## Pharmacy Policy

# Simponi

**Policy Number:** 9.128
**Revision Number:** R0
**Version Effective Date:** 1/1/2021

| Product Applicability | ☐ **All Plan+ Products** |
|---|---|
| **Well Sense Health Plan** | **Boston Medical Center HealthNet Plan** |
| ☒ New Hampshire Medicaid | ☐ MassHealth - MCO<br>☐ MassHealth - ACO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options |

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

**Products Affected:**

- Simponi (golimumab)
- Simponi Aria (golimumab)

The Plan may authorize coverage of the above products for members meeting the following criteria:

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| **Covered Use** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | Use in combination with another biologic |
| **Required Medical Information** | Diagnosis of one of the following:<br>1. Ankylosing Spondylitis (AS); ***AND***<br>a. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs ***AND***<br>b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx, OR a clinical rationale for use of the requested agent instead of Enbrel, |

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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| | Humira or Cosentyx<br>2. Ulcerative Colitis(UC) (Simponi ONLY); ***AND***<br>a. An inadequate response, contraindication or intolerance to use of **ALL** of the following:<br>i. 5-aminosalicylic acid (e.g. mesalamine)<br>ii. 6-mercaptopurine, azathioprine, and/or methotrexate<br>iii. corticosteroids; ***AND***<br>b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira.<br>3. Psoriatic Arthritis (PsA); ***AND***<br>a. An inadequate response or intolerance to at least one non-biologic DMARD; ***AND***<br>b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx, OR a clinical rationale for use of the requested agent instead of Enbrel, Humira and Cosentyx.<br>4. Rheumatoid Arthritis (RA); ***AND***<br>a. An inadequate response or intolerance to at least one formulary non-biologic DMARD, or is currently on methotrexate; ***AND***<br>b. An inadequate response, intolerance, or contraindication to Enbrel or Humira or a clinical rationale for the use of the requested agent instead of Enbrel or Humira |
| **Age Restrictions** | AS, PsA, RA: Prescribed by or in consultation with a rheumatologist<br>CD: Prescribed by or in consultation with a gastroenterologist |
| **Prescriber Restriction** | 18 years of age or older |
| **Coverage Duration** | 12 months |
| **Other criteria** | Reauthorization:<br>1. Currently receiving medication via Well Sense benefit or member has previously met initial approval criteria; **AND**<br>2. Patient's clinical condition has improved or stabilized |

**Applicable Coding:**

| Code | Medication |
|---|---|
| **J1602** | Simponi Aria (golimumab injection for IV use ) |

## Clinical Background Information and References


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15. Sandborn WJ, Feagan BG, Marano C, et al. Subcutaneous Golimumab Induces Clinical Response and Remission in Patients With Moderate to Severe Ulcerative Colitis. Gastroenterology. 2013 Jun 2. pii: S0016-5085(13)00846-9.
16. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech Inc.; May 2018
17. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech Inc.; October 2017.

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| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee, NH DHHS |

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | 9.192 Simponi Policy retired, new policy created; updated policy to align with NH state PDL requirements | 1/1/2021 | P&T Committee, NH DHHS |

## Next Review Date

2021

## Other Applicable Policies

9.015 Quantity Limitation Policy

## Reference to Applicable Laws and Regulations, If Any

**Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.