Mass General Brigham
Health Plan

Simponi Aria (golimumab for infusion)
Effective 06/30/2023

Plan	☒ MassHealth PUF ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
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	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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)**

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. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Simponi Aria instead of Enbrel® and Humira®

Psoriatic Arthritis (PsA)
ALL of the following:

1. Diagnosis of psoriatic arthritis
2. Appropriate dosing †
3. **If reviewing under Pharmacy Benefit:** Prescriber provides clinical rationale for use of Simponi Aria instead of Enbrel® and Humira®

Ankylosing spondylitis (AS)
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. **If reviewing under Pharmacy Benefit:** 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

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

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.
06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement for requests through the MB. Effective 6/30/23