

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 Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel & Humira (if appropriate for indication) 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.

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
- Ankylosing Spondylitis
- 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 pernio
- 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.

References:

1. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011 Feb 7. [Epub ahead of print].
2. National Institutes of Health, Clinicaltrials.gov. [cited 9/16/2014]; Available from: <http://www.clinicaltrials.gov>.
3. Singh, J., et al., (2012). 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Anti-rheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*, 64(5), 625-639.
4. Rheumatoid Arthritis. *Arthritis & Rheumatology (Arthritis Care & Research)*, 64:5, 625-639, May 2012.
5. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2014.
6. *Gastroenterology*. 2013 Dec;145(6):1459-63.
7. Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2015.
8. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF- α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013 Dec;145(6):1459-63.
9. Simponi [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: January, 2014.
10. Simponi Aria [prescribing information]. Horsham, PA; Janssen Biotech, Inc.: December, 2014.
11. Higgins J, Green S, editors. Cochrane handbook for systematic reviews of interventions, Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. Available from: URL:www.cochrane-handbook.org.
12. FDA Approves New Drug for Rheumatoid Arthritis; *Pharmacist's Letter*; March 2010; Vol: 26 Rheumatoid arthritis: the role of DMARDs. *Pharmacist's Letter/Prescriber's Letter* July 2012;25(2):250210.

