

Simponi Aria (golimumab)
Effective 01/01/2024

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input 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.		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Golimumab is a tumor necrosis factor (TNF) inhibitor that suppresses the physiologic response to tumor necrosis factor, which is part of the inflammatory response.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
2. Active psoriatic arthritis (PsA)
3. Active ankylosing spondylitis (AS)
4. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)

Authorization may be granted 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 when the following criteria is met:

1. The member has a diagnosis of moderate to severely active rheumatoid arthritis (RA)
2. Member has minimum duration of a 3-month trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses:
 - a. Methotrexate
 - b. Leflunomide
 - c. Sulfasalazine

Active psoriatic arthritis (PsA)

Authorization may be granted 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 when the following criteria is met:

1. The member has a diagnosis of active psoriatic arthritis (PsA)
2. The member meets ONE of the following:
 1. Actively inflamed joints
 2. Dactylitis
 3. Enthesitis
 4. Axial disease
 5. Active skin and/or nail involvement

Active ankylosing spondylitis (AS)

Authorization may be granted 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 when the following criteria is met:

1. The member has a diagnosis of active ankylosing spondylitis
2. Member has minimal duration of 1-month trial and failure, contraindication, or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) at maximally tolerated doses.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Authorization may be granted 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 when the following criteria is met:

1. The member has a diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis (PJIA)
2. Member has a minimal duration of a 6-week trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses:
 - a. Leflunamide
 - b. Methotrexate

Continuation of Therapy

Reauthorization may be granted for members who achieve or maintain positive clinical response after at least 3 months of therapy with Simponi Aria as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months
2. The following quantity limits apply:

Simponi	4 per 8 weeks
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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 – Implemented

02/28/11 – Reviewed

02/27/12 – Reviewed

02/25/13 – Reviewed

08/26/13 – Weight-based QL applied to PA

01/13/14 – Simponi Aria update

02/24/14 – Reviewed

02/23/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Adopted SGM & PDS

02/26/18 – Updated

02/20/19 – Updated

11/20/19 – Added Rinvoq as a preferred trial for RA. Added UC indications to Simponi. Combined Simponi and Simponi Aria

10/31/2020 – Reviewed; Updated criteria for Comm/Exch strategy for implementation on 1/1/21. Separated out Simponi and Simponi Aria.

09/22/2022 – Reviewed and Updated for Sept P&T. Updated QL to allow for 4 inj per 8 weeks in line with FDA dosing. Effective 11/1/2022.

11/15/2023 – Reviewed and Updated for Nov P&T; Removed Appendices. Removed TB requirement. For Psoriatic arthritis: removed conventional therapies and added examples of active PSA. Rheumatoid arthritis: updated conventional therapies to include methotrexate, leflunomide, sulfasalazine. Added indication of Polyarticular Juvenile Idiopathic Arthritis (PJIA). Effective 1/1/2024

