SPECIALTY GUIDELINE MANAGEMENT

SIMPONI (golimumab for subcutaneous injection)

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA)
- Active ankylosing spondylitis (AS)
- Moderately to severely active ulcerative colitis (UC)

Compendial Uses
- Axial spondyloarthritis

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Pretreatment tuberculosis (TB) screening with TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) and TB treatment status (if applicable) documented in member’s chart or medical record
  - Members who have received at least a 28-day supply of Simponi, any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) through a pharmacy or medical benefit in the previous 120 days of the continuation request are exempted from requirements related to TB screening and treatment in this Policy.

C. EXCLUSIONS
- Untreated latent TB infection
  - Treatment must be initiated prior to starting Simponi.
- Active tuberculosis infection
  - Treatment must be completed prior to starting Simponi.

D. CRITERIA FOR APPROVAL
1. Moderately to severely active rheumatoid arthritis (RA)
   a. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Simponi, any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Simponi.

   i. Simponi must be prescribed in combination with methotrexate (MTX) unless the member has contraindication or intolerance to MTX.

Contraindications to MTX – Examples:
- History of intolerance or adverse event
- Alcoholic liver disease or other chronic liver disease
- Elevated liver transaminases
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Renal impairment
- Pregnancy or planning pregnancy (male or female)
- Breastfeeding
b. Authorization of 24 months may be granted for members who meet BOTH of the following criteria:
   i. Member is prescribed Simponi in combination with methotrexate (MTX) or has contraindication or intolerance to MTX.
   ii. Member meets at least one of the following criteria:
       a) Inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to 25-30 mg/week)
       b) Intolerance or contraindication to MTX (See 1.a. above).
       c) Inadequate response to at least a 3-month trial of a prior biologic DMARD or a targeted synthetic DMARD (e.g., Xeljanz)
       d) Intolerance to a prior biologic or targeted synthetic DMARD
       e) Severely active RA that warrants a biologic DMARD as first-line therapy

2. Active psoriatic arthritis (PsA)
   a. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Simponi or any other biologic DMARD indicated for active psoriatic arthritis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Simponi.
   b. Authorization of 24 months may be granted for members who meet ANY of the following criteria:
      i. Member has experienced an inadequate response to at least a 3-month trial of MTX, sulfasalazine, or leflunomide
      ii. Member has intolerance or contraindication to MTX, sulfasalazine, or leflunomide.
         Contraindications to MTX, sulfasalazine, or leflunomide – Examples:
         - History of intolerance or adverse event
         - Alcoholic liver disease or other chronic liver disease
         - Elevated liver transaminases
         - Interstitial pneumonitis or clinically significant pulmonary fibrosis
         - Renal impairment
         - Pregnancy or planning pregnancy
         - Breastfeeding
         - Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
         - Myelodysplasia
         - Hypersensitivity
         - Significant drug interaction
         - Intestinal obstruction
         - Urinary obstruction
         - Porphyria
      iii. Member has experienced an inadequate response to at least a 3-month trial of a prior biologic DMARD.
      iv. Member has experienced intolerance to a prior biologic DMARD.
      v. Member’s condition is severely active as evidenced by ANY of the following:
         a) Multiple swollen joints
         b) Structural damage in the presence of inflammation
         c) Clinically relevant extra-articular manifestations
            Extra-articular manifestations of psoriatic arthritis – Examples:
            - Cutaneous involvement
            - Psoriasis
            - Erythema nodosum
            - Keratoderma blenorrhagicum
            - Circinate balanitis
            - Pyoderma gangrenosum
Extra-articular manifestations of psoriatic arthritis – Examples (continued):

- Bowel involvement
  - Crohn’s disease (CD),
  - Ulcerative colitis (UC)
  - A specific colitis (in presence of inflammatory bowel disease (IBD) that cannot be classified as CD or UC)
  - Severe and persistent diarrhea

- Ocular involvement
  - Uveitis
  - Conjunctivitis

- Cardiovascular involvement
  - Aortic insufficiency
  - Conduction disturbances (e.g., atrioventricular blocks, bundle branch blocks, and intraventricular blocks)
  - Thrombosis
  - Phlebitis

- Urogenital involvement
  - Urethritis
  - Prostatitis
  - Balanitis
  - Vaginitis
  - Cervicitis amyloidosis (AA type)
  - IgA nephropathy

- Pulmonary involvement: Apical pulmonary fibrosis

vi. Member has active enthesitis and/or dactylitis (i.e., sausage digit) and/or predominant axial disease (i.e., extensive spinal involvement).

3. Active ankylosing spondylitis (AS) and axial spondyloarthritis

a. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Simponi or any other biologic DMARD indicated for active ankylosing spondylitis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Simponi.

b. Authorization of 24 months may be granted for members who meet ALL of the following criteria:
   i. Member has experienced an inadequate response to at least two NSAIDs over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose, OR has intolerance and/or contraindication to 2 or more non-steroidal anti-inflammatory drugs.
   **Intolerance and contraindications to NSAIDs – Examples:**
   - History of intolerance or adverse event
   - Asthma
   - Urticaria
   - Allergic-type reaction following aspirin or other NSAID administration
   - Gastrointestinal bleeding
   - Significant drug interaction

   ii. Member has at least one of the following:
   a) Predominant axial disease (i.e., extensive spinal involvement)
   b) Inadequate response to a synthetic DMARD (e.g., sulfasalazine)
   c) Intolerance or contraindication to a synthetic DMARD
   d) Inadequate response to at least a 3-month trial of a prior biologic DMARD
   e) Intolerance to a prior biologic DMARD
4. Moderately to severely active ulcerative colitis (UC)
   a. Authorization of 24 months may be granted for members who have received at least a 28-day supply of Simponi or any other biologic DMARD indicated for moderately to severely active ulcerative colitis in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Simponi.
   b. Authorization of 24 months may be granted for members who meet ANY of the following criteria:
      i. Member has corticosteroid dependence as evidenced by ANY of the following:
         a) Member requires continuous corticosteroid therapy.
         b) Corticosteroids cannot be successfully tapered without a return of ulcerative colitis symptoms.
      ii. Member has an inadequate response, intolerance or contraindication to at least ONE conventional therapy option:
         Conventional therapy options for UC – Examples (not all-inclusive):
         - Mild to moderate disease – induction of remission:
           o Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
           o Rectal mesalamine (e.g., Canasa, Rowasa)
           o Rectal hydrocortisone (e.g., Colocort, Cortifoam)
           o Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
         - Mild to moderate disease – maintenance of remission:
           o Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
           o Alternatives: azathioprine, mercaptopurine, sulfasalazine
         - Severe disease – induction of remission:
           o Prednisone, hydrocortisone IV, methylprednisolone IV
           o Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
         - Severe disease – maintenance of remission:
           o Azathioprine, mercaptopurine
           o Alternative: sulfasalazine
         - Pouchitis: Metronidazole, ciprofloxacin
           o Alternative: rectal mesalamine

E. CONTINUATION OF THERAPY
Authorization of 24 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Simponi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. Dosing Limits
   The following dosing limits apply:
   a. Ulcerative colitis
      - Initial loading dose for the initial 14 days: 200 mg total
      - Maintenance dose: 100 mg per 28 days
   b. All other indications
      - 50 mg per 30 days

REFERENCES


