SPECIALTY GUIDELINE MANAGEMENT

SIMPONI ARIA (golimumab injection for intravenous use)

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.

FDA-Approved Indications
Moderately to severely active rheumatoid arthritis, in combination with methotrexate

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

II. CRITERIA FOR INITIAL APPROVAL

Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 24 months may be granted for members who have received Simponi Aria or any other biologic DMARD or targeted synthetic DMARD (e.g. Xeljanz) indicated for the treatment of moderate to severe RA in a paid claim through a pharmacy or medical benefit in the previous 120 days of the initial request for Simponi Aria. Simponi Aria must be prescribed in combination with methotrexate unless the member has a contraindication or intolerance to methotrexate (see Appendix).

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 Aria in combination with methotrexate or has a contraindication or intolerance to methotrexate.
b. Member meets any of the following criteria:
   - o 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).
   - o Member has an intolerance or contraindication to methotrexate (See Appendix).

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 Aria 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 Aria or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) in a paid claim through a pharmacy or medical benefit in the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

V. APPENDIX: 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

VI. REFERENCES

1. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2016.
2. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. *Ann Rheum Dis.* 2014;73:492-509.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol.* 2016;68(1)1-26.
4. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* 2008;59(6):762-784.