

## Specialty Pharmacy Program

### Enbrel® (etanercept)

#### DESCRIPTION

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, juvenile idiopathic arthritis, and psoriatic arthritis.

#### APPROVAL DURATION AND QUANTITY LIMITS

Approval duration: lifetime

Quantity limits:

- Chronic Plaque Psoriasis:
  - Initial Therapy (12 weeks): 8 injections (50 mg/ml) per 28 days
  - Continuation of Therapy: 4 injections (50 mg/ml) per 28 days
- Rheumatoid Arthritis (RA) OR Juvenile Idiopathic Arthritis OR Psoriatic Arthritis OR Ankylosing Spondylitis:
  - 8 injections (25 mg/ml) per 28 days or
  - 4 injections (50 mg/ml) per 28 days

#### APPROVAL CRITERIA

- I. None of the following are present:
  - A. Tuberculosis, or other active serious infections, or a history of recurrent infections.
  - B. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
  - C. Moderate to severe (NYHA Class III/IV) Congestive Heart Failure (CHF).
  - D. Latex allergy as Enbrel pre-filled syringe cover contains latex.
  - E. Concurrent administration of live vaccines.
  - F. Patient is currently receiving cyclophosphamide therapy, other TNF antagonists, anakinra (Kineret), or abatacept (Orencia).
- II. Active Ankylosing Spondylitis
  - A. Patient is 18 years of age or older, AND
  - B. Patient has diagnosis of Ankylosing Spondylitis AND
  - C. Patient has had an inadequate response to conventional treatment (below), or such therapy is contraindicated or not tolerated.
    1. Non-steroidal anti-inflammatory drugs (ibuprofen, naproxen, others)
    2. Methotrexate
    3. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
- III. Chronic Plaque Psoriasis
  - A. Patient is 18 years of age or older, AND
  - B. Patient has a diagnosis of moderate to severe plaque psoriasis with either of the following:
    1. Patient has greater than 10% of body surface area with plaque psoriasis OR
    2. Less than or equal to 10% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND
  - C. Patient's disease is not controlled with topical therapy, AND
  - D. Patient has had an inadequate response to phototherapy or systemic therapies, or such therapy is contraindicated or not tolerated:

1. Methotrexate
2. Acitretin (Soriatane)
3. Cyclosporine (Neoral, Sandimmune)

#### IV. Rheumatoid Arthritis

- A. Patient is 18 years of age or older, AND
- B. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
  1. Auranofin (Ridaura)
  2. Azathioprine (Imuran)
  3. Cyclophosphamide (Cytoxan or Neosar)
  4. Cyclosporine (Neoral or Sandimmune)
  5. Gold sodium thiomalate (Myochrysine)
  6. Hydroxychloroquine (Plaquenil)
  7. Leflunomide (Arava)
  8. Methotrexate
  9. Minocycline (Minocin or Dynacin)
  10. Penicillamine (Cuprimine, Depen)
  11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

#### V. Juvenile Idiopathic (previously known as Juvenile Rheumatoid Arthritis) Arthritis

- A. Patient is 2 years of age or older, AND
- B. Patients with a diagnosis of moderate to severe active polyarticular-course juvenile idiopathic arthritis (JIA) (previously known as Juvenile Rheumatoid arthritis or JRA) AND
- C. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
  1. Auranofin (Ridaura)
  2. Azathioprine (Imuran)
  3. Cyclophosphamide (Cytoxan or Neosar)
  4. Cyclosporine (Neoral or Sandimmune)
  5. Gold sodium thiomalate (Myochrysine)
  6. Hydroxychloroquine (Plaquenil)
  7. Leflunomide (Arava)
  8. Methotrexate
  9. Minocycline (Minocin or Dynacin)
  10. Penicillamine (Cuprimine, Depen)
  11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

#### VI. Psoriatic Arthritis

- A. Patient is 18 years of age or older, AND
- B. Patient has active arthritis, with at least 3 swollen joints and 3 tender joints AND
- C. Patient has arthritis in any of the following distributions:
  1. Distal interphalangeal joint involvement
  2. Polyarticular arthritis, without rheumatoid nodules
  3. Arthritis mutilans
  4. Asymmetric arthritis
  5. Ankylosing spondylitis-like arthritis AND
- D. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
  1. Auranofin (Ridaura)
  2. Azathioprine (Imuran)
  3. Cyclophosphamide (Cytoxan or Neosar)
  4. Cyclosporine (Neoral or Sandimmune)
  5. Gold sodium thiomalate (Myochrysine)
  6. Hydroxychloroquine (Plaquenil)
  7. Leflunomide (Arava)

8. Methotrexate
9. Minocycline (Minocin or Dynacin)
10. Penicillamine (Cuprimine, Depen)
11. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
  - i. Enbrel (etanercept) may be administered with methotrexate if patient is not responding adequately to methotrexate alone.