Approval Criteria Department of Pharmacy Services

Generic Name: etanercept
Brand Name: Enbrel®
Medication Class: TNF Inhibitor

FDA Approved Uses
- Ankylosing spondylitis – for reducing signs and symptoms in patients with active ankylosing spondylitis
- Plaque psoriasis – in adults 18 years and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Polyarticular juvenile idiopathic arthritis – for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years and older
- Psoriatic arthritis – for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Etanercept can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone
- Rheumatoid arthritis – for reducing the signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Etanercept can be initiated in combination with methotrexate or used alone

Criteria for use
- Rheumatoid Arthritis (RA)
  - Must be 18 years of age or older
  - Clinical diagnosis of moderately to severely active RA
  - Trial and failure, or contraindication to, one or more non-biologic disease modifying anti-rheumatic agent (DMARDs) [azathioprine, 6-mercaptopurine, methotrexate]
- Plaque psoriasis
  - Must be 18 years of age or older
  - Clinical diagnosis of chronic moderate to severe plaque psoriasis with EITHER of the following:
    - Plaque psoriasis involving greater than 5% of body surface area (BSA)
    - Plaque psoriasis involving less than 5% of BSA involving sensitive areas or areas that would significantly impact daily function (palms, soles of feet, head/neck, or genitalia)
  - Trial and failure, or contraindication to, phototherapy or other systemic therapies (methotrexate, acitretin, or cyclosporine)
- Ankylosing spondylitis
  - Must be 18 years of age or older
  - Clinical diagnosis of active Ankylosing spondylitis
  - Trial and failure, or contraindication to, conventional therapy (NSAIDs or non-biologic DMARDs)
- Juvenile idiopathic arthritis
  - Age 2 and older
  - Clinical diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis (JIA)
  - Trial and failure, intolerance to, or contraindication to, one or more non-biologic disease modifying anti-rheumatic agents (DMARDs)
- Psoriatic arthritis
  - Must be age 18 years and older
  - Clinical diagnosis of active psoriatic arthritis
  - Trial and failure to, intolerance to, or contraindication to one or more non-biologic DMARD

Not Approved For
- Any indication or criteria not met above
- If used in combination with any other TNF agent
- If used in combination with the following non-TNF immunomodulatory drugs: abatacept, anakinra or cyclophosphamides
- Tuberculosis, invasive fungal infection, other serious infection, or a history of recurrent infections
- Individuals who have not had a tuberculin skin test, or CDC-recommended equivalent, to evaluate for latent tuberculosis
- Treatment of asthma
- Treatment of disc-herniation-induced radiculopathy or sciatica
- Treatment of Graft-versus-Host disease
- Treatment of inclusion-body myositis
- Treatment of inflammatory bowel disease
- Hidradenitis suppurative
- Sarcoidosis
- Septic shock
- Sjogren’s syndrome
- Wegener’s granulomatosis

Required Medical Information
- Clinical documentation of diagnosis (medical record)
- Clinical documentation of past medical history with dates of treatments and response to therapy
- Pharmacy claims history to support previous treatment

Contraindications
- Sepsis
- Active or latent tuberculosis

Dosing
- Ankylosing spondylitis
  - 50mg weekly subcutaneously
- Plaque psoriasis
  - Initial - 50mg twice weekly subcutaneously for 3 months
  - Maintenance – 50mg weekly subcutaneously
- Psoriatic arthritis
  - 50mg weekly subcutaneously
- Rheumatoid arthritis
  - 50mg weekly subcutaneously.
Authorization

- Chronic Plaque psoriasis
  - Initial – 12 weeks (8 injections / 28 days)
  - Continuation – 1 year (4 injections / 28 days)
- RA / JIA / PA / AS
  - 1 year

Approved by P&T: 07/16/2013, Reviewed: 3/18/2014

References


