

# Drug Therapy Guidelines

## Enbrel® (etanercept)

*Applicable*

<b>Medical Benefit</b>		<b>Effective: 1/1/18</b>
<b>Pharmacy- Formulary 1</b>	x	<b>Next Review: 12/18</b>
<b>Pharmacy- Formulary 2</b>	x	<b>Date of Origin: 2/00</b>
<b>Pharmacy- Formulary 3/Exclusive</b>	x	<b>Review Dates: 2/1/00, 1/6/01, 9/18/01, 1/15/02, 1/7/03, 1/20/04, 1/18/05, 12/7/05, 10/15/06, 11/5/07, 12/15/08, 12/09, 1/11, 9/11, 9/12, 9/13, 9/14, 12/15, 12/16, 12/17</b>
<b>Pharmacy- Formulary 4/AON</b>	x	

### I. Medication Description

Etanercept binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors (TNFRs). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

### III. Policy

Coverage for Enbrel is provided for the following conditions when the listed criteria are met:

- Ankylosing spondylitis (active disease):
  - Prescribed by a rheumatologist **AND**
  - The member has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)
- Juvenile idiopathic arthritis:
  - Prescribed by a rheumatologist **AND**
  - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)
- Plaque psoriasis (moderate to severe disease):
  - Prescribed by a rheumatologist or dermatologist **AND**
  - At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
  - Member has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
  - Member has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated **AND**
    - Member is under the age of 18 (child/adolescent) **OR**
    - Member is 18 years of age or older (adult) **AND**
      - Has tried therapy with plan-preferred medication (Humira) first **OR** the following criteria have been met:
        - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has resulted in inadequate results

**AND**

- At least one of the following is met:
  - The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
  - The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member's prescription drug regimen.
  - The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
  - The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where "stable" is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
  - The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member's adherence or to compliance with the member's plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member's ability to achieve or maintain reasonable functional ability in performing daily activities.
- Psoriatic arthritis (active disease):
  - Prescribed by a rheumatologist or dermatologist **AND**
  - One of the following:
    - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)
- OR**
- If predominantly axial disease is documented, the member has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)
- Rheumatoid arthritis (moderate to severe disease):
  - Prescribed by a rheumatologist **AND**
  - Member has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)

IV. Quantity Limitations

- Psoriasis: 400 mg per 28 days for first 84 days, then 200 mg per 28 days
- All other indications: 200 mg per 28 days

V. Coverage Duration

Initial coverage is provided for 12 months and may be renewed.

#### VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Clinical response and remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug

#### VII. Billing/Coding Information

- Available as:
  - 50mg single-use prefilled syringe
  - 50mg single-use prefilled SureClick autoinjector
  - 50 mg solution in Enbrel Mini™ single-dose pre-filled cartridge for use with the AutoTouch™ reusable autoinjector only
  - 25mg single-use prefilled syringe
  - 25mg multiple-use vial
- Pertinent indications:
  - Plaque Psoriasis and Psoriatic arthritis: L40.0 – L40.9
  - Rheumatoid arthritis: M05.0 – M05.9, M05.60 - M06.9
  - Juvenile rheumatoid arthritis: M08.0, M08.2, M08.3, M08.4
  - Ankylosing spondylitis: M45.0 – M45.9

#### VIII. Summary of Policy Changes

- 4/1/11:
  - Clarification of prior DMARD use requirements
  - Clarification of preferred medications: Humira and Enbrel
- 1/1/12: no changes
- 12/15/12: Addition of Black Box Warning for malignancy
- 12/15/13: no policy changes
- 1/1/15:
  - clarified when topical therapy in psoriasis is first required
  - PsA guidelines updated to include recommendations for axial disease
  - requirements for one non-biologic DMARD in RA setting clarified
- 7/1/15: formulary distinctions made, removal of need for Tb testing on members not at high risk
- 3/15/16: no policy changes
- 1/1/17: Humira preferred over Enbrel for the treatment of adult plaque psoriasis
- 5/1/17: step therapy criteria added
- 1/1/18: available products updated

### XIII. References

1. Up-to-date Online, retrieved November 2017
2. Clinical Pharmacology Online, retrieved November 2017
3. Facts and Comparisons Online, retrieved November 2010
4. Product Information: Enbrel (etanercept). Revised 10/2017
5. Singh JA, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2012 May;64(5):625-39.
6. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *American College of Rheumatology*. DOI 10.1002/acr.21641.
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9. Menter A, et al. Guidelines of care for management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol*. 2008;58:851-64.
10. Coates LC, et al. The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics. *Rheumatology*. 2013;52(10):1754-1757.
11. Singh J, Reston J, Gladman D, et al.. American College of Rheumatology (ACR) and National Psoriasis Foundation (NPF) Psoriatic Arthritis Guideline. *American College of Rheumatology*. November 2016.
12. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J American Academy Dermatol*. Volume 58, Number 5.
13. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *American College of Rheumatology*. 2015 DOI 10.1002.

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*