Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

SIMPONI® (golimumab)

GPI CODING:

66270040002020

DESCRIPTION:

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

APPROVAL DURATION:

Approval duration: 3 years for all diagnoses except Ulcerative Colitis (UC)
For UC, initial approvals are for 8 weeks and all renewals are yearly

Quantity limit:
1 pre-filled syringe (50 mg/0.5 mL) OR 1 pre-filled SmartJect Autoinjector (50 mg/0.5 mL) per 28 days
For UC, initial loading dose of 4 syringes for 28 days, then 1 syringe per 28 days

CRITERIA FOR SIMPONI

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 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)

   AND

E. Patient has had an inadequate response, intolerance, or confirmed adverse event to Enbrel (etanercept) and Humira (adalimumab) OR has contraindication to Enbrel or Humira

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:
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)

AND
D. Patient has had an inadequate response, intolerance, or confirmed adverse event to Enbrel and Humira OR has a contraindication to Enbrel or Humira

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:
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)

AND
D. Patient has had an inadequate response, intolerance, or confirmed adverse event to Humira AND
E. Patient has had an inadequate response, intolerance, or confirmed adverse event to Enbrel OR patient has extra-articular manifestations of ankylosing spondylitis (eg, uveitis)

V. Moderate to Severe Ulcerative Colitis
A. Patient is 18 years of age or older AND

B. Patient has had an inadequate response to conventional therapy, or such therapy is contraindicated or not tolerated:
   1. sulfasalazine (Azulfidine, Azulfidine Entabs)
   2. Mesalamine (Asacol, Pentasa, Apriso, Lialda, Rowasa, Canasa)
   3. Azathioprine (Imuran)
   4. 6-mercaptopurine
   5. Budesonide (Entocort EC, Uceris)

AND

C. Patient has had an inadequate response, intolerance, or confirmed adverse event to Humira or Remicade OR has a contraindication to Remicade or Humira AND

D. For renewals, the patient must have achieved clinical remission while on Simponi