

**Simponi (golimumab)  
Effective 11/01/2022**

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	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
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	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. Ulcerative colitis [(UC)

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, 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 had a documented inadequate response or intolerable adverse event with Enbrel, Humira AND Rinvoq or a clinical reason to avoid these products



3. Member meets one of the following:
  - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
  - b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

#### **Active psoriatic arthritis (PsA)**

Authorization may be granted for members new to plan who are currently receiving treatment with Simponi, 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. Member has had a documented inadequate response or intolerable adverse event with Cosentyx, Enbrel, Humira, Stelara, Otezla, Rinvoq AND Skyrizi or a clinical reason to avoid these products
3. Member meets one of the following:
  - a. The member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
  - b. The member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

#### **Active ankylosing spondylitis (AS)**

Authorization may be granted for members new to plan who have previously received Simponi or any other biologic DMARD indicated for active ankylosing spondylitis.

#### **OR**

Authorization may be granted when the following criteria is met:

1. The member has a diagnosis of active ankylosing spondylitis
2. Member has had a documented inadequate response or intolerable adverse event with Cosentyx, Enbrel, Rinvoq AND Humira or a clinical reason to avoid these products
3. Member meets one of the following criteria:
  - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose.
  - b. Member has an intolerance and/or contraindication to two or more NSAIDs

#### **Ulcerative colitis (UC)**

Authorization may be granted for members new to the plan who are currently receiving treatment with Simponi 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 ulcerative colitis (UC)
2. Member has had intolerance, inadequate response, or contraindication to ONE conventional therapy (see Appendix B)
3. Member has had intolerance, inadequate response, or contraindication to Humira, Rinvoq, and Stelara

#### **Continuation of Therapy**

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Simponi as evidenced by low disease activity or improvement in signs and symptoms of the condition.

**Limitations**

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
  - a. Note: Members who have received Simponi or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.
3. The following quantity limits apply:

Simponi	1 per 28 days
---------	---------------

**Appendices**

**Appendix A**

**Examples of Contraindications to Methotrexate**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

**Appendix B**

**Examples of Conventional Therapy Options for UC**

1. Mild to moderate disease – induction of remission:
  - a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa)
  - b. Rectal mesalamine (e.g., Canasa, Rowasa)
  - c. Alternatives: azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
  - a. Oral mesalamine, rectal mesalamine
  - b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
  - a. Sulfasalazine
4. Severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: sulfasalazine

**References**

1. Simponi (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.  
03/16/2022 – Reviewed and updated for March P&T; Added Rinvoq and Skyrizi as preferred trial for PsA. Effective 05/01/2022  
09/21/2022 – Reviewed and Updated for Sept P&T; added Rinvoq as preferred agent for diagnosis of ankylosing spondylitis and ulcerative colitis. Effective 11/01/2022

### **Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin age, disability, or sex.