CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Simponi Aria (golimumab)
BILLING CODE	J1602 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel, Humira, Cosentyx QUANTITY LIMIT— 120 units every 56 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Humira, Cimzia and Cosentyx. Treatment failure requires at least for 12 weeks of therapy with each drug; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Current imaging results show an inflammation of one or both of the sacroiliac joints; AND
7. 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
8. 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
9. 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 with each NSAID without an adequate response.
10. **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.

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)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member must have tried and failed treatment with at least **two** of the following: Enbrel, Humira, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug; 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 with each NSAID without an adequate response;
   c) Member has predominately non-axial disease (e.g., peripheral synovitis or dactylitis or nail involvement) and has tried and failed to respond to treatment with at least 8-week trial of methotrexate and NSAID taken at the maximum recommended dosages (if unable to tolerate or has contraindication to methotrexate than 8-week trial of sulfasalazine or azathioprine or cyclosporine).
6. **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.

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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)) within 12 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 has tried and failed treatment with at least **two** of the following: Actemra, Cimzia, Enbrel, Humira, Kevzara, Olumiant and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
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
05/10/2017	New policy for Simponi Aria created. Policy SRx-0042 archived. List of diagnoses considered not medically necessary was added.
11/13/2017	New indications of AS and PsA added.
02/26/2019	Dosing information corrected. Humira was removed from criteria; Actemra, Cimzia, Cosentyx, Kevzara, Olumiant, Otezla and Xeljanz added to trial agents list. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. References added. Symptoms of back pain for AS extended till before age of 50. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
01/23/2020	Updated trial agents to match Ohio Department of Medicaid Unified Preferred Drug List.

References:

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