Policies Repository

Independence Blue Cross

Policy Title	Etanercept (Enbrel®)
Policy Number	FS.CLIN.27

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Etanercept (Enbrel®) is indicated for the treatment of moderate to severe rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis (JIA) and moderate to severe plaque psoriasis.

The use of etanercept (Enbrel®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Etanercept (Enbrel®) is a biologic agent, a dimeric fusion protein that consists of the extracellular ligand-binding portion of the human tumor necrosis factor (TNF) receptor linked to human immunoglobulin G1 (IgG1). TNF is a naturally occurring protein in the human body that is involved in normal inflammatory and immune responses. Etanercept (Enbrel®) reduces disease activity by binding specifically to TNF and limiting its inflammatory activity in the body. By reducing TNF to normal levels, etanercept (Enbrel®) has been shown to produce symptomatic relief in individuals.

Policy Guideline Inclusion

Etanercept (Enbrel®) is approved when **any** of the following inclusion criteria is met:

- Documentation of a diagnosis of moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis or Psoriatic Arthritis and ALL of the following:
  - Patient is an adult (≥ 18 years)
  - Medication is being recommended and prescribed by a rheumatologist
  - Patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
    - Methotrexate
    - Hydroxychloroquine
    - Leflunomide
    - Azathioprine
    - Sulfasalazine

        - Adalimumab (Humira®)
    - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
    - Patient does not have active infections or sepsis
    - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
    - Patient does not have active malignancy

- Documentation of a diagnosis of moderate to severe Juvenile Idiopathic Arthritis (JIA) and ALL of the following:
    - Patient is ⩾ 2 years old
    - Medication is being recommended and prescribed by a rheumatologist
    - Patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
        - Methotrexate
        - Hydroxychloroquine
        - Leflunomide
        - Azathioprine
        - Sulfasalazine
        - Adalimumab (Humira®)
    - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
    - Patient does not have active infections or sepsis
    - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
    - Patient does not have active malignancy

- Documentation of a diagnosis of moderate to severe chronic Plaque Psoriasis and ALL of the following:
    - Patient is an adult (⩾ 18 years)
    - Medication is being recommended and prescribed by a dermatologist
    - Patient had at least a 30 day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
        - Topical Calcipotriene containing products
        - Topical Anthralin
        - Topical Steroids
        - Topical immunomodulators (Elidel®, Protopic®)
        - Topical retinoids
        - Efudex
        - Adalimumab (Humira®)
    - Patient is not on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
    - Patient does not have active infections or sepsis
    - Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis
    - Patient does not have active malignancy

Policy Guideline Exclusion

For a diagnosis of moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis or Psoriatic Arthritis, **Etanercept (Enbrel®)** is denied when **any** of the following exclusion criteria is present:

- Patient is less than 18 years old
- Medication is not being prescribed by a rheumatologist

- Patient does not have at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) or contraindication to ALL of the following DMARDs:
  - Methotrexate
  - Hydroxychloroquine
  - Leflunomide
  - Azathioprine
  - Sulfasalazine
  - Adalimumab (Humira®)
- Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
- Patient has active malignancy

For a diagnosis of moderate to severe Juvenile Idiopathic Arthritis (JIA), **Etanercept (Enbrel®)** is denied when **any** of the following exclusion criteria is present:

- Patient is less than 2 years old
- Medication is not being prescribed by a rheumatologist
- Patient does not have at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) or contraindication to ALL of the following DMARDs:
  - Methotrexate
  - Hydroxychloroquine
  - Leflunomide
  - Azathioprine
  - Sulfasalazine
  - Adalimumab (Humira®)
- Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
- Patient has active malignancy

For a diagnosis of moderate to severe chronic Plaque Psoriasis, **Etanercept (Enbrel®)** is denied when **any** of the following exclusion criteria is present:

- Patient is less than 18 years old
- Medication is not being prescribed by a dermatologist
- Patient does not have at least a 30 day trial and failure with ONE of the following drugs OR contraindication to ALL of the following drugs:
  - Topical Calcipotriene containing products
  - Topical Anthralin
  - Topical Steroids
  - Topical immunomodulators (Elidel®, Protopic®)
  - Topical retinoids
  - Efudex
  - Adalimumab (Humira®)
- Patient is on concurrent therapy with Anakinra (Kineret®) or other tumor necrosis factor

antagonists
- Patient has active infections or sepsis
- Patient has not been evaluated using tuberculin skin test
- Patient has active or latent tuberculosis
- Patient has active malignancy

Policy List of Applicable Drugs

Brand Name	Generic Name
Enbrel	Etanercept

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

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Policy Link to Related Policies

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