Commercial PA Criteria

Effective: January 1, 2019

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
5. Plaque Psoriasis

Exclusion Criteria:

1. Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
2. Crohn's Disease
3. Inflammatory Myopathies (Polymyositis, Dermatomyositis, Inclusion Body Myositis
4. Hidradenitis Suppurativa.
5. Polymyalgia Rheumatica (PMR).
6. Sarcoidosis.
7. Large Vessel Vasculitis (e.g., Giant Cell Arteritis, Takayasu's Arteritis).
8. Wegener's Granulomatosis.

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

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

Prescriber Restrictions:

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

Coverage Duration:

Initial: 6 months
Continuation: 1 year

Other Criteria:

1. **Ankylosing Spondylitis**
   Initial therapy: Approve if the patient meets the following criteria
   A. Patient has clinically diagnosed ankylosing spondylitis **AND**
   B. Prescribed by or in consultation with a rheumatologist.

2. Juvenile Idiopathic Arthritis (JIA).
Initial therapy: Approve if the patient meets the following criteria
Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

A. Patient has tried one other systemic medication for this condition; **OR**
Note: Examples of other systemic therapy for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count.

B. Patient will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; **OR**
Note: Examples of other systemic therapy for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested drug also counts as a trial of one agent for JIA. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.

C. Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; **OR**
Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.

D. Patient has aggressive disease, as determined by the prescriber

3. **Plaque Psoriasis**.
Initial Therapy. Approve if the patient meets ALL of the following criteria
   A. Patient is ≥ 4 years of age; **AND**
   B. Patient meets one of the following conditions (i **OR** ii):
      i. Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; **OR**
      Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already has a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. . A

patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

ii. Patient has a contraindication to methotrexate, as determined by the prescriber

4. **Psoriatic Arthritis**.
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has clinically diagnosed psoriatic arthritis **AND**
   B. Prescribed by or in consultation with a rheumatologist or dermatologist

5. **Rheumatoid Arthritis**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD
   Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already had a 3-month trial with at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 6 months of therapy with Enbrel as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Enbrel® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Immunex/Amgen; June 2023.

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	Removal of DMARD use for Ankylosing Spondylitis	Other Criteria	07/19/2019

4	Update	Addition to Exclusion Criteria; Crohn's Disease, Inflammatory Myopathies, Polymyositis, Dermatomyositis, Inclusion Body Myositis, Hidradenitis Suppurativa, Polymyalgia Rheumatica (PMR), Sarcoidosis, Large Vessel Vasculitis (e.g., Giant Cell Arteritis, Takayasu's Arteritis), Wegener's Granulomatosis. Removal of *EmblemHealth does not consider alcohol use to be a clinical reason to use Enbrel over methotrexate. Removal of: Dosing Limitations 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). Ankylosing Spondylitis A.The patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy. 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 AND D. Patient has failed an adequate trial of preferred Adalimumab Product. Coverage duration update: Initial was 3 months changed to 6 months. Continuation changed from 3 years to 1 year Selected Revision to update to label.	Exclusion criteria	12/18/2023