Simponi Aria
(golimumab injection for intravenous use)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Simponi Aria drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. 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

1. Adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
2. Active psoriatic arthritis (PsA) in patients 2 years of age and older
3. Adult patients with active ankylosing spondylitis (AS)
4. Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older

Compendial Uses

Oligoarticular juvenile idiopathic arthritis

POLICY

Criteria for Initial Approval

A. Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g. Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis. Simponi Aria must be prescribed in combination with

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methotrexate unless the member has a clinical reason not to use methotrexate (see Appendix A).

2. Authorization of 12 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 clinical reason not to use 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 (See Appendix A).

B. Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

C. Active articular juvenile idiopathic arthritis

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD indicated for active articular juvenile idiopathic arthritis
2. Authorization of 12 months may be granted for treatment of active articular juvenile idiopathic arthritis when any of the following criteria are met:
   a). The member has had an inadequate response to methotrexate or another non-biologic DMARD administered at an adequate dose and duration.
   b). The member has risk factors (See Appendix C) and the member also meets one of the following:
      a. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
      b. High disease activity.
      c. Are judged to be at high risk for disabling joint disease.

D. Active ankylosing spondylitis (AS)

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis 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 (see Appendix B).

<u>Continuation of Therapy</u>

Authorization of 12 months may be granted for all members (including new members) who are using Simponi Aria for an indication outlined in the Criteria for Initial Approval and who achieve or maintain positive clinical response with Simponi Aria as evidenced by low disease activity or improvement in signs and symptoms of the condition.

<u>Other</u>

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs associated with an increased risk of TB, and repeated yearly for members with risk factors** for TB that are continuing therapy with biologics.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease. Do not administer golimumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of golimumab.

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** Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Simponi Aria concomitantly with any other biologic DMARD or targeted synthetic DMARD

Simponi Aria is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

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

Appendix

Appendix A: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, 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 currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

Appendix B: Examples of Contraindications to the Use of NSAIDs

1. Allergic-type reaction following aspirin or other NSAID administration
2. Asthma
3. Gastrointestinal bleeding
4. History of intolerance or adverse event
5. Significant drug interaction
6. Urticaria

Appendix C: Risk factors for Articular Juvenile Idiopathic Arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1602 Injection, golimumab, 1 mg, for intravenous use

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.13
Reviewed: January 2021
Revised: February 2021
Current Effective Date: March 1, 2021

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