



## ETANERCEPT (ENBREL®) UTILIZATION MANAGEMENT CRITERIA

<b>DRUG CLASS:</b>	Disease Modifying Anti-Rheumatic Drug (DMARD)
<b>BRAND (Generic) NAME:</b>	Enbrel (etanercept)
Enbrel® is supplied as 25-mg lyophilized powder (vial) for subcutaneous injection	

### FDA INDICATIONS:

#### 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.

<b>ICD-9 CODES:</b>	Rheumatoid Arthritis	714.0
	Juvenile Rheumatoid Arthritis	714.3
	Psoriatic Arthropathy	696.0
	Ankylosing Spondylitis	720
	Plaque Psoriasis	696.1

### BENEFIT DESIGN:

**Rheumatoid and Psoriatic Arthritis:** Coverage is provided immediately (without initiating a coverage review) for the treatment of rheumatoid and psoriatic arthritis in the presence of a prescription within the previous 18 months for any of the following disease-modifying anti-rheumatic drugs (DMARDs):

- Methotrexate
- Leflunomide (Arava®)
- Etanercept (Enbrel®)
- Adalimumab (Humira®)
- Anakinra (Kineret™)

In situations where none of the above DMARDs exist in history, coverage for Enbrel is determined through the coverage authorization criteria.

**Plaque Psoriasis (chronic moderate to severe):** Coverage is provided immediately (without initiating a coverage review) for the treatment of plaque psoriasis in the presence of a prescription within the previous 18 months for any of the following drugs and if the prescribing physician is a dermatologist:

- Methoxsalen (Oxsoralen<sup>®</sup>)
- Methotrexate
- Cyclosporine
- Acitretin (Soriatane<sup>®</sup>)
- Etanercept (Enbrel)

In situations where the above does not apply, coverage for Enbrel is determined through the coverage authorization criteria.

**COVERAGE AUTHORIZATION CRITERIA:**

Coverage is provided for the following conditions:

- **Rheumatoid or Psoriatic Arthritis** when a patient has experienced a therapeutic failure/inadequate response with methotrexate  
**OR**  
Is unable to receive methotrexate (e.g. use of methotrexate is contraindicated in the patient)  
**OR**  
Rheumatoid or Psoriatic Arthritis is rapidly progressive and advancing
- Diagnosis of **Ankylosing Spondylitis**
- **Plaque Psoriasis, Pustular Psoriasis, or Erythrodermic Psoriasis**  
**AND**  
Member is being managed by a dermatologist  
**AND**  
Body Surface Area (BSA) involvement of at least 5%  
**OR**  
Involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment  
**AND**  
Failure of systemic therapy (methotrexate, cyclosporine, Soriatane,) or patient has contraindication to these treatments

\*Coverage of Enbrel is not provided for use in combination with Kineret, Remicade<sup>®</sup>, Humira, Cimzia<sup>®</sup>, Simponi<sup>®</sup>, Amevive<sup>®</sup>, or Stelara<sup>®</sup>.

\*For all covered indications, the provider must have considered and screened for the presence of latent tuberculosis (TB) infection.

**QUANTITY LIMITATIONS (effective 10/1/11)**

- 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.
- 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 a short period of time.

**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.

**RATIONALE:**

- For RA and Psoriatic Arthritis, a treatment program that includes methotrexate as initial therapy may be considered for most patients unless a patient has a contraindication to or is unable to receive methotrexate (e.g., such as in the presence of liver or lung disease).
- Conventional therapy for moderate to severe psoriasis includes phototherapy and/or oral medications such as methotrexate and cyclosporine. Due to the potential for serious side effects, the cost impact, and the monitoring requirements, Enbrel® is considered second-line therapy after topical treatment, phototherapy, and other systemic medications currently used for psoriasis (i.e. methotrexate, cyclosporine, Soriatane®).

**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

**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.

**DRUG INTERACTIONS:**

- Live vaccines – should not be given with Enbrel
- Anakinra – increased risk of serious infection
- Abatacept – increased risk of serious adverse events, including infections
- Cyclophosphamide – use with Enbrel is not recommended

**REFERENCES:**

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