Pharmacy Medical Necessity Guidelines:
Simponi® and Simponi Aria® (golimumab)

Effective: August 8, 2017

Prior Authorization Required: √

Type of Review – Care Management

Not Covered

Type of Review – Clinical Review: √

Pharmacy (RX) or Medical (MED) Benefit: RX / MED

Department to Review: RXUM

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
☐ Tufts Health Direct – Health Connector
☒ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

OVERVIEW
FDA-APPROVED INDICATIONS
Simponi (golimumab) injection, for subcutaneous use, is a tumor necrosis factor (TNF) blocker indicated as follows:

- **Ankylosing Spondylitis**
  Simponi (golimumab) is indicated for the treatment of adult patients with active ankylosing spondylitis.

- **Psoriatic Arthritis**
  Simponi (golimumab), alone or in combination with methotrexate, is indicated for the treatment of adult patients with active psoriatic arthritis.

- **Rheumatoid Arthritis**
  Simponi (golimumab), in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

- **Ulcerative Colitis**
  Simponi (golimumab) is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for:
  - inducing and maintaining clinical response
  - improving endoscopic appearance of the mucosa during induction
  - inducing clinical remission
  - achieving and sustaining clinical remission in induction responders

Simponi Aria (golimumab) injection, for intravenous use, is a TNF blocker indicated in combination with methotrexate for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

*Note:* Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient’s tolerance.

COVERAGE GUIDELINES
The plan may authorize coverage for Simponi (golimumab) injection, for subcutaneous use, for Members when the following criteria are met:

**Ankylosing Spondylitis**
1. The member has a documented diagnosis of ankylosing spondylitis
   **AND**
2. The member has been evaluated by a rheumatologist
   **AND**
3. The member is 18 years of age or older

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4. The member has previously tried and failed treatment with, or the Member has a contraindication to, at least one non-steroidal anti-inflammatory drug (NSAID)

5. The member has tried and failed treatment with, the provider indicated clinical inappropriateness of Humira and Enbrel

OR

6. The member is new to the plan and has been stable on Simponi prior to enrollment

**Psoriatic Arthritis**
1. The member has a documented diagnosis of psoriatic arthritis

2. The member has been evaluated by a rheumatologist

3. The member is 18 years of age or older

4. The member has tried and failed treatment with, or the Member has a contraindication to one DMARD’s (Disease Modifying Anti-rheumatic Drugs), such as methotrexate, azathioprine, gold therapy, hydroxychloroquine, penicillamine, sulfasalazine, cyclosporine or leflunomide

5. The member has tried and failed treatment with, the provider indicated clinical inappropriateness of Humira and Enbrel

OR

6. The member is new to the plan and has been stable on Simponi prior to enrollment

**Rheumatoid Arthritis (Simponi and Simponi Aria)**
1. The member has a documented diagnosis of rheumatoid arthritis

2. The member has been evaluated by a rheumatologist

3. The member is 18 years of age or older

4. The member is currently taking, has tried and failed treatment with, or the Member have a contraindication to methotrexate and one other DMARD’s (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, penicillamine, sulfasalazine, cyclosporine or leflunomide

5. The member has tried and failed treatment with Humira and Enbrel

OR

6. The member is new to the plan and has been stable on Simponi or Simponi Aria prior to enrollment

**Ulcerative Colitis**
1. The member has a documented diagnosis of moderately to severely active ulcerative colitis

2. The member has been evaluated by a gastroenterologist
3. The member is 18 years of age or older

AND

4. The member has tried and failed treatment with, or does the patient have a contraindication to, at least two of the following: aminosalicylates (sulfasalazine, mesalamine), immunosuppressive agents (azathioprine, 6-mercaptopurine, cyclosporine, methotrexate), corticosteroids (prednisone, hydrocortisone, methylprednisolone, budesonide)

AND

5. The member has tried and failed treatment with Humira

OR

6. The member is new to the plan and has been stable on Simponi prior to enrollment

LIMITATIONS

1. Initial approval of Simponi / Simponi Aria (golimumab) will be limited to 1 year. Subsequent authorization may be given in 12-month intervals based on submission of current progress notes from the physician documenting efficacy

2. Coverage of Simponi (golimumab) injection, for subcutaneous use for the diagnoses of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis will be limited to 28-day supplies as follows:
   - Simponi 50mg pre-filled syringe or SmartJect autoinjector – 1 syringe per 28 days.

3. Coverage of Simponi (golimumab) for the diagnosis of ulcerative colitis will be limited to 28-day supplies as follows:
   - Simponi 100mg pre-filled syringe or SmartJect autoinjector – 3 syringes for the initial 28 days, then 1 syringe per 28 days thereafter.

4. Coverage of Simponi Aria (golimumab) intravenous solution for the diagnoses of rheumatoid arthritis will be limited to 28-day supplies as follows:
   - Simponi Aria 50 mg/4 mL intravenous solution – 1 vial at weeks 0, 4, and then every 8 weeks thereafter.

CODES

The following HCPCS/CPT code(s) for Simponi Aria (golimumab) apply only to the intravenous use injection:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J1602</td>
<td>Injection, golimumab, 1 mg, for intravenous use</td>
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Note: Medical billing codes may not be used for Simponi (golimumab) injection, for subcutaneous use. This formulation must be obtained via the Member’s pharmacy benefit.

REFERENCES


7. Emery P, Fleischmann RM, Doyle MK, et al. Golimumab, a human anti-TNF monoclonal antibody, injected subcutaneously every 4 weeks in MTX-naive patients with active rheumatoid arthritis: 1-
APPROVAL HISTORY

November 15, 2011: Reviewed by the Pharmacy and Therapeutics Committee. This policy replaces the Medical Necessity Guidelines for Simponi (golimumab) in "Rheumatoid Arthritis – Injectable Drugs" originating in August 2002 (Document ID# 1035134).

Subsequent endorsement date(s) and changes made:
- October 9, 2012: No changes
- June 11, 2013: Added the indication of ulcerative colitis to the Medical Necessity Guidelines.
- September 10, 2013: Added coverage guidelines for Simponi Aria (golimumab) injection, for intravenous use.
- December 10, 2013: Removed Humira (adalimumab) as a prerequisite for the indication of ulcerative colitis.
- October 7, 2014: No changes.
- March 10, 2015: Reviewed by the Pharmacy and Therapeutics Committee
- October 6, 2015: Removed Enbrel as a prerequisite requirement for the diagnosis of ulcerative colitis.
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
- August 8, 2017: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.