

Subject: Enbrel® (Etanercept) Injections	
<input type="checkbox"/> Original	Last P&T Committee Approval: October 19, 2007
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 3, 2008
	Last Review: October 2007

1. **Background:**

Etanercept (Enbrel®) Is A Self-Injectable Drug:

Self-injectable drugs, subject to various pharmacy benefit restrictions, will be covered by the pharmacy benefit unless the patient has conditions that prohibit him/her from self-administration of the medication. These conditions include but are not limited to:

- a) The member and family are physically unable to perform administration and adaptive equipment is not available, and
- b) The member and/or family lacks the cognitive ability to manage self-injection, recognize side effects, or understand when to notify their provider if problems occur.

Tumor necrosis factor-alpha (TNF-) is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Etanercept (Enbrel®) binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors, rendering TNF biologically inactive and reducing the inflammation associated with rheumatoid arthritis (RA), and psoriatic arthritis.

2. **Indications/Criteria:**

In ALL cases, the patient must meet ALL of the following criteria:

- Four years old or older, and
- No evidence of sepsis, active infection including tuberculosis, or pancytopenia.

1. Active Ankylosing Spondylitis:
No other requirements.

2. Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Psoriatic Arthritis:

At least one of the following criteria must be met:

- The patient has tried methotrexate (MTX), up to 25 mg per week, for at least 6 to 12 weeks and failed the treatment as defined by the following:
 - No decrease in number of swollen or painful joints,
 - No decrease in pain or disability,
 - No improvement in global assessment that includes patient activity/functional assessment, OR
 - Radiographic evidence of disease progression.

OR

- The patient did not tolerate methotrexate due to documented side effects such as stomatitis, severe diarrhea, increase in liver enzymes, new onset of significant lung disease, leucopenia, thrombocytopenia, vasculitis, hemorrhage or blurred vision.

OR

- Methotrexate is contraindicated for the patient (pre-existing liver disease, renal impairment, significant lung disease, alcohol abuse, pregnancy).

Recommended Dose:

The recommended dose for patients older than 17 years is 25 mg subcutaneous injection twice a week or 50 mg subcutaneous injection once a week.

The recommended dose for patients 4-17 years old is 0.8 mg/kg subcutaneous injection once a week with a maximum recommended dose of 50 mg per week.

3. Plaque Psoriasis:

There must be documentation that the patient has undergone adequate trials of more conservative therapy and has failed to respond. Such conservative trials must include all of the following:

- Vitamin D analogues,
- Topical steroids, and
- Coal tar,

AND

There must be documentation that the patient has tried and failed phototherapy (UVB, PUVA) or has a contraindication to such therapy,

AND

There must be documentation that the patient has tried and failed systemic treatments including all of the following:

- Cyclosporine,
- Methotrexate, and
- Oral retinoids.

Recommended Dose for Plaque Psoriasis:

The recommended dose for patients older than 17 years is 50 mg subcutaneous injection twice a week for 3 months followed by a reduction to a maintenance dose of 50 mg per week.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required
Basic Health Plan:	None; pre-authorization required
GAU:	None; pre-authorization required
Medicare Advantage:	None; pre-authorization required

4. Required Review and Approvals:

Etanercept (Enbrel®) injections require prior authorization by the CHP Medical Director or his/her designee.

5. References:

1. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis: 2002 Update. *Arthritis Rheum* 2002;46:328-46.
2. Furst DE, et al. Updated consensus statement on biological agents for the treatment of rheumatoid arthritis and other rheumatic diseases. *Ann Rheum Dis* 2002 May;61(Suppl 2):ii2-ii7.
3. Immunex Corporation. Enbrel® (etanercept) prescribing information. Thousand Oaks (CA): Immunex Corporation; 2003 Oct.
4. Van de Kerkhof PCM. Comparisons and combinations. In: van de Kerkhof PCM, editor. *Textbook of psoriasis*. Osney Mead (Oxford): Blackwell Science Ltd; 1999:275-283.
5. Krueger JG. The immunologic basis for the treatment of psoriasis with new biologic agents. *J Am Academy Dermatol* 2002;46:1-23.
6. Milliman Care Guidelines, 11th Edition, 2007.