

Specialty Pharmacy Program

Cimzia® (certolizumab pegol)

DESCRIPTION

Cimzia is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis and Crohn's disease.

APPROVAL DURATION AND QUANTITY LIMITS

Approval duration: lifetime

Quantity limits:

- One pack or kit (2 x 200 mg vials) per 28 days
- One syringe kit (2 x 200 mg/ml syringes) per 28 days
- May approve three additional packs (2 x 200 mg vials) or syringe kits (2 x 200 mg/ml syringes) one time only for the first month for initial dosing.

APPROVAL CRITERIA

I. Cimzia is considered NOT medically necessary for patients with any of the following:

- A. Tuberculosis or other active serious infections, including chronic or localized infections.
- B. Individuals who have not had a tuberculin skin (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis.
- C. Currently receiving other TNF blockers, anakinra (Kineret), or abatacept (Orencia).
- D. Any other indication not listed.

II. Crohn's Disease

- A. Patient is 18 years of age or older; AND
- B. Patient has a diagnosis of moderate to severe Crohn's disease; AND
- C. Patient has had an inadequate response to conventional therapy, or such therapy is contraindicated or not tolerated:
 1. 5-Aminosalicylates
 - i. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
 - ii. Mesalamine (Asacol, Pentasa, Lialda, Apriso)
 2. Systemic corticosteroids (eg, prednisone)
 3. Azathioprine (Imuran)
 4. 6-Mercaptopurine
 5. Methotrexate
 6. Cyclosporine (Neoral, Sandimmune)
 7. Antibiotics (eg, metronidazole)

III. Rheumatoid Arthritis (RA)

- A. Patient is 18 years of age or older; AND
- B. Patient has a diagnosis of moderately to severely active RA; 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)
- D. Patient has failed to respond to, is intolerant of, or has a medical contraindication to Remicade (infliximab), Enbrel (etanercept), or Humira (adalimumab).