Overview
Etanercept is a recombinant DNA-derived protein composed of tumor necrosis factor receptor (TNFR) linked to the Fc portion of human IgG1. Etanercept binds tumor necrosis factor (TNF) and blocks its interaction with cell surface receptors.

Coverage Guidelines
Authorization may be granted for members who are currently receiving treatment with Enbrel, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members meeting all the following diagnosis-specific criteria and documentation is provided.

1. Moderately to severely active rheumatoid arthritis (RA)
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week) OR
   b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

2. Moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)
   a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate OR,
   b. Member has intolerance or contraindication to methotrexate (see Appendix A).

3. Active psoriatic arthritis (PsA)
   a. Member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide OR,
   b. Member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.
4. **Active ankylosing spondylitis (AS) and nonradiographic axial spondyloarthritis (nr-axSpA)**
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) **OR**
   b. Member has an intolerance or contraindication to two or more NSAIDs.

5. **Moderate to severe chronic plaque psoriasis**
   a. Member has at least 5% of body surface area (BSA) is affected **OR** crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected **AND**
   b. Member meets **ANY** of the following criteria:
      i. Member has had an inadequate response or intolerance to TWO conventional therapies in any of the following combinations:
         I. 1 topical agent + 1 systemic agent (acitretin, cyclosporine, methotrexate)
         II. 1 topical agent + 1 phototherapy
         III. 1 systemic agent + 1 phototherapy
         IV. 2 systemic agents
      OR member meets any of the following:
      i. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

**Continuation of Therapy**
Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member’s condition.

**Limitations**
1. Approvals will be granted for 24 months.
2. **For all indications**, member must have a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).*
   a. Note: * Members who have received Enbrel or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from all requirements related to TB screening in this Policy.

**Appendices**
**Appendix A: Examples of Contraindications to Methotrexate**
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction
Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Alcoholism, alcoholic liver disease, or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

References


Review History
03/21/2005 – Reviewed
05/15/2005 – Effective
02/27/2006 – Reviewed
02/25/2008 – Reviewed
02/23/2009 – Reviewed
02/22/2010 – Reviewed
02/28/2011 – Reviewed
02/27/2012 – Reviewed
02/25/2013 – Reviewed
02/24/2014 – Reviewed
02/23/2015 – Reviewed
02/22/2016 – Reviewed
02/2017 – Reviewed (switched to SGM)
02/26/2018 – Reviewed (switched to Custom) in P&T Meeting
02/20/2019 – Reviewed
07/22/2020 – Reviewed and updated July P&T Mtg; reworded overview; removed compendial use of reactive arthritis; changed diagnosis of axial spondyloarthritis to nonradiographic axial spondyloarthritis. Effective 10/01/2020.

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