CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Simponi Aria (golimumab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Simponi Aria is a tumor necrosis factor (TNF) alpha-inhibitor initially approved by the FDA in 2017 for rheumatoid arthritis. Since that time, Simponi Aria has been approved for three additional indications: psoriatic arthritis, ankylosing spondylitis and polyarticular juvenile idiopathic arthritis. This medication is given as an intravenous infusion.

Simponi Aria (golimumab) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS)

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 active AS; AND
4. Member shows at least **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; 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 have been provided showing improvement of signs and symptoms of disease such as decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc.

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

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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; AND
3. Member has a confirmed diagnosis of active pJIA; AND

4. Member has had an adequate trial and failure of a conventional DMARD (e.g., methotrexate, leflunomide, etc.) for 8 weeks, unless not tolerated or contraindicated; AND
5. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; AND
6. Member has had a negative tuberculosis test within the past 12 months.
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 such as decreased joint swelling and pain and improved quality of life.

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 PsA; AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated dose AND a 3-month trial of a conventional DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Conventional DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and conventional 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
5. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; AND
6. Member has had a negative tuberculosis test within the past 12 months.
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 (body surface area) 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 such as 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.
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 **TWO** preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor; 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 such as 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	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.
10/12/2020	New diagnosis of pJIA added. Replaced list of excluded diagnoses with the generic statement. Updated references. For all diagnoses: Removed repeat TB in reauth for all diagnoses. For AS: Removed list of symptoms of spondyloarthritis because imaging result should be sufficient. Removed peripheral arthritis requirement – not relevant for this diagnosis. For PsA: Age requirement expanded to 2 years or older. Updated dosing and biologic trials reflective of age label change. Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). For RA: Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
01/24/2022	Transferred to new template. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1. Removed Xeljanz, Olumiant from try first options per recent JAK inhibitor label changes; also

	changed from other specific drug names to say 2 preferred biologics one of which is a TNF inhibitor. Added preferred biologic trial with TNFi and Clarified reauth criteria for PsA and AS.
08/09/2024	AS: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; removed criteria requiring back pain for 3 or more months before the age of 50 and inflammation of one or both of the sacroiliac joints and added that member must have elevated CRP or sacroiliitis on MRI per EULAR 22 guidelines pJIA: added examples of improvement in reauthorization criteria; changed non-biologic DMARD to conventional DMARD; changed trial of Enbrel and Actemra to trial of two preferred biologic DMARDs for 3 months each, one of which must be a TNF inhibitor. PsA: changed non-biologic DMARD to conventional DMARD 11/19/2024 Approved by ODM

References:

1. Simponi Aria [prescribing information]. Horsham, PA; Janssen Biotech, Inc.; 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. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis.* 2023;82(1):19-34. doi:10.1136/ard-2022-223296
4. Deodhar A, Reveille JD, Harrison DD, et al. Safety and Efficacy of Golimumab Administered Intravenously in Adults with Ankylosing Spondylitis: Results through Week 28 of the GO-ALIVE Study [published correction appears in J Rheumatol. 2018 Feb;45(2):291]. *J Rheumatol*. 2018;45(3):341-348.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guidelines for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res* (Hoboken). 2019 Jun;71(6):717-734.
6. Ruperto N, Brunner HI, Pacheco-Tena C, et al. Open-label phase 3 study of intravenous golimumab in patients with polyarticular juvenile idiopathic arthritis. *Rheumatology (Oxford).* 2021;60(10):4495-4507. doi:10.1093/rheumatology/keab021
7. Kavanaugh A, et al. Golimumab in psoriatic arthritis: one-year clinical efficacy, radiographic, and safety results from a phase III, randomized, placebo-controlled trial. *Arthritis Rheum*. 2012 Aug;64(8):2504-17.
8. Michelon MA, et al. Role of golimumab, a TNF-alpha inhibitor, in the treatment of the psoriatic arthritis. *Clin Cosmet Investig Dermatol*. 2010;3:79-84.
9. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021 [published correction appears in Nat Rev Rheumatol. 2022 Dec;18(12):734. doi: 10.1038/s41584-022-00861-w]. *Nat Rev Rheumatol.* 2022;18(8):465-479. doi:10.1038/s41584-022-00798-0
10. Coates LC, Kavanaugh A, Mease PJ, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis 2015 Treatment Recommendations for Psoriatic Arthritis. *Arthritis Rheumatol*. 2016 May;68(5):1060-71.
11. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis*. 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531
12. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
13. Smolen JS, Landewé RBM, Bijlsma JWJ, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. *Ann Rheum Dis*. 2020;79(6):685-699.
14. Smolen JS. Insights into the efficacy of golimumab plus methotrexate in patients with active rheumatoid arthritis who discontinued prior anti-tumour necrosis factor therapy: post-hoc analyses from the GO-AFTER study. *Ann Rheum Dis*. 2014 Oct;73(10):1811-8.
15. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752

16. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
17. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
18. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov

Effective date: 01/01/2025
Revised date: 08/09/2024