

Simponi Aria (golimumab for infusion)
Effective 03/01/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

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)

Prescriber provides documentation of **ALL** of the following:

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. Paid claims or physician documented inadequate response or adverse reaction to **ONE** or contraindication to **ALL** traditional DMARD (see Appendix B)
 - b. Paid claims or physician documented 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)

Prescriber provides documentation of **ALL** of the following:

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)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of ankylosing spondylitis
2. Paid claims or physician documented 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®

† Requests for more frequent or higher doses – see Appendix C

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.

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. The following quantity limits apply:

Simponi Aria Solution 50mg	4 units per 8 weeks
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Appendix A: Dosing

Simponi Aria (golimumab for infusion)	Rheumatoid arthritis (moderate-severe), Psoriatic arthritis, and Ankylosing spondylitis: 2 mg/kg IV at weeks 0 and 4, then every 8 weeks in combination with methotrexate
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Appendix B. Examples of Traditional DMARDs

Traditional DMARDs*
azathioprine
cyclosporine
hydroxychloroquine*
leflunomide
methotrexate*
sulfasalazine*
thalidomide



Appendix C. 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. Physician documentation of 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

References

1. Simponi Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; May 2018.
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.

