MEDICAL MUTUAL®

Drug Policy

Policy:	**201001**	**Initial Effective Date: 02/18/2010**
Code(s):	**HCPCS J3590**	**Annual Review Date: 05/16/2024**
SUBJECT:	**Simponi® (golimumab - Subcutaneous Injection)**	**Last Revised Date: 05/16/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Overview

Simponi is a recombinant human monoclonal antibody specific for human tumor necrosis factor alpha (TNFα).[1] Simponi neutralizes the biological activity of TNFα and inhibits binding of TNFα with its receptors. TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. Increased levels of TNF are found in the synovial fluid of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), and ankylosing spondylitis (AS). TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of these diseases. Simponi SC is also indicated for those with moderately to severely active ulcerative colitis who had an inadequate response or failure to oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine.

Boxed Warnings

Simponi has boxed warnings concerning risks of serious infection and the risk of malignancy.[1] Prior to initiating therapy with Simponi, patients should be evaluated for active tuberculosis (TB) infection, and periodically during therapy patients should be assessed for latent TB infection. Patients should also be monitored for signs and symptoms of infection during and after treatment with Simponi, and if a serious infection or sepsis develops, Simponi should be discontinued. It is also recommended that patients treated with any TNF antagonist should be monitored for malignancies.

Policy Statement

This policy involves the use of Simponi SC. Prior authorization is recommended for medical benefit coverage of Simponi SC. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Simponi SC as well as the monitoring required for AEs and long-term efficacy, initial approval requires Simponi SC be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Simponi is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations.

Recommended Authorization Criteria
Coverage of Simponi is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Rheumatoid Arthritis (RA) in an Adult**.
   - **A.** Initial Therapy. Approve for 6 months in patients that meet the following criteria (i, ii and iii):
     - **i.** The patient meets one of the following (a, b, or c):
       - **a)** The patient has tried one conventional synthetic DMARD (brand or generic; oral or injectable) for at least 3 months; OR
       - **b)** The patient has a contraindication or intolerance to MTX or leflunomide, as determined by the prescribing physician; OR
       - **c)** The patient has tried ONE biologic disease-modifying antirheumatic drug (DMARD), for at least 3 months [Refer to Appendix A for examples]; OR
     - **ii.** Simponi is prescribed by or in consultation with a rheumatologist; AND
     - **iii.** Site of care medical necessity is met*.

B. Patient is Currently Receiving Simponi (Subcutaneous or Aria). Approve for 1 year if the patient meets BOTH of the following (i and ii):

- **i.** Patient has been established on therapy for at least 6 months; AND
  Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
- **ii.** Patient meets at least one of the following (a or b):
  - **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR
    Note: Examples of standardized and validated measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).
  - **b)** Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

Simponi is indicated in combination with MTX for moderate or severe active RA in adults. Most patients will have received initial therapy with MTX, another oral DMARD(s) (e.g., hydroxychloroquine, leflunomide, sulfasalazine, MTX), or combination DMARD therapy (including double or triple therapy).[7] However, current recommendations from ACR (2012) note that patients with early RA (defined as disease duration < 6 months) with important markers of poor prognosis may be started early on a TNF antagonist, either alone or in combination with MTX. The criteria for patients with contraindications or intolerance to DMARDs are recommended based on the professional opinion of specialized physicians.

Dosing in Rheumatoid Arthritis. The recommended Simponi dose regimen is 50 mg administered by subcutaneous injection once a month.

Initial Approval/Extended Approval.
Initial Approval: 6 months (180 days)
Extended Approval: 1 year (365 days)

Duration of therapy in RA. Indefinite if the patient is responding.

2. **Ankylosing Spondylitis (AS).**
   - **A.** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist AND site of care medical necessity is met*.
   - **B.** Patients Currently Receiving Simponi. Approve for 1 year if the patient has had a response (e.g., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria). Site of care medical necessity must be met*.

Simponi is indicated for AS and can be used alone or in combination with MTX or other non-biologic DMARDs. Guidelines from the Assessment of SpondyloArthritis International Society (ASAS)/EULAR (2016) recommend biologics (e.g., TNFis, Cosentyx) in patients with persistently high disease activity despite traditional conventional treatments (e.g., nonpharmacological management, NSAIDs). Purely axial disease should not be treated with conventional synthetic DMARDs. Guidelines from the American College of Rheumatology (ACR) and the Spondyloarthritis Research and Treatment Network (SPARTAN) [2015] recommend TNFis for patients with active disease despite treatment with an NSAID (includes patients with non-radiographic axial [nr-ax]SpA). Predominantly axial manifestations are not recommended for a conventional synthetic DMARD prior to a TNFi. However, for symptomatic peripheral arthritis, a conventional synthetic DMARD is recommended (preferably sulfasalazine).

Dosing in Ankylosing Spondylitis. The recommended Simponi dose regimen is 50 mg administered by subcutaneous injection once a month.

Initial Approval/Extended Approval.
Initial Approval: 6 months (180 days)
Extended Approval: 1 year (365 days)

Duration of therapy in AS. Indefinite if the patient is responding.

3. **Psoriatic Arthritis (PsA).**
   - **A.** Initial Therapy. Approve for 6 months if Simponi SC is prescribed by or in consultation with a rheumatologist or a dermatologist[10] AND site of care medical necessity is met*.

B. Patients Currently Receiving Simponi. Approve for 1 year if the patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvements in acute phase reactants [for example, C-reactive protein {CRP}]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria). Site of care medical necessity must be met*.

Simponi is indicated for PsA and can be used alone or in combination with MTX or other non-biologic DMARDs.[1] In clinical trials, Simponi was effective in patients with active PsA despite therapy with a NSAID or DMARD. There are few well-controlled, prospective studies with adequate duration that have evaluated the efficacy of the oral DMARDs.[10] Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with PsA and in those who were previously treated with an oral therapy. The TNF inhibitors are equally effective for treatment of PsA, inhibition of radiographic progression, and improving physical function in patients with PsA. The traditional DMARDs have not been shown to prevent the progression of radiographic (structural) damage or to have significant impact on axial disease, dactylitis, or enthesitis in PsA. This is in contrast with the newer biological DMARDs which have shown efficacy in well-controlled trials in reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with PsA.

Dosing in Psoriatic Arthritis. The recommended Simponi dose regimen is 50 mg administered by subcutaneous injection once a month.[1]

Initial Approval/Extended Approval.
Initial Approval: 6 months (180 days)
Extended Approval: 1 year (365 days)

Duration of therapy in PsA. Indefinite if the patient is responding.

4. Ulcerative Colitis (UC) in an Adult.

A. Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii,and iii):

i. Patient is ≥ 18 years of age; AND
ii. The patient meets ONE of the following conditions (1, 2 or 3):
   1. Patient has had a 2-month trial of one conventional systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone); OR
   2. The patient has tried ONE biologic disease-modifying antirheumatic drug (DMARD) [Refer to Appendix A for examples]; OR
   3. The patient has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema, or Rowasa® (mesalamine) enema; AND
iii. Simponi is prescribed by or in consultation with a gastroenterologist; AND
iv. Site of care medical necessity is met*.

b) Patients Currently Receiving Simponi. Approve for 1 year if the patient has had a response (e.g., decreased stool frequency or rectal bleeding), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria). Site of care medical necessity must be met*.

Simponi is indicated inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders in adults with moderate-to-severe ulcerative colitis (UC) 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. Updated ACG guidelines for UC (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: Uceris tablets; Oral or intravenous systemic corticosteroids, Entyvio, Xeljanz, or TNFis. Other treatment options include maintenance probiotics, oral or topical budesonide, anti-inflammatory drugs (e.g. mesalamine), or immunosuppressive drugs (e.g. Remicade). In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for pouchitis.

Dosing in Ulcerative Colitis. The recommended Simponi induction dosage regimen is a 200 mg subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then maintenance therapy with 100 mg every 4 weeks.

Initial Approval/Extended Approval.
Initial Approval: 6 months (180 days)
Extended Approval: 1 year (365 days)

Duration of therapy in UC. Indefinite if the patient is responding.

Other Uses with Supportive Evidence

5. **Spondyloarthritis (SpA), Subtypes Other than Ankylosing Spondylitis or Psoriatic Arthritits. [Simponi]** (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter's disease]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications].
   - **A. Initial Therapy.** Approve for 6 months if the patient meets one of the following conditions ((a or b) AND (c and d)):
     a) The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD (e.g., methotrexate [MTX], leflunomide, sulfasalazine) has been tried; OR
     b) The patient has axial spondyloarthritis; AND
     c) Simponi SC is prescribed by or in consultation with a rheumatologist; AND
     d) Site of care medical necessity is met*.
   - **B.** Continuation Therapy. Approve for 1 year if patient is currently established on Simponi for ≥ 90 days and has responded to therapy, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria). Site of care medical necessity must be met*.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)

B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Simponi SC has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD). or with Xeljanz.** Simponi should not be administered in combination with another biologic agent for an inflammatory condition [See Appendix A for examples] Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[15] Xeljanz® (tofacitinib) should not be used in combination with biologic DMARDs such as Remicade.[16] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Simponi SC.

2. **Plaque Psoriasis without Psoriatic Arthritis.** Simponi has been studied in patients with psoriatic arthritis who had plaque psoriasis. Plaque psoriasis improved in these patients with a Psoriasis Area Severity Index (PASI)-75 being attained by 40% of patients on Simponi 50 mg every 4 weeks and by 58% in the Simponi 100 mg group at week 14.[6] Simponi is indicated in patients with psoriatic arthritis, but not in patients with plaque psoriasis without psoriatic arthritis. Prospective, controlled trials are needed to determine safety and efficacy in plaque psoriasis. Other TNFα antagonists (Enbrel, Humira, and Remicade) are indicated for the treatment of plaque psoriasis.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***MMO Site of Care Medical Necessity Criteria:**

Medications in this policy will be administered in a place of service that identifies the location to be a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

1. Age less than 18 years*; or
2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
3. History of a severe adverse event from previous administration of the prescribed medication; or
4. Requested medication is being administered as follows:
   - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
   - administered with dialysis; or
5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or

6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

No initial doses are allowed in a hospital based outpatient facility without other above criteria being met.
* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
†This criterion does not apply to Medicare or Medicare Advantage members.

REFERENCES

- Simponi® injection [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
- Kornbluth A, Sachar DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010;105(3):501-523.
- Singh JA, Saag KG, Bridges L, et al. 2015 American College of Rheumatology Guidelines for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2016 Jan;68(1):1-25. doi: 10.1002/acr.22783.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
- van der Heijde D, Ramiro S, Landewé R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;76(6):978-991.
- Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2016;68(2):282-298.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Code J3590†.

†When *unclassified biologics* (J3590) is determined to be Simponi.

Edits and Denials:

Prior Approval: Prior approval is required for Simponi **(HCPCS Code J3490)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within the Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3490** will edit with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3590	Unclassified biologics

Appendix A

	Mechanism of Action	**Examples of Inflammatory Indications***
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsA, PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD

Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARDs – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.