

<u>Targeted Immunomodulators</u> Simponi Aria (golimumab for infusion) Effective 06/01/2025

Plan	☑ MassHealth UPPL☐ Commercial/Exchange		⊠ Prior Authorization	
Benefit	☐ Pharmacy Benefit ☑ Medical Benefit	Program Type	☐ Quantity Limit☐ Step Therapy	
Specialty Limitations	N/A			
	Medical and Specialty Medications			
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693	
Information	Non-Specialty Medications			
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029	
	Simponi Aria is also available on the pharmacy benefit. Please see the MassHealth Drug			
Notes	<u>List</u> for coverage and criteria.			
Hotes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.			

Overview

Simponi Aria is a tumor necrosis factor (TNF) blocker indicated for:

- Treatment of moderately to severely active Rheumatoid Arthritis (RA)
- Treatment of ankylosing spondylitis
- Treatment of psoriatic arthritis (PsA)
- Treatment of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with Simponi Aria excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Rheumatoid Arthritis (RA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)

- 1. Diagnosis of **ONE** of the following:
 - a. Moderate to severe rheumatoid arthritis
 - b. Moderate to severe polyarticular juvenile idiopathic arthritis
- 2. **ONE** of the following:
 - a. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARD (see Appendix)
 - b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
- 3. Appropriate dosing

4. Prescriber provides clinical rationale for use of Simponi Aria instead of Enbrel and Humira

Psoriatic Arthritis (PsA)

- 1. Diagnosis of psoriatic arthritis
- 2. Appropriate dosing
- 3. Prescriber provides clinical rationale for use of Simponi Aria instead of Enbrel and Humira

Ankylosing spondylitis (AS)

- 1. Diagnosis of anklyosing spondylitis
- 2. Inadequate response or adverse reaction to TWO NSAIDs or contraindication to ALL NSAIDs
- 3. Appropriate dosing
- 4. Prescriber provides clinical rationale for use of Simponi Aria instead of Enbrel and Humira

More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics may be approved if ALL of the following is provided:

- 1. Severe disease
- 2. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** other injectable biologic which is FDA-approved for the requested indication
- 3. Partial response to FDA-approved dosing of current biologic therapy
- 4. Specialist consult for the requested indication

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Limitations

- 1. Initial approvals will be for 6 months.
- 2. Reauthorizations will be for 12 months.
- 3. New members currently stable on Simponi Aria can be approved without documentation of failed trials with the conventional therapies if they have a documented history of hospitalization for one of the above immune conditions.

Appendix

Examples of Traditional DMARDs

Traditional DMARDs			
azathioprine			
cyclosporine			
hydroxychloroquine			
leflunomide			
methotrexate			
sulfasalazine			
thalidomide			

References

1. Simponi Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; Feb 2025.



- 2. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017; 0:1-18.
- 3. SBraun J, Baraliakos X, Hermann KG, et al. The effect of two golimumab doses on radiographic progression in ankylosing spondylitis: results through 4 years of the GO-RAISE trial. Ann Rheum Dis 2014; 73:1107.
- 4. Weinblatt ME, Bingham CO 3rd, Mendelsohn AM, et al. Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GOFURTHER trial. Ann Rheum Dis. 2013 Mar; 72(3):381-9

Review History

02/22/10 - Reviewed

04/05/10 - Effective

02/28/11 - Reviewed

02/27/12 - Reviewed

02/25/13 - Reviewed

01/13/14 – Reviewed and revised (Simponi Aria update; 08/26/13 file & plan decision wt-based QL applied to PA)

02/23/15 - Reviewed

02/22/16 - Reviewed

02/27/17 - Reviewed and revised (adopted SGM& ST) in P&T Meeting

03/01/18 – Reviewed (adopted MH RS)

02/20/19 - Reviewed in P&T Meeting

10/21/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

03/17/2021 – Reviewed and Updated; Added moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) to criteria. Effective 06/01/2021.

01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members with a documented history of hospitalization. Added examples of traditional DMARDs and higher dosing criteria to appendix. Effective 3/1/23.

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Moved "More Frequent or Higher Doses" criteria to Coverage Guidelines. Effective 6/1/25

