PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Simponi Subcutaneous Prior Authorization Policy
- Simponi® (golimumab subcutaneous injection – Janssen)

REVIEW DATE: 05/11/2022

OVERVIEW

Simponi Subcutaneous, a tumor necrosis factor inhibitor (TNFi), is approved for the following uses:[1]

- **Ankylosing spondylitis,** in adults with active disease either alone or in combination with methotrexate or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
- **Psoriatic arthritis,** in adults with active disease either alone or in combination with methotrexate or other non-biologic DMARDs.
- **Rheumatoid arthritis,** in adults with moderate to severe active disease in combination with methotrexate.
- **Ulcerative colitis,** 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.

Guidelines

TNFis feature prominently in guidelines for treatment of inflammatory conditions.

- **Psoriatic Arthritis:** Guidelines from American College of Rheumatology (ACR) [2019] recommend TNFis over other biologics for use in treatment-naïve patients and in those who were previously treated with an oral therapy.[3]
- **Rheumatoid Arthritis:** Guidelines from ACR (2015) have TNFis and non-TNF biologics, administered with or without methotrexate, equally positioned as a recommended therapy following a trial of a conventional synthetic DMARD (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine).[4]
- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] TNFis are recommended for the initial biologic. In those who are secondary non-responders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Ulcerative Colitis:** Updated American College of Gastroenterology guidelines for ulcerative colitis (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: budesonide tablets; oral or intravenous systemic corticosteroids, Entyvio® (vedolizumab intravenous infusion), Xeljanz®/XR (tofacitinib tablets/extended-release tablets), or TNFis (adalimumab, Simponi Subcutaneous, infliximab).[5] In addition to the approved indication, clinical guidelines for the management of pouchitis, published in 2009, indicate that first-line therapy for pouchitis is antibiotic therapy (e.g. metronidazole, ciprofloxacin).[8] Other treatment options include maintenance probiotics, oral or topical budesonide, anti-inflammatory drugs (e.g., mesalamine), or immunosuppressive drugs (e.g., infliximab).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Simponi Subcutaneous. Because of the specialized skills required for evaluation and diagnosis of patients treated with Simponi Subcutaneous as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Simponi Subcutaneous 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 Subcutaneous is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist.
   - **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)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi); OR
         Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
       - **b)** Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
   - **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
   - **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)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi; OR

Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

3. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following conditions (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

i. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND

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 other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Rheumatoid Arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to "step back" and try a conventional synthetic DMARD.

ii. The medication is prescribed by or in consultation with a rheumatologist.

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.

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

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

i. Patient is ≥ 18 years of age; AND

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

a) Patient has tried one systemic therapy; OR

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of one biologic other

than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for ulcerative colitis.

b) Patient meets BOTH of the following [(1) and (2)]:
(1) Patient has pouchitis; AND
(2) Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa (mesalamine) enema; AND
Note: Examples of antibiotics include metronidazole and ciprofloxacin. Hydrocortisone enema is an example of a corticosteroid enema.

iii. The medication is prescribed by or in consultation with a gastroenterologist.

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) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi); OR
Note: Examples of assessment for inflammatory response include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b) Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

Other Uses with Supportive Evidence

5. Spondyloarthritis, Other Subtypes. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: This includes undifferentiated arthritis, non-radiographic axial spondyloarthritis, and reactive arthritis (Reiter's disease). For Ankylosing Spondylitis or Psoriatic Arthritis, refer to the respective criteria under FDA-approved indications.

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following conditions (i and ii):
i. Patient meets ONE of the following (a or b):
a) Patient meets both of the following [(1) and (2)]:
(1) Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet; AND
(2) Patient has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); OR
Note: Examples of conventional synthetic DMARDs include methotrexate, leflunomide, and sulfasalazine.
b) 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 elevated beyond the upper limit of normal for the reporting laboratory; OR
(2) Sacroiliitis reported on magnetic resonance imaging; AND
ii. The medication is prescribed by or in consultation with a rheumatologist.

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) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Simponi); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Simponi), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Simponi Subcutaneous is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Simponi Subcutaneous 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 adverse events with combinations and lack of data supportive of additional efficacy.
Note: This does not exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Simponi Subcutaneous.

2. **Plaque Psoriasis without Psoriatic Arthritis.** Simponi Subcutaneous is indicated in patients with psoriatic arthritis, but it has not been evaluated and it is not indicated in patients with plaque psoriasis without psoriatic arthritis. Prospective, controlled trials are needed to determine safety and efficacy in plaque psoriasis. Other TNFis (e.g., etanercept, adalimumab, and infliximab products, Cimzia® [certolizumab pegol subcutaneous injection]) 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® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; September 2019.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association 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. 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.

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Ulcerative Colitis:** To align with other policies with criteria for Ulcerative Colitis,	05/12/2021

	criteria were changed to require one previous systemic therapy and examples of corticosteroids were moved into a Note. Previously criteria required one conventional systemic agent or a corticosteroid. Since a specific duration of therapy is not required for a trial of a systemic therapy, the exception for those who are intolerant was removed.	
Selected Revision	**Ankylosing Spondylitis:** Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Psoriatic Arthritis:** Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Rheumatoid Arthritis:** Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Ulcerative Colitis:** Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. **Spondylitis, Other Subtypes:** Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving, it was clarified that this applies to a patient who is receiving for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.	12/01/2021
Annual Revision	No criteria changes.	05/11/2022

APPENDIX

* Not an all-inclusive list of indications (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; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.