PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Simponi® (golimumab for subcutaneous injection – Janssen Biotech, Inc.)

DATE REVIEWED: 04/29/2020

OVERVIEW

Simponi SC is a recombinant human monoclonal antibody specific for human tumor necrosis factor alpha (TNFα).[1] It is indicated for the following uses:

1. Ankylosing spondylitis (AS), for treatment of adults with active AS either alone or in combination with MTX or other non-biologic DMARDs; AND
2. Psoriatic arthritis (PsA), for treatment of adults with active PsA either alone or in combination with MTX or other non-biologic disease-modifying antirheumatic drugs (DMARDs); AND
3. Rheumatoid arthritis (RA), for treatment of adults with moderate to severe active RA in combination with methotrexate (MTX); AND
4. Ulcerative colitis (UC), for 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 disease 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.

Disease Overview

TNF is a naturally occurring cytokine that mediates inflammation and modulates cellular immune responses. Increased levels of TNF have been implicated in the pathology of inflammatory conditions such as inflammatory bowel disease, psoriatic arthritis, and rheumatoid arthritis (RA). Increased levels of TNF are found in the synovial fluid of patients with RA and TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of this disease. In Crohn's disease, increased levels of TNF are found in the bowel wall in areas involved by Crohn's disease. Simponi SC neutralizes the biological activity of TNFα and inhibits binding of TNFα with its receptors.

Guidelines

TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- Spondyloarthritis: Guidelines for ankylosing spondylitis and nonradiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] TNFis are recommended for the initial biologic. In those who are secondary nonresponders to a TNFi, a second TNFi is recommended over switching out of the class.
- Psoriatic Arthritis: 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.[3]
- Rheumatoid Arthritis: Guidelines from the American College of Rheumatology (ACR) [2015] have TNF inhibitors and non-TNF biologics, administered with or without MTX, equally positioned as a recommended therapy following a trial of a conventional synthetic DMARD (e.g., MTX, leflunomide, hydroxychloroquine, sulfasalazine).[4]
- Ulcerative Colitis: 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 (adalimumab, Simponi SC, infliximab).[5]

Safety

Simponi SC has Boxed Warnings concerning risks of serious infection and the risk of malignancy.[1] Prior to initiating therapy, patients should be evaluated for active tuberculosis (TB) infection; in addition, patients should be assessed for latent TB infection periodically during therapy. Patients should also be monitored for signs and symptoms of infection during and after treatment with Simponi SC; if a serious infection or sepsis develops, Simponi SC should be discontinued. Lymphoma and other malignancies have been reported in patients who have taken TNFis such as Simponi SC.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Simponi SC. Because of the specialized skills required for evaluation and diagnosis of patients treated with Simponi SC as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Simponi SC to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration listed below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Simponi SC is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Ankylosing Spondylitis (AS).** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 3 months if prescribed by or in consultation with a rheumatologist.
   - **B)** Patients Currently Receiving Simponi (SC or Aria). Approve for 3 years if the patient has had a response, as determined by the prescriber.
     Note: Examples of a response include decreased pain or stiffness and improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria).

2. **Psoriatic Arthritis (PsA).** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 3 months if Simponi SC is prescribed by or in consultation with a rheumatologist or a dermatologist.
   - **B)** Patients Currently Receiving Simponi (SC or Aria). Approve for 3 years if the patient has had a response as determined by the prescriber.
     Note: Examples of a response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; and improvements in acute phase reactants such as C-reactive protein (CRP). The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria).

3. **Rheumatoid Arthritis (RA)**. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

i. The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months.
Note: Examples of conventional synthetic DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic. Refer to Appendix for examples of biologics used for RA. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD; AND

ii. Simponi SC is prescribed by or in consultation with a rheumatologist.

B) Patients Currently Receiving Simponi (SC or Aria). Approve for 3 years if the patient has had a response, as determined by the prescriber.
Note: Examples of a response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria).

4. Ulcerative Colitis (UC). Approve for the duration noted if the patient meets ONE of the following conditions (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets BOTH of the following criteria (i, ii. and iii):

i. The patient is ≥ 18 years of age; AND

ii. The patient meets ONE of the following conditions (a or b):

a) Patient has had a trial of one conventional systemic agent or a corticosteroid such as prednisone or methylprednisolone, or was intolerant to one of these agents for ulcerative colitis.
Note: Examples of systemic therapies for ulcerative colitis include 6-mercaptopurine, azathioprine, cyclosporine, and tacrolimus. An exception to this criterion can be made if the patient has already tried a biologic. These patients who have already received a biologic are not required to "step back" and try another agent. Refer to Appendix for examples of biologics used for ulcerative colitis; OR

b) The patient meets BOTH of the following [(1) and (2)]:

(1) The patient has pouchitis; AND

(2) The patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa® (mesalamine) enema.
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Hydrocortisone enemas is an examples of a corticosteroid enemas; AND

iii. Simponi SC is prescribed by or in consultation with a gastroenterologist.

B) Patients Currently Receiving Simponi (SC or Aria). Approve for 3 years if the patient has had a response, as determined by the prescriber.
Note: Examples of a response include decreased stool frequency or rectal bleeding. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria).

Other Uses with Supportive Evidence

5. **Spondyloarthritis (SpA), Other Subtypes** (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]. Approve for the duration noted if ONE of the following conditions are met (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following conditions (i and ii):
     - **i.** The patient meets ONE of the following (a or b):
       - **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 has been tried.
         Note: Examples of conventional synthetic DMARDs include methotrexate (MTX), leflunomide, and sulfasalazine; OR
       - **b)** The patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following [(1) or (2)]:
         - **(1)** C-reactive protein (CRP) elevated beyond the upper limit of normal for the reporting laboratory; OR
         - **(2)** Sacroiliitis reported on magnetic resonance imaging (MRI); AND
     - **ii.** Simponi SC is prescribed by or in consultation with a rheumatologist.
   - **B)** Patients Currently Receiving Simponi (SC or Aria). Approve for 1 year if the patient has had a response, as determined by the prescriber.
     Note: Examples of a response include decreased pain or stiffness and improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria).

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).** Simponi SC should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of AEs with combinations and lack of data supportive of additional efficacy.[6,7] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with an adalimumab product.

2. **Plaque Psoriasis without Psoriatic Arthritis.** Simponi SC 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 SC every 4 weeks and by 58% in the Simponi 100 mg SC group at Week 14.[8] Simponi SC 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.

REFERENCES

1. Simponi® injection [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
2. of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
3. 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.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
6. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
7. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer Inc; February 2016.
8. Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor alpha antibody, administered every four weeks as a subcutaneous injection in psoriatic arthritis: Twenty-four-week efficacy and safety results of a randomized, placebo-controlled study. *Arthritis Rheum*. 2009;60:976-986.

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications for Products*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, PJIA, PsO, PsA, RA, SJIA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, PJIA, PsO, PsA, RA, SJIA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PJIA, PsO, PsA, RA, SJIA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, 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: PJIA, PSA, RA
		IV formulation: PJIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Ilaris (canakinumab SC injection**)**	Inhibition of IL-1β	SJIA
Kineret® (anakinra SC injection)	Inhibition of IL-1	RA, SJIA^
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, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi™ (risankizumab-rzza SC injection)	Inhibition of IL-23	PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of the JAK pathways	RA

Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib extended-release tablets)	Inhibition of the 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; IV – Intravenous, IL – Interleukin; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AS – Ankylosing spondlylitis; CD – Crohn's disease; PJIA – Polyarticular juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; SJIA – Sytemice juvenile idiopathic arthritis; UC – Ulcerative colitis. ^ Off-label use of SJIA supported in guidelines.