Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

**Effective Date: 02/14/2019**

**Simponi Aria® (golimumab)**

**FDA approval:** 2013  
**HCPCS:** J1602  
**Benefit:** Medical

**Policy:**

*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 all the following are met:**

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. Treatment with one DMARD is ineffective after at least a three-month trial, except if contraindicated or not tolerated based on clinical documentation. Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquin, cyclosporine, gold and penicillamine  
   iii. Used in combination with methotrexate (unless contraindicated)  
   iv. Trial and failure of all preferred agents as specified in the BCBSM/BCN drug list

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 with one DMARD is ineffective after at least a three-month trial, except if contraindicated or not tolerated based on clinical documentation. Examples of DMARDs include: methotrexate, sulfasalazine, cyclosporine, and leflunomide  
   iii. Trial and failure of all preferred agents as specified in the BCBSM/BCN drug list

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. Trial and failure of all preferred agents as specified in the BCBSM/BCN drug list

d. **Will not be used in combination with other biologics (including but not limited to: Humira, Infliximab, Stelara, Cosentyx, Actemra)**

**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 Simponi Aria
ii. Approval duration: 1 year

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

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

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

   *Please refer to most recent prescribing information.
   https://www.simponiaria.com/

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.

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<th>Cross References</th>
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<td>Guidelines for Treatments of Advanced Rheumatoid Arthritis</td>
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This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
C. Efficacy

*Please refer to most recent prescribing information.

D. Medication Safety Considerations

a. Boxed Warning: Yes

*Please refer to most recent prescribing information.

E. Dosing and administration

a. Dosing: 2 mg/kg intravenous infusion at weeks 0, 4, then every 8 weeks.

*Please refer to most recent prescribing information.

F. How supplied

a. 50 mg/4 mL single-use vials

References:

Policy History

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<td>-Updated criteria for PsA diagnosis</td>
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<td>-Updated language regarding combination therapy with other biologics</td>
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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