

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

Effective: November 20, 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/ MM
<p>This Pharmacy Medical Necessity Guideline applies to the following:</p> <p>Tufts Health Plan Commercial Plans</p> <input type="checkbox"/> Tufts Health Plan Commercial Plans – large group plans <input type="checkbox"/> Tufts Health Plan Commercial Plans – small group and individual plans <p>Tufts Health Public Plans</p> <input type="checkbox"/> Tufts Health Direct – Health Connector <input type="checkbox"/> Tufts Health Together – A MassHealth Plan <input checked="" type="checkbox"/> Tufts Health RITogether – A RItE Care + Rhody Health Partners Plan <p>Tufts Health Freedom Plan products</p> <input type="checkbox"/> Tufts Health Freedom Plan - large group plans <input type="checkbox"/> Tufts Health Freedom Plan - small group plans		<p>Fax Numbers:</p> <p><i>Simponi:</i> RXUM: 617.673.0988</p> <p><i>Simponi Aria:</i> MM: 888.415.9055</p>	

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 (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 member has been evaluated by a rheumatologist
3. The member is 18 years of age or older
4. The member has previously tried and failed treatment with, or the Member has a contraindication to, at least two non-steroidal anti-inflammatory drugs (NSAIDs)
5. The member has tried and failed treatment with, the provider indicated clinical inappropriateness of Humira and Enbrel
6. The member is new to the plan and has been stable on Simponi/Simponi Aria 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
6. The member is new to the plan and has been stable on Simponi/Simponi Aria prior to enrollment

Rheumatoid Arthritis

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
6. The member is new to the plan and has been stable on Simponi/Simponi Aria 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 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:

Code	Description
J1602	Injection, golimumab, 1 mg, for intravenous use

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

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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 – Injectible 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.
- January 1, 2014: Administrative update: Removed miscellaneous billing codes J3590 and C9399, added J1602.
- 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. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria for ankylosing spondylitis to require a trial and failure of two NSAIDs.
- 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 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.

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