



**PHARMACY PRIOR AUTHORIZATION
Clinical Guideline
Tumor Necrosis Factor (TNF) Inhibitor
Enbrel® (etanercept)**

FDA Indications

For treatment of:

- **Ankylosing spondylitis**
- **Plaque psoriasis:** Adult patients (18 years of age or older)
- **Psoriatic arthritis:** May be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
- **Rheumatoid arthritis (RA):** May be used in combination with methotrexate (MTX)
- **Polyarticular-course juvenile idiopathic rheumatoid arthritis (JIA):** in patients 2 yrs of age and older

Dosage Forms

- **25 mg powder for injection (vial)**
- **25mg/0.5ml prefilled syringe**
- **50 mg/ml prefilled syringe, 50mg/ml SureClick autoinjector**

Dosage

- **Ankylosing spondylitis, psoriatic arthritis, RA (adults):** 50 mg/week, given as one 50 mg injection or two 25 mg injections on the same day or 3–4 days apart
- **Plaque psoriasis (adults):** 50 mg twice weekly for 3 months, then reduce to the maintenance dose of 50 mg/week, given as one 50 mg injection or two 25 mg injections on the same day or 3–4 days apart
- **JRA (2–17 years old):** 0.8 mg/kg/week up to maximum dose of 50 mg/week

Authorization Guidelines

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines to assess the medical necessity of the request for a prescription for Enbrel. If the guidelines are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

For patients who meet all of the following:

- **Medical records to support medication will be administered in provider's office. Self administered injectable medications are available through the Delaware Medicaid pharmacy benefit. Members should be directed to Delaware retail pharmacies with prescriptions to obtain these drugs.**
- No hypersensitivity to etanercept, or any of the product components
- No evidence of malignancy within the last 5 years per medical records
- No evidence of sepsis per medical records
- No active infections as documented in medical records for patients with a history of recurrent infections or an underlying condition that may predispose them to infections (i.e., advanced or uncontrolled diabetes mellitus, malignancy, immunosuppression [including long term corticosteroid

therapy])

- No active or latent tuberculosis infection per medical records
- Not concurrently receiving live vaccines, other TNF-inhibitors, or Kineret
- If under 21 years of age, is up to date on immunizations in accordance with current Early and Periodic Screening Diagnosis and Treatment (EPSDT) immunization guidelines prior to initiating therapy

In Addition:

For treatment of ankylosing spondylitis:

- Medical records documenting diagnosis **AND**
- Trial and failure of two different formulary NSAIDs within the last 60 days **OR**
- Documented contraindication or intolerance to NSAIDs

For treatment of chronic moderate to severe plaque psoriasis:

- Medical records document a diagnosis of plaque psoriasis with at least 10% body surface area (BSA) affected, a minimum Psoriasis Area and Severity Index (PASI) score of 12; **AND**
- Trial and failure of UVB therapy or documentation showing contraindication to therapy; **AND**
- Trial and failure of a compliant regimen of methotrexate for at least 3 consecutive months **OR** documentation showing contraindication to therapy

For treatment of diagnosis of moderate to severe psoriatic arthritis:

- Medical records document a diagnosis of moderate to severe psoriatic arthritis **AND**
- Trial and failure of a compliant regimen of at least two DMARDs (i.e., sulfasalazine, leflunomide) one of which should be methotrexate for at least 3 months

For treatment of moderate to severe RA:

- Age 18 years of age and older **AND**
- Trial and failure of a compliant regimen of one DMARD in combination with methotrexate for at least 3 months: sulfasalazine, leflunomide, or hydroxychloroquine + methotrexate (unless methotrexate is contraindicated) **OR**
- Trial and failure of a compliant regimen of 2 DMARDs as sequential monotherapy (i.e., sulfasalazine or leflunomide) one of which should be methotrexate for at least 3 months (unless methotrexate is contraindicated) **OR**
- Documented intolerance to methotrexate or other DMARDs (for any length of time)

For treatment of JIA:

- Age ≥2 years of age **AND**
- Medical records documenting diagnosis **AND**
- Trial and failure of at least 3 months of methotrexate

Prior Authorization Requirements

Initial Approval

- **Plaque psoriasis: 3 months (dose: 50 mg twice weekly)**
- **Others: 6 months**

Renewal

- **Plaque psoriasis: 1 year (maintenance dose: 50mg weekly)**
- **Others: 1 year**

- Supporting medical records
- Review of Rx history (compliance)

Follow-up Renewal

- 1 year
- Supporting medical records (optional)
- Review of Rx history (compliance)

Additional Information

Black Box Warning:

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.

Table 1: Live Vaccines:

BCG VACCINE, LIVE

INFLUENZA VIRUS VACCINE LIVE, INTRANASAL

MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE

MEASLES, MUMPS, RUBELLA, AND VARICELLA VIRUS VACCINE, LIVE, ATTENUATED

ROTAVIRUS VACCINE, LIVE, ORAL

TYPHOID VACCINE, LIVE, ORAL

VARICELLA VIRUS VACCINE, LIVE

YELLOW FEVER VACCINE, LIVE

ZOSTER VACCINE, LIVE

References

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