Enbrel® (Etanercept)  

UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Disease Modifying Anti-Rheumatic Drug (DMARD)

**BRAND (generic) NAMES:** Enbrel (etanercept)
- Injection kit 25 mg
- Prefilled syringe 25 mg/0.5 mL
- Prefilled syringe 50 mg/mL
- Sure Click Auto-Injector 50 mg/mL

**FDA-APPROVED INDICATIONS**

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

- **Rheumatoid Arthritis (RA)**
  - Enbrel 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 methotrexate (MTX) or used alone.

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

- **Psoriatic Arthritis (PsA)**
  - Enbrel 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 in combination with methotrexate (MTX) in patients who do not respond adequately to MTX alone.

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

- **Plaque Psoriasis (PsO)**
  - Enbrel is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
COVERAGE AUTHORIZATION CRITERIA

Enbrel (etanercept) may be eligible for coverage for **Rheumatoid Arthritis** when the following criteria are met:

1. The patient is diagnosed with rheumatoid arthritis; **AND**
2. The patient has experienced a therapeutic failure or inadequate response to methotrexate; **OR**
3. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to methotrexate.

Enbrel (etanercept) may be eligible for coverage for **Psoriatic Arthritis** when the following criteria are met:

1. The patient is diagnosed with psoriatic arthritis; **AND**
2. The patient has experienced a therapeutic failure or inadequate response to methotrexate; **OR**
3. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to methotrexate.

Enbrel (etanercept) may be eligible for coverage for **Polyarticular Juvenile Idiopathic Arthritis** when the following criteria are met:

1. The patient is diagnosed with polyarticular juvenile idiopathic arthritis; **AND**
2. The patient is 2 years of age or older; **AND**
3. The patient has experienced a therapeutic failure or inadequate response to methotrexate; **OR**
4. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to methotrexate.

Enbrel (etanercept) may be eligible for coverage for **Moderate to Severe Plaque Psoriasis** when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient is diagnosed with moderate to severe plaque psoriasis; **AND**
3. The patient is being managed by a dermatologist; **AND**
4. The patient has Body Surface Area (BSA) involvement of at least 5%; **OR**
5. The patient has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment; **AND**
6. The patient has tried and failed, is intolerant to, or has a clinical contraindication to systemic therapy (methotrexate (oral or IM), cyclosporine, or acitretin); **OR**
7. The patient has tried and failed, is intolerant to, or has a clinical contraindication to phototherapy.

Enbrel (etanercept) may be eligible for coverage for **Ankylosing Spondylitis** when the following criteria are met:

1. The patient is diagnosed with ankylosing spondylitis.

For all covered diagnoses: The patient will not be using Enbrel in combination with biologic DMARDs (including Humira, Stelara, Simponi, Remicade, Actemra, Kineret, Xeljanz, Cimzia, Orencia, Entyvio, Tysabri, or Rituxan) or potent immunosuppressants (e.g., azathioprine, tacrolimus or cyclosporine).
QUANTITY LIMIT EXCEPTION CRITERIA

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The allowed quantity for maintenance doses is four 50 mg injections every 28 days or eight 25 mg injections every 28 days. This corresponds to maintenance doses of 50 mg per week.

Starting dose for plaque psoriasis only: For patients with psoriasis who may require higher doses for the first 12 weeks of therapy, eight 50 mg injections every 28 days may be approved for 12 weeks.

Quantities above the quantity limit for Enbrel may be eligible for coverage when the following are met:

1. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert; OR
2. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

WARNINGS: SERIOUS INFECTIONS AND MALIGNANCIES

SERIOUS INFECTIONS

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
- Enbrel should be discontinued if a patient develops a serious infection or sepsis during treatment.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Enbrel.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

MALIGNANCIES

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including Enbrel.
WARNINGS AND PRECAUTIONS

- Do not start Enbrel during an active infection. If an infection develops, monitor carefully and stop Enbrel if infection becomes serious.
- Demyelinating disease, exacerbation or new onset, may occur.
- Cases of lymphoma have been observed in patients receiving TNF blocking agents.
- Congestive heart failure, worsening or new onset, may occur.
- Advise patients to seek immediate medical attention if symptoms of pancytopenia or aplastic anemia develop, and consider stopping Enbrel.
- Monitor hepatitis B virus carriers for reactivation during and several months after therapy. If reactivation occurs, consider stopping Enbrel and beginning anti viral therapy.
- Anaphylaxis or serious allergic reactions may occur.
- Stop Enbrel if lupus-like syndrome or autoimmune hepatitis develops.

DOSAGE AND ADMINISTRATION

Enbrel is administered by subcutaneous injection.

- Adult Rheumatoid Arthritis and Psoriatic Arthritis
  - 50 mg once weekly with or without methotrexate (MTX)
  - Based on a study of 50 mg Enbrel twice weekly in patients with RA that suggested higher incidence of adverse reactions but similar ACR response rates, doses higher than 50 mg per week are not recommended.
- Ankylosing spondylitis
  - 50 mg once weekly
- Adult Plaque Psoriasis
  - 50 mg twice weekly for 3 months, followed by 50 mg once weekly
- Juvenile Idiopathic Arthritis
  - 0.8 mg/kg weekly, with a maximum of 50 mg per week

REFERENCES


POLICY IMPLEMENTATION/UPDATE INFORMATION

- December 2015: Updated criteria under “Coverage is provided for Moderate to Severe Plaque Psoriasis”. The intent of the criteria is if phototherapy is unavailable to the patient, then the patient would need to meet the criteria for Stelara by try/fail/clinical contraindication to systemic therapy.
- The patient has been treated with phototherapy, unless the patient is not a candidate for phototherapy or phototherapy is not available to the patient. Revised to: The patient has tried and failed, is intolerant to, or has a clinical contraindication to phototherapy.
- Removed: “For all covered indications, the provider must have considered and screened for the presence of latent tuberculosis (TB) infection”.
- Added coverage criteria for polyarticular juvenile arthritis.
- Removed from the Rheumatoid and Psoriatic Arthritis coverage: Rheumatoid Arthritis or Psoriatic Arthritis is rapidly progressive and advancing.