Mass General Brigham
Health Plan

Simponi (golimumab)
Effective 01/01/2024

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
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 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 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. 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)
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 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)
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 moderately to severely active ulcerative colitis (UC)
2. ONE of the following:
    a. Greater than 6 stools per day
    b. Frequent blood in stools
    c. Frequent urgency
    d. Presence of ulcers
    e. Abnormal lab values (e.g., hemoglobin, ESR, CRP)
    f. Dependent on, or refractory to, corticosteroids
3. 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)

<u>Continuation of Therapy</u>
Reauthorization may be granted for members who 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. The following quantity limits apply:

Simponi	1 per 28 days

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 11/01/22.
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