

Blue Cross Blue Shield of Vermont and The Vermont Health Plan Prior Approval Guidelines Enbrel® (etanercept)

Description: Etanercept binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors. TNF is a naturally occurring cytokine involved in the body's inflammatory and immune responses.

- Indications:**
- ◆ For reduction in signs and symptoms and inhibition of the progression of structural damage in patients with moderately to severely active Rheumatoid Arthritis (RA). Enbrel® can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone
 - ◆ For the reduction in signs and symptoms of arthritis in patients with Psoriatic Arthritis; may be used in combination with methotrexate
 - ◆ For reducing the signs and symptoms in patients with active ankylosing spondylitis
 - ◆ For reduction in signs and symptoms of moderately to severely active Polyarticular juvenile idiopathic arthritis in patients who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs)
DMARDs include:
Hydroxychloroquine (Plaquenil®), Azathioprine (Imuran®), Sulfasalazine (Azulfidine®), Cyclophosphamide (Cytoxan®), Cyclosporine (Neoral®/Sandimmune®), Methotrexate (Rheumatrex®), Leflunomide
 - ◆ Treatment of adult patients (18 years or older) with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy

Reasons for Prior Authorization: Cost Potential for misuse Toxicity

- Criteria for Approval:**
- 1) Diagnosis is an FDA-Labeled Indication (moderately to severely active Rheumatoid Arthritis, psoriatic arthritis, psoriasis, ankylosing spondylitis, Polyarticular juvenile idiopathic arthritis) **and**
 - 2) Patient has demonstrated a negative tuberculin skin test **and**
 - 3) Patient has no contraindications to treatment (See Below) **and**
 - 4) Patient is at least **2** years of age or older.

Benefit Approval

Initial approval: 12 weeks at which time patient should be evaluated for response to therapy. If patient is responding to therapy, an additional 9 months will be approved. ONLY dispensed in 30 days supplies.

- Reasons for Denial of Benefit:**
- 1) Patient has the following **contraindication**
 - a) Sepsis/ Active Infection
 - b) History of hypersensitivity to Enbrel or any of its components
 - 2) Patient does not meet above criteria

- References:**
1. Enbrel® Prescribing Information, Wyeth Ayerst & Immunex Corporation. Seattle, WA 2002.
 2. Baumgartner SW. Tumor Necrosis Factor Inactivation in the Management of Rheumatoid Arthritis. *South Med J*; 2000 93(8): 753-759.
 3. Baton JM, Martin RW, Fleischmann RM, et.al. A Comparison of Etanercept and Methotrexate in Patients with Early Rheumatoid Arthritis. *NEJM*; November 30, 2000; 343: 1586-1593.
 4. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis. *Arthritis & Rheumatism* 2002; 46(2): 328-346.