Simponi Aria (golimumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### ANKYLOSING SPONDYLITIS (AS)

For **initial** authorization:
1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member has had back pain for 3 months or more that began before the age of 45; AND
5. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
6. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
   a) Arthritis;
   b) Elevated serum C-reactive protein;
   c) Inflammation at the tendon, ligament or joint capsule insertions;
   d) Positive HLA-B27 test;
   e) Limited chest expansion;
   f) Morning stiffness for 1 hour or more; AND
7. Member meets at least one of the following scenarios:
   a) Member has Axial (spinal) disease;
   b) Member has peripheral arthritis without axial involvement and has tried and failed treatment with methotrexate or sulfasalazine. Treatment failure requires at least 3 months of therapy without an adequate response; AND
8. Member has tried and failed to respond to treatment with at least two prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response; AND
9. Member has tried and failed treatment with **both** Enbrel and Humira.
10. **Dosage allowed:** 50 mg subcutaneously once a month.

**If member meets all the requirements listed above, the medication will be approved for 12 months.**
For **reauthorization**:  
1. Must have been retested for TB with a negative result within the past 12 months; AND  
2. Member must be in compliance with all other initial criteria; AND  
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.  

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.**

### PSORIATIC ARTHRITIS (PsA)  
For **initial authorization**:  
1. Member must be 18 years of age or older; AND  
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND  
3. Medication must be prescribed by a rheumatologist or dermatologist; AND  
4. Member has tried and failed treatment with both Enbrel and Humira; AND  
5. Member meets at least one of the following scenarios:  
   a. Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence;  
   b. Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e. limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy without an adequate response;  
   c. Member has predominately non-axial disease and has tried and failed to respond to treatment with at least an 8 week trial of methotrexate and NSAID.  
6. **Dosage allowed**: 50 mg subcutaneously once a month.  

**If member meets all the requirements listed above, the medication will be approved for 12 months.**

For **reauthorization**:  
1. Must have been retested for TB with a negative result within the past 12 months; AND  
2. Member must be in compliance with all other initial criteria; AND  
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.  

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.**

### RHEUMATOID ARTHRITIS (RA)  
For **initial** authorization:  
1. Member must be 18 years of age or older with moderate to severe active RA; AND  
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND  
3. Medication must be prescribed by a rheumatologist; AND  
4. Medication is being given in combination with methotrexate or with another immunosuppressive agent if the member cannot tolerate methotrexate; AND  
5. Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks; AND
6. Member must have tried and failed treatment with both Enbrel and Humira.
7. **Dosage allowed:** 2 mg/kg intravenous infusion over 30 minutes at weeks 0 and 4, then every 8 weeks.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

For **reauthorization**:
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

CareSource considers Simponi Aria (golimumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Crohn’s disease
- Dissecting scalp cellulitis
- For use in combination with TNF-inhibitors (Enbrel, Humira, Remicade, Kineret)
- Giant-cell arteritis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis
- Takayasu’s arteritis
- Ulcerative colitis
- Vogt-Koyanagi

### DATE ACTION/DESCRIPTION

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
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<tbody>
<tr>
<td>05/10/2017</td>
<td>New policy for Simponi Aria created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.</td>
</tr>
<tr>
<td>11/13/2017</td>
<td>New indications of AS and PsA added.</td>
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</table>

References:


Effective date: 11/29/2017
Revised date: 11/13/2017