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.

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

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  
   AND
3. The Member is 18 years of age or older  
   AND
4. The member has previously tried and failed treatment with, or does the patient have a contraindication to, at least two non-steroidal anti-inflammatory drugs (NSAIDs)  
   OR
5. The Member has tried and failed treatment with another biological agent for the treatment of ankylosing spondylitis  
   OR
6. 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
2. The prescription is written by a dermatologist
3. The Member is 4 years of age or older
4. The Member has tried and failed treatment with, or does the patient have a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine or methotrexate (MTX)
5. The Member has tried and failed treatment with another biological agent for the treatment of plaque psoriasis
6. 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
2. The prescription is written by a rheumatologist
3. The Member is 2 years of age or older
4. The Member has previously tried and failed treatment with, or does the patient have a contraindication to, at least one disease modifying anti-rheumatic drug (DMARD), such as azathioprine, gold therapy, hydroxychloroquine, MTX, penicillamine, sulfasalazine, cyclosporine or leflunomide
5. The Member has tried and failed treatment with another biological agent for the treatment of polyarticular juvenile idiopathic arthritis
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
2. The prescription is written by a rheumatologist
3. The Member is 18 years of age or older
4. For Members with low to moderate disease activity, documentation of at least one of the following:
   a. The Member has tried and failed treatment with, has a documented contraindication, or has a documented clinical inappropriateness to treatment with a triple generic
5. The Member has tried and failed treatment with another biological agent for the treatment of psoriatic arthritis
6. 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
2. The prescription is written by a rheumatologist
3. The Member is 18 years of age or older
4. For Members with low to moderate disease activity, documentation of at least one of the following:
   a. The Member has tried and failed treatment with, has a documented contraindication, or has a documented clinical inappropriateness to treatment with a triple generic
DMARD regimen of MTX, sulfasalazine, and hydroxychloroquine for a period of at least 3 to 6 months
b. The Member has tried and failed treatment with another biologic for the treatment of rheumatoid arthritis
c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

5. For Members with high disease activity:
   a. Documentation of high disease activity as evidenced by at least one of the following:
      i. Clinical Disease Activity Index (CDAI): >22
      ii. Disease Activity Score 28 erythrocyte sedimentation rate (DAS28 ESR): >5.1
      iii. Patient Activity Scale (PAS or PASII): ≥8.0
      iv. Routine Assessment of Patient Index Data (RAPID): >4.0 to 10.0
      v. Simplified Disease Activity Index (SDAI): >26
   AND
b. Documentation of at least one of the following:
   i. The Member has tried and failed treatment with or has a documented contraindication to at least one DMARD, such as azathioprine, gold therapy, hydroxychloroquine, MTX, penicillamine, sulfasalazine, cyclosporine or leflunomide
   ii. The Member has tried and failed treatment with another biological agent for the treatment of rheumatoid arthritis
   iii. The Member is new to the plan and has been stable on Enbrel prior to enrollment

LIMITATIONS
1. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
2. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
3. Initial approval of Enbrel (etanercept) will be limited to 12 months. Subsequent authorizations may be given in 12 month intervals when the provider indicates improvement with therapy.
4. 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:
   • Enbrel 25 mg syringe – 8 syringes per 28 days
   • Enbrel 50 mg syringe – 4 syringes per 28 days
5. Coverage for Enbrel (etanercept) for the diagnosis of plaque psoriasis will be limited to a 28-day supply as follows:
   • Enbrel 25 mg syringe – 16 syringes per 28 days (initial 12 weeks) then 8 syringes per 28 days thereafter
   • Enbrel 50 mg syringe – 8 syringes per 28 days (initial 12 weeks) then 4 syringes per 28 days thereafter

Note: Patients’ already stable on Enbrel (etanercept) for 3 months will receive:
   • Enbrel 25 mg syringe – 8 syringes per 28 days
   • Enbrel 50 mg syringe – 4 syringes per 28 days

CODES
Medical billing codes may not be used for this medication. This medication must be obtained via the Member’s pharmacy benefit.

REFERENCES


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.
- 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.
- August 8, 2017: No changes
- September 12, 2017: Effective 1/1/18, for the treatment rheumatoid arthritis, changed the prerequisite DMARD trial to a three drug generic regimen of methotrexate, sulfasalazine, hydroxychloroquine for patients with low to moderate disease activity.
- 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. For the diagnosis of rheumatoid arthritis in Members with low to moderate disease activity, removed the requirement of a documented clinical assessment scale score.

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. Tufts Health 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 Medicare Preferred, please refer to Tufts 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
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.