PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Simponi Aria (golimumab)

5. Member has had an adequate trial and failure of a non-biologic DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
6. Member must have tried and failed treatment with both Enbrel and Actemra. Treatment failure requires at least 12 weeks of therapy with each drug.
7. Dosage allowed/Quantity limit: 80 mg/m^2 (body surface area) intravenous infusion at week 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met , the medication will be approved for 12 months.

For reauthorization :
1. Chart notes have been provided showing improvement of signs and symptoms of disease.

If all the above requirements are met , the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For initial authorization:
1. Member must be 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or a dermatologist; AND
3. Member has a documented diagnosis of active psoriatic arthritis (PsA); AND
4. Member has had a negative tuberculosis test within the past 12 months;
5. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless one of the following situations is met:
   a) Non-biologic DMARD is not required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are not required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi Aria).
7. Dosage allowed/Quantity limit:
   Adults: 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.
   Pediatrics: 80 mg/m2 (BSA) intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met , the medication will be approved for 6 months.

For reauthorization :
1. Chart notes have been provided showing improvement of signs and symptoms of disease (ie. decreased joint swelling and pain, improved skin appearance, improved quality of life, etc).

If all the above requirements are met , 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; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;

Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine; AND

5. Simponi Aria will be given in combination with methotrexate or with another conventional DMARD if member is unable to tolerate methotrexate; AND
6. Member has tried and failed at least two preferred biologic DMARDs for at least 3 months each, one of which must be another TNF inhibitor (same class as Simponi Aria); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. Dosage allowed/Quantity limit: 2 mg/kg intravenous infusion at weeks 0 and 4, and every 8 weeks thereafter.

If all the above requirements are met , the medication will be approved for 12 months.

For reauthorization :

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

If all the above requirements are met , the medication will be approved for an additional 12 months.

CareSource considers Simponi Aria (golimumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off- Label policy.

DATE	

References:

1. Simponi Aria [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: February 2021.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2019 Oct;71(10):1599-1613. doi: 10.1002/art.41042. Epub 2019 Aug 22.
3. . (10)6.1 H1454 ((bo>>BDp k0.5 (r)-1.3 n (:)3.6 (5 ((y)0.9/)45);.9G)0.6 (Jal)1.un;g9 6 (71 (10)645 6)-2)1. (:)3.4 (:)0.5 (71)-

Appendix : Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Juvenile Idiopathic Arthritis	• Actemra *(requires step through Humira)* • Enbrel • Humira
Approved for Ankylosing Spondylitis	• Cosentyx • Enbrel • Humira • Rinvoq
Approved for Non-radiographic Axial	• Cimzia • Cosentyx
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Cosentyx • Enbrel • Humira • Otezla • Skyrizi • Stelara • Tremfya
Approved for Psoriasis	• Cosentyx • Enbrel • Humira • Humira