Simoni Aria® (golimumab)

Effective Date: 05/03/2018

FDA approval: 2013
HCPCS: J1602
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when the member is ≥ 18 years of age and when all of the below criteria are met. Coverage requests must be supported by submission of chart notes and patient specific documentation.

   a. Rheumatoid arthritis (RA): treatment of patients with moderately to severely active RA when all of the following criteria are met:
      i. Prescribing physician is a rheumatologist
      ii. Used in combination with methotrexate
      iii. Treatment failure with preferred therapies

   b. Psoriatic arthritis (PsA): treatment of patients with active PsA when all of the following criteria are met:
      i. Prescribing physician is a dermatologist or rheumatologist
      ii. Treatment failures with preferred therapies

   c. Ankylosing spondylitis (AS); treatment of patients with active AS when all of the following criteria are met:
      i. Prescribing physician is a rheumatologist
      ii. Treatment failures with preferred therapies

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Limited to FDA-labeled dosing
   b. Initial Authorization Period: 1 year
   c. Renewal Criteria: RA, PsA, AS
      i. Continuation of coverage requires documentation of beneficial clinical response to Simoni Aria
      ii. Approval duration: 1 year

C. Simoni Aria is considered investigational when used for all other conditions, including but not limited to:
   a. Non-FDA labeled indications

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Therapeutic considerations:

A. FDA approved indication / Diagnosis
   - Simponi Aria is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with:
     - Moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate
     - Active Psoriatic Arthritis (PsA)
     - Active Ankylosing Spondylitis (AS)

   *Please refer to most recent prescribing information. [http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf]*

B. Background Information
   a. AS
      i. The prevalence of ankylosing spondylitis is 0.1% to 1.4%. Ankylosing spondylitis is a long-term inflammatory disease. In the patient’s vertebrae and joints this condition leads to excessive formation of new bone and this can lead the vertebrae to fuse. This condition can be very painful and debilitating and lead to irreversible spinal damage. According to the updated ASAS/EULAR (Assessment of SpondyloArthritis International Society/European League against Rheumatism) guidelines anti-TNF therapy should be used in patients with high disease activity despite the use of conventional treatments.

   b. PsA
      i. Psoriatic arthritis is a long-term inflammatory disease of the joints and skin affecting between 0.3% and 1% of the general population. This condition can lead to significant disability and reduced life expectancy. Psoriatic arthritis is associated with psoriasis and approximately 30% of patients who have psoriasis also have psoriatic arthritis. Possible first line therapy for psoriatic arthritis includes methotrexate, TNF blockade or combination of these therapies.

   c. RA
      i. Rheumatoid arthritis is a chronic inflammatory, autoimmune disease with a prevalence of approximately 1% and an annual incidence of 0.04%. Up to 50% of patients with RA are unable to work 10 years after diagnosis. Non steroidal anti-inflammatory drugs (NSAIDs) have little effect on the underlying course of RA, but they have some anti-inflammatory and analgesic properties. Disease modifying antirheumatic drugs (DMARDs) have been shown to slow progression of RA and are currently recommended early in the course of treatment of RA which is when disease progression is most rapid.

   Cross References
   Drug Review

C. Efficacy
   a. RA
      i. Approval based on large-scale, Phase 3, double-blind, placebo-controlled study involving 592 patients.

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1. **GO-FURTHER**: 59% of patients receiving treatment with Simponi Aria plus methotrexate versus 25% of patients receiving placebo plus methotrexate a difference with 95% (CI 25.9, 41.4) experienced significant improvements in signs and symptoms at week 14, as demonstrated by at least 20% improvement in American College of Rheumatology criteria (ACR 20 – a standard measure used to assess clinical improvement in RA), the study’s primary endpoint. A higher proportion of patients receiving SIMPONI ARIA plus methotrexate achieved at least a 50 percent improvement in ACR criteria (ACR 50) compared with patients receiving placebo plus methotrexate at week 14 (30 percent versus 9 percent, respectively, a difference with 95 percent CI 15.3, 27.2).

   b. **PsA & AS**
      i. Approvals based on two large-scale, pivotal Phase 3 studies involving more than 600 patients:
         1. **GO-VIBRANT** (PsA): 75% of patients ≥ 18 years of age receiving Simponi Aria, compared with 22% of patients receiving placebo (P < 0.001), achieved at least a 20% improvement in the American College of Rheumatology (ACR20) response at week 14. Treatment with Simponi Aria resulted in the inhibition of the progression of structural joint damage and improvement in physical function associated with PsA at week 24.
         2. **GO-ALIVE** (AS): 73% of patients ≥ 18 years of age receiving Simponi Aria, compared with 26% of patients receiving placebo (P < 0.001), achieved at least a 20% improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS20) at week 16 (ASAS20 - a standard measure used to assess clinical improvement in AS

*Please refer to most recent prescribing information.

**D. Medication Safety Considerations**

Black Box Warning: Yes

*Please refer to most recent prescribing information.

**E. Dosing and administration**

   a. Dosing:
      i. RA, PsA, AS
      1. 2 mg/kg intravenous infusion at weeks 0, 4, then every 8 weeks.

*Please refer to most recent prescribing information.

**F. How supplied**

   a. Vials
      i. Packs of 1 vial: each single-use vial contains 50mg of Simponi Aria per 4 mL of solution

**References:**


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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm

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