**Enbrel® (etanercept)**

*Effective: 10/1/15*

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**OVERVIEW**

**FDA-APPROVED INDICATIONS**

**Ankylosing Spondylitis**

Enbrel (etanercept) is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).

**Plaque Psoriasis**

Enbrel (etanercept) is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) 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 (JIA) 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 (PsA). Enbrel (etanercept) can be used in combination with methotrexate (MTX) in patients who do not respond adequately to MTX alone.

**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 (RA). Enbrel can be initiated in combination with methotrexate (MTX) or used alone.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of Enbrel (etanercept) for Members when the following criteria are met and limitations do not apply:

**For 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 one Non-Steroidal Anti-inflammatory Agent (NSAID) **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 Tufts Health Plan – Network Health and has been stable on etanercept prior to enrollment.

**For Plaque Psoriasis**

1. The Member has a documented definitive diagnosis from a dermatologist of moderate-to-severe chronic plaque psoriasis **AND**
2. The prescription is written by a dermatologist **AND**
3. The Member is 18 years of age or older **AND**
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 **OR**
5. The Member has tried and failed treatment with another biological agent for the treatment of plaque psoriasis **OR**
6. The Member is new to Tufts Health Plan – Network Health and has been stable on etanercept prior to enrollment.
For 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 previously tried and failed treatment with, or does the patient have a contraindication to, at least one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate, penicillamine, sulfasalazine, cyclosporine or leflunomide 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 Tufts Health Plan – Network Health and has been stable on etanercept prior to enrollment.

For 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 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 one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate, penicillamine, sulfasalazine, cyclosporine or leflunomide OR
5. The Member has tried and failed treatment with another biological agent for the treatment of psoriatic arthritis OR
6. The Member is new to Tufts Health Plan – Network Health and has been stable on etanercept prior to enrollment.

For Rheumatoid Arthritis
1. The Member has a documented diagnosis of rheumatoid 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 previously tried and failed treatment with, or does the patient have a contraindication to, at least one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate, penicillamine, sulfasalazine, cyclosporine or leflunomide OR
5. The Member has tried and failed treatment with another biological agent for the treatment of Rheumatoid Arthritis OR
6. The Member is new to Tufts Health Plan – Network Health and has been stable on etanercept prior to enrollment.

LIMITATIONS
1. Initial requests will be approved for 1 year. Subsequent authorizations for may be given in 12 month intervals when the provider indicates improvement with therapy.
2. 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
3. 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
- October 2006: Reviewed by the Pharmacy and Therapeutics Committee
- October 2013: Reviewed by the Pharmacy and Therapeutics Committee
- October 7, 2014: Reviewed by the Pharmacy and Therapeutics Committee
- September 16, 2015: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health 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 –
Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List formulary in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.