Mass General Brigham
Health Plan

Simponi (golimumab)
Effective 07/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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
Simponi (golimumab) is a tumor necrosis factor (TNF) inhibitor indicated for the treatment of adult patients with:

1. Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
2. Active psoriatic arthritis (PsA), alone or in combination with methotrexate
3. Active ankylosing spondylitis (AS)
4. Moderate to severe ulcerative colitis (UC) and the patient is either corticosteroid dependent or has had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:
    a. Inducing and maintaining clinical response
    b. Improving endoscopic appearance of the mucosa during induction
    c. Inducing clinical remission
    d. Achieving and sustaining clinical remission in induction responders

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following diagnosis-specific criteria have been met:

Moderately to severely active rheumatoid arthritis (RA)

1. Diagnosis of moderately 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)

1. Diagnosis of active psoriatic arthritis (PsA)
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

Active ankylosing spondylitis (AS)

1. 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.

Ulcerative colitis (UC)

1. Diagnosis of moderately to severely active ulcerative colitis (UC)
2. ONE of the following:
    a. Member is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)
    b. Trial and failure, intolerance, or contraindication to ONE of the following conventional therapies:
        i. 6-mercaptopurine
        ii. Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
        iii. Azathioprine
        iv. Corticosteroids (e.g., prednisone)
    c. Disease severity warrants systemic biologic as first-line therapy

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be granted when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition 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. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limitation
Simponi prefilled syringe/autoinjector	1 injection per 28 days

References

1. 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.
2. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; April 2025.
3. 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.

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 11/01/22.
11/15/2023 – Reviewed and Updated for Nov P&T; Simponi will be preferred agent for all indications. Removed prior use of preferred agents. Removed Appendices. Removed TB requirement. For Psoriatic arthritis: removed conventional therapies and added examples of active PSA. Ulcerative Colitis: added examples of moderate to severe UC. Updated conventional therapies to include examples. Rheumatoid arthritis: updated conventional therapies to include methotrexate, leflunomide, sulfasalazine. Effective 1/1/2024
10/09/2024 – Reviewed and updated for October P&T. Updated reauthorization criteria to require documentation of clinical response to therapy. Effective 1/1/2025.
05/14/2025 – Reviewed and updated for May P&T. Updated criteria for ulcerative colitis to remove disease characteristic requirement and allow for approval if disease severity warrants systemic biologic as first-line therapy. Effective 07/1/2025.