Simponi and Simponi Aria (golimumab)
Effective January 1, 2020

Plan	☐ MassHealth ☒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.		
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	Simponi Aria is available on both the medical and pharmacy benefit. Simponi is only available on the pharmacy benefit.		

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) – Simponi only]

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

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)

1. Authorization may be granted for members who are currently receiving treatment with Simponi or Simponi Aria, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
   OR
2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:

a. Member has experienced an inadequate response or intolerance to all preferred products (Enbrel, Humira and Rinvoq)
b. Member has a contraindication to all preferred products (Enbrel, Humira and Rinvoq) and meets one of the following:
    - 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).
    - Member has an intolerance or contraindication to methotrexate (see Appendix A).

Active psoriatic arthritis (PsA)

1. Authorization may be granted for members who are currently receiving treatment with Simponi, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
   OR
2. Authorization may be granted for treatment of active psoriatic arthritis (PsA) if any of the following criteria is met:
    a. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara).
    b. Member has a contraindication to all the preferred products AND meets one of the following:
        - Patient has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
        - Patient has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Active ankylosing spondylitis (AS)

1. Authorization may be granted for members who have previously received Simponi Aria or any other biologic DMARD indicated for active ankylosing spondylitis.
   OR
2. Authorization may be granted for treatment of active ankylosing spondylitis when all the following criteria is met:
    a. Member has had a documented inadequate response or intolerable adverse event with Cosentyx, Enbrel AND Humira or a clinical reason to avoid these products.
    b. Member meets any of the following criteria:
        - 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.
        - Member has an intolerance and/or contraindication to two or more NSAIDs

Ulcerative colitis (UC) [Simponi only]

1. Authorization may be granted for members who are currently receiving treatment with Simponi excluding when the product is obtained as samples or via manufacturer's patient assistance programs
   OR
2. Authorization may be granted for members who had an inadequate response, intolerance or contraindication to BOTH of the following:

a. Humira (adalimumab)
b. ONE conventional therapy option (See Appendix B)

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 Aria 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 Simponi Aria 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 Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; May 2018.
2. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; May 2018
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. 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.
5. 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

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