Commercial/Healthcare Exchange PA Criteria

Effective: December 2004

Prior Authorization: Enbrel

Products Affected: Enbrel (etanercept) subcutaneous solution

Medication Description: TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. It plays an important role in the inflammatory processes of RA, polyarticular JIA, PsA, and AS and the resulting joint pathology. In addition, TNF plays a role in the inflammatory process of PsO. Elevated levels of TNF are found in involved tissues and fluids of patients with RA, JIA, PsA, AS, and PsO.

Two distinct receptors for TNF (TNFRs), a 55 kilodalton protein (p55) and a 75 kilodalton protein (p75), exist naturally as monomeric molecules on cell surfaces and in soluble forms. Biological activity of TNF is dependent upon binding to either cell surface TNFR.

Etanercept is a dimeric soluble form of the p75 TNF receptor that can bind TNF molecules. Etanercept inhibits binding of TNF-α and TNF-β (lymphotoxin alpha [LT-α]) to cell surface TNFRs, rendering TNF biologically inactive. In in vitro studies, large complexes of etanercept with TNF-α were not detected and cells expressing transmembrane TNF (that binds Enbrel) are not lysed in the presence or absence of complement.

Covered Uses:

1. Rheumatoid Arthritis
2. Polyarticular Juvenile Idiopathic Arthritis
3. Psoriatic Arthritis
4. Ankylosing Spondylitis—REM--
5. Plaque Psoriasis

Exclusion Criteria: Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

Juvenile idiopathic arthritis: 2 years of age or older.
Plaque psoriasis: 4 years of age or older.
Ankylosing spondylitis, Psoriatic arthritis, Rheumatoid arthritis: 18 years of age or older.

Prescriber Restrictions:

Psoriatic Arthritis: Must be prescribed by, or in consultation with, a dermatologist or rheumatologist.
Rheumatoid Arthritis/Ankylosing Spondylitis/ Juvenile idiopathic arthritis: Must be prescribed by, or in consultation with, a rheumatologist.
Plaque Psoriasis: Must be prescribed by, or in consultation with, a dermatologist.

Coverage Duration:
Initial: 3 months
Continuation: 3 years

Other Criteria:

Dosing Limitations: Only allow additional quantity for loading dose purposes
Subcutaneous Adult Dosage Regimen (Ankylosing spondylitis, Rheumatoid arthritis, Psoriatic arthritis)
1. ***The recommended dose is 50 mg weekly***

Subcutaneous Adult Dosage Regimen (Plaque Psoriasis)
1. ***The recommended dose in adult patients is 50mg twice weekly for 3 months, then 50mg once weekly thereafter***

Subcutaneous Pediatric Dosage Regimen (Plaque Psoriasis and Juvenile Idiopathic Arthritis)
1. ***The recommended dose in patients weighing 63kg or more is 50mg weekly***
2. ***The recommended dose in patients weighing 63kg or less is 0.8mg/kg weekly***

*Note: Enbrel is a preferred product for RA, PsA, JIA, and AS and does not require the use of Humira first

Rheumatoid Arthritis, Psoriatic Arthritis, Polyarticular juvenile idiopathic arthritis:
A. The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy**; AND**
B. The patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine).

Plaque psoriasis
A. Patient has chronic (greater than or equal to 1 year) plaque psoriasis; **AND**
B. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; **AND**
C. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed;* **AND**
D. Patient has failed an adequate trial of **Humira**. [documentation required]

Ankylosing Spondylitis
A. The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 therapy

Continuation
A. Patient meets all initial authorization criteria; AND
B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Enbrel as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Enbrel over methotrexate.

References:

1. ENBREL(R) subcutaneous injection, etanercept subcutaneous injection. Immunex Corporation (per FDA), Thousand Oaks, CA, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019
2	Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019
3	Update	CCI Adopted EH template CCI P&T Review History:12/04, 12/05, 12/06, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 11/16, 11/17, 11/18 CCI Revision Record: 10/13, 9/14, 2/16, 11/16, 5/17, 9/18, 1/19	All	7/3/2019
4	Update	Removed DMARD requirement for AS diagnosis	Other Criteria	7/22/2019

5	Update	Added Dosing Limitations according to FDA label	Other Criteria	5/5/2020