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

Effective: November 20, 2017

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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 Direct – Health Connector**
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RITE Care + Rhody Health Partners Plan

Fax Numbers:
- Simponi: RXUM: 617.673.0988
- Simponi Aria: All plans except Tufts Health Direct – Health Connector
  PRECERT: 617.972.9409
- Tufts Health Freedom Plan products
  - Tufts Health Freedom Plan - large group plans
  - Tufts Health Freedom Plan - small group plans
  MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-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 (RA).

- **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 as follows:

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

- **Psoriatic Arthritis**
  Simponi Aria (golimumab) is indicated for the treatment of adult patients with active psoriatic arthritis.

- **Rheumatoid Arthritis**
  Simponi Aria (golimumab), in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active RA.
Note: Maximal doses of methotrexate are defined as 15 mg to 25 mg per week depending on the patient’s tolerance.

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

**Ankylosing Spondylitis**
1. The Member has a documented diagnosis of ankylosing spondylitis
2. The prescription is written by a rheumatologist
3. The Member is 18 years of age or older
4. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
5. The Member is new to the plan and has been stable on Simponi (golimumab)/Simponi Aria (golimumab) prior to enrollment

**Psoriatic Arthritis**
1. The Member has a documented diagnosis of psoriatic arthritis
2. The prescription is written by a rheumatologist
3. The Member is 18 years of age or older
4. The Member has a documented inadequate response or inability to take methotrexate (MTX) or sulfasalazine at maximal doses for three months
5. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
6. The Member is new to the plan and has been stable on Simponi (golimumab)/Simponi Aria (golimumab) prior to enrollment

**Rheumatoid Arthritis**
1. The Member has a documented diagnosis of rheumatoid arthritis
2. The prescription is written by a rheumatologist
3. The Member is 18 years of age or older
4. The Member has a documented inadequate response to methotrexate after three months at optimal doses or an inability to take MTX
5. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis
6. The Member is new to the plan and has been stable on Simponi (golimumab)/Simponi Aria (golimumab) prior to enrollment

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

**Ulcerative Colitis**
1. The Member has a documented diagnosis of moderately to severely active ulcerative colitis
2. The prescription is written by a gastroenterologist
3. The Member is 18 years of age or older
4. The Member has demonstrated an inadequate response to an appropriate trial with two or more of the following agents:
   a) Corticosteroids (e.g., prednisone, prednisolone, methylprednisolone)
   b) 5- Aminosalicylates (e.g., sulfasalazine, Apriso®, Azulfidine®, Delzicol®, Pentasa®, Rowasa®, Dipentum®, Colazal®)
   c) 6-mercaptopurine (6-MP, Purinethol®) and/or azathioprine (Imuran®)
   d) MTX  

OR

5. The Member has tried and failed treatment with another biological agent indicated for the treatment of ulcerative colitis  

OR

6. The Member is new to the plan and has been stable on Simponi (golimumab) prior to enrollment

LIMITATIONS
1. Initial approval of Simponi (golimumab) injection, for subcutaneous use, for the diagnosis of ulcerative colitis will be limited to eight weeks. For continued coverage authorization, documentation of evidence of clinical response must be submitted.
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 50 mg 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 100 mg pre-filled syringe or SmartJect autoinjector – 3 syringes for the initial 28 days, then 1 syringe per 28 days thereafter.

CODES
The following HCPCS/CPT code(s) are:

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<th>Code</th>
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<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

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.
- October 6, 2015: No changes.
- January 1, 2016: Administrative change to rebranded template.
- January 1, 2017: Added exception language for Members new to the plan and stable on Simponi or Simponi Aria prior to enrollment. Changed failure of intolerance to Remicade to trial and failure of another biological agent for ulcerative colitis. Added trial and failure with another biological agent indicated for the same condition.
- April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
- August 8, 2017: No changes
- November 14, 2017: Added Simponi Aria (golimumab) injection for intravenous use to the coverage criteria for ankylosing spondylitis and psoriatic arthritis based on updated package labeling.

**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 CareLink℠ 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.