Specialty Pharmacy Program

Simponi® (golimumab)

DESCRIPTION

Simponi is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.

APPROVAL DURATION AND QUANTITY LIMITS

Approval duration: lifetime

Quantity limits: 1 pre-filled syringe (50 mg/0.5 mL) OR 1 pre-filled SmartJect Autoinjector (50 mg/0.5 mL) per 28 days

APPROVAL CRITERIA

I. None of the following are present:
   A. Currently receiving other TNF antagonists, abatacept (Orencia), or anakinra (Kineret).
   B. Tuberculosis, invasive fungal infections, other active serious infections, or a history of recurrent infections.
   C. Individuals who have not had a tuberculin skin test (TST) or a CDC-recommended equivalent to rule out latent tuberculosis.

II. Rheumatoid Arthritis
   A. Patient must be 18 years of age or older AND
   B. Patient has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND
   C. Patient is taking Simponi in combination with methotrexate or with another immunosuppressive agent if the patient is intolerant to methotrexate; 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, AND:
      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)
   E. Patient has had an inadequate response to Enbrel (etanercept), Humira (adalimumab) or Remicade (infliximab), or such therapy is contraindicated or not tolerated.

III. Psoriatic Arthritis
   A. Patient is 18 years of age or older; AND
   B. Patient has a diagnosis of active Psoriatic Arthritis; AND
   C. Patient has had an inadequate response to conventional therapy (eg, nonbiologic disease modifying anti-rheumatic agents [DMARDs]), or such therapy is contraindicated or not tolerated, AND:
      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 had an inadequate response to Enbrel (etanercept), Humira (adalimumab) or Remicade (infliximab), or such therapy is contraindicated or not tolerated.

IV. Active Ankylosing Spondylitis

A. Patient is 18 years of age or older AND
B. Patient has a diagnosis of active ankylosing spondylitis AND
C. Patient has had an inadequate response to conventional therapy (eg, nonbiologic disease modifying anti-rheumatic agents [DMARDs]), or such therapy is contraindicated or not tolerated, AND:
    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)
C. Patient has had an inadequate response to Enbrel (etanercept), Humira (adalimumab) or Remicade (infliximab), or such therapy is contraindicated or not tolerated.