Reference number(s)
2014-A

SPECIALTY GUIDELINE MANAGEMENT

SIMPONI (golimumab for subcutaneous injection)

POLICY

I. 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.

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

B. Compendial Uses
1. Axial spondyloarthritis

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

II. CRITERIA FOR INITIAL APPROVAL

A. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 24 months may be granted for members who have previously received Simponi or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis. Simponi must be prescribed in combination with methotrexate unless the member has a contraindication or intolerance to methotrexate (see Appendix A).

2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
   a. Member is prescribed Simponi in combination with methotrexate or has a contraindication or intolerance to methotrexate.
   b. Member meets any of the following criteria:
      i. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
      ii. Member has an intolerance or contraindication to methotrexate.

B. Active psoriatic arthritis (PsA)

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

C. Active ankylosing spondylitis (AS) and axial spondyloarthritis

1. Authorization of 24 months may be granted for members who have previously received Simponi or any other biologic DMARD indicated for active ankylosing spondylitis.

2. Authorizations of 24 months may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when any of the following criteria is met:
   a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
   b. Member has an intolerance or contraindication to two or more NSAIDs.

D. Moderately to severely active ulcerative colitis (UC)

1. Authorization of 24 months may be granted for members who have previously received Simponi or any other biologic indicated for moderately to severely active ulcerative colitis.

2. Authorization of 24 months may be granted for treatment of moderately to severely active UC when any of the following criteria is met:
   a. Member has corticosteroid dependence as evidenced by any of the following:
      i. Member requires continuous corticosteroid therapy.
      ii. Corticosteroids cannot be successfully tapered without a return of ulcerative colitis symptoms.
   b. Member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).

III. 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.

IV. OTHER

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Simponi or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

V. APPENDICES

Appendix A: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Conventional Therapy Options for UC

1. Mild to moderate disease – induction of remission:

a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
b. Rectal mesalamine (e.g., Canasa, Rowasa)
c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine

2. Mild to moderate disease – maintenance of remission:
   a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
   b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
   a. Prednisone, hydrocortisone IV, methylprednisolone IV
   b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
   a. Azathioprine, mercaptopurine
   b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
   a. Alternative: rectal mesalamine

VI. REFERENCES

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