarticular juvenile idiopathic arthritis OR
6. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Psoriatic Arthritis**
1. The Member has a documented diagnosis of psoriatic arthritis AND
2. The prescription is written by a rheumatologist AND
3. The Member has a documented inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months OR
4. The Member has tried and failed treatment with another biological agent for the treatment of psoriatic arthritis OR
5. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Rheumatoid Arthritis**
1. The Member has a documented diagnosis of rheumatoid arthritis AND
2. The prescription is written by a rheumatologist AND
3. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate the DMARD methotrexate OR
4. The Member has tried and failed treatment with another biological agent for the treatment of rheumatoid arthritis

OR

5. The Member is new to the plan and has been stable on Enbrel prior to enrollment

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

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<th>Limitations</th>
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<td>1. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.</td>
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<td>2. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.</td>
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<td>3. Coverage for Enbrel (etanercept) for the diagnoses of ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis and rheumatoid arthritis will be limited to a 28-day supply as follows:</td>
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<td>- Enbrel 25 mg syringe – 8 syringes per 28 days</td>
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<tr>
<td>- Enbrel 50 mg syringe – 4 syringes per 28 days</td>
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<tr>
<td>4. Coverage for Enbrel (etanercept) for the diagnosis of plaque psoriasis will be limited to a 28-day supply as follows:</td>
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<td>- Enbrel 25 mg syringe – 16 syringes per 28 days (initial 12 weeks) then 8 syringes per 28 days thereafter.</td>
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<td>- Enbrel 50 mg syringe – 8 syringes per 28 days (initial 12 weeks) then 4 syringes per 28 days thereafter.</td>
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<td>Medical billing codes may not be used for these medications. These medications must be obtained via the Member’s pharmacy benefit.</td>
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**APPROVAL HISTORY**

November 15, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 15, 2011: This policy replaces the Medical Necessity Guidelines for Enbrel (etanercept) in "Rheumatoid Arthritis – Injectable Drugs” originating in August 2002 (Document ID#1035134) and "Injectable Drugs for the Treatment of Psoriasis” originating in November 2003 (Document ID# 2099988)
- October 9, 2012: No changes.
- October 15, 2013: No changes.
- October 7, 2014: No changes.
- September 16, 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 Enbrel prior to enrollment. Added trial and failure with another biological agent indicated for the same condition.
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- November 15, 2016: Updated approval criteria to members at least 4 years of age for the indication of plaque psoriasis based on updated package labeling.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- August 8, 2017: No changes
- November 14, 2017: Administrative update adding a limitation to clarify that for plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
- April 10, 2018: Effective 6/12/18, added the Limitation that documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.

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 CareLinkSM 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.