# Drug Coverage Policy

**Effective Date……08/01/2026**
**Coverage Policy Number……IP0667**
**Policy Title……Simponi Subcutaneous Prior Authorization Policy**

# Inflammatory Conditions – Simponi Subcutaneous Prior Authorization Policy

- Simponi® (golimumab subcutaneous injection – Janssen)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## OVERVIEW

Simponi subcutaneous injection, a tumor necrosis factor inhibitor (TNFi), is indicated for the following uses:[1]

- **Ankylosing spondylitis,** in adults with active disease.
- **Psoriatic arthritis,** in adults with active disease either alone or in combination with methotrexate.
- **Rheumatoid arthritis,** in adults with moderate to severe active disease in combination with methotrexate.
- **Ulcerative colitis,** for the treatment of adults and pediatric patients weighing ≥ 15 kg with moderately to severely active disease.

### Guidelines

TNFis are featured 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 (2021) recommend addition of a biologic or a targeted synthetic disease-modifying antirheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.[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 as 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 (UC):** The American Gastroenterological Association (AGA) [2024] and the American College of Gastroenterology (ACG) [2025] have clinical practice guidelines on the management of moderate to severe UC.[5,8] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNFis, Entyvio® (vedolizumab), interleukin (IL)-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.[8] Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.[5,8]

# Coverage Policy

## POLICY STATEMENT

Prior Authorization is required for benefit coverage of Simponi Subcutaneous. 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. 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.

**NOTE: This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Employer Plans: Standard/Performance, and Total Savings Prescription Drug Lists (PSM001), Legacy Prescription Drug Lists (PSM017), Value/Advantage Prescription Drug Lists (PSM020), or Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.**

**Simponi subcutaneous is considered medically necessary when ONE of the following is met (1, 2, 3, 4, or 5):**

**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 the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 18 years of age; 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), 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 (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is 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 (A or B):

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

**i.** Patient is ≥ 18 years of age; AND

**ii.** 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 had a 3-month trial with 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 BOTH of the following (i and ii):

**i.** Patient weighs ≥ 15 kilograms (kg); AND

**ii.** The medication is prescribed by or in consultation with a gastroenterologist; OR

**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 ALL of the following (i, ii, and iii):

**i.** Patient is ≥ 18 years of age; AND

**ii.** 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

**iii.** 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 Covered**

**Simponi subcutaneous for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

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.

## References


1. Simponi® subcutaneous injection [prescribing information]. Horsham, PA: Janssen; October 2025.
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. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123.
5. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
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.
8. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224.


## Revision Details

| Summary of Changes | Review Date | Effective Date |
|---|---|---|
| New policy | 09/12/2024 | 11/01/2024 |
| No criteria changes. | 06/12/2025 | 07/01/2025 |
| **Ulcerative Colitis:** For initial therapy, removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an | 07/31/2025 | 09/01/2025 |

| | | |
|---|---|---|
| antibiotic, probiotic, corticosteroid enema, or mesalamine enema. | | |
| **Ulcerative Colitis:** For initial therapy, the requirement that patient is ≥ 18 years of age was removed. A requirement was added that patient weighs ≥ 15 kilograms (kg). | 10/30/2025 | 11/15/2025 |
| No criteria changes. | 06/25/2026 | 07/01/2026 |
| No criteria changes.<br><br>**Appendix:** Icotyde (icotrokinra tablets) was added. | 07/09/2026 | 08/01/2026 |

The policy effective date is in force until updated or retired.

## APPENDIX

| | Mechanism of Action | Examples of 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, RA |
| **Infliximab IV Products** (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC |
| **Zymfentra®** (infliximab-dyyb SC injection) | Inhibition of TNF | CD, 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 |
| **Tocilizumab Products** (Actemra® IV, biosimilar; Actemra SC, biosimilar) | 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 |
| **Omvoh®** (mirikizumab IV infusion, SC injection) | Inhibition of IL-23 | CD, UC |
| **Ustekinumab Products** (Stelara® IV, biosimilar; Stelara SC, biosimilar) | 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; secukinumab IV infusion) | Inhibition of IL-17A | SC formulation: AS, ERA, nr-axSpA, PsO, PsA |
| | | IV formulation: AS, nr-axSpA, PsA |
| **Taltz®** (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA |
| **Bimzelx®** (bimekizumab-bkzx SC injection) | Inhibition of IL-17A/17F | PsO, AS, nr-axSpA, PsA |
| **Ilumya®** (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO |

| | | |
|---|---|---|
| **Skyrizi®** (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion) | Inhibition of IL-23 | SC formulation: CD, PSA, PsO, UC |
| | | IV formulation: CD, UC |
| **Tremfya®** (guselkumab SC injection, guselkumab IV infusion) | Inhibition of IL-23 | SC formulation: CD, PsA, PsO, UC |
| | | IV formulation: CD, UC |
| **Entyvio®** (vedolizumab IV infusion, vedolizumab SC injection) | Integrin receptor antagonist | CD, UC |
| **Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs** | | |
| **Icotyde®** (icotrokinra tablets) | Inhibition of IL-23 receptor | PsO |
| **Otezla®** (apremilast tablets) | Inhibition of PDE4 | PsO, PsA |
| **Otezla XR™** (apremilast extended-release tablets) | Inhibitor of PDE4 | PsO, PsA |
| **Cibinqo™** (abrocitinib tablets) | Inhibition of JAK pathways | AD |
| **Olumiant®** (baricitinib tablets) | Inhibition of JAK pathways | RA, AA |
| **Litfulo®** (ritlecitinib capsules) | Inhibition of JAK pathways | AA |
| **Leqselvi®** (deuruxolitinib tablets) | Inhibition of JAK pathways | AA |
| **Rinvoq®** (upadacitinib extended-release tablets) | Inhibition of JAK pathways | AD, AS, nr-axSpA, RA, PsA, CD, UC |
| **Rinvoq® LQ** (upadacitinib oral solution) | Inhibition of JAK pathways | PsA, PJIA |
| **Sotyktu®** (deucravacitinib tablets) | Inhibition of TYK2 | PsO |
| **Xeljanz®** (tofacitinib tablets/oral solution) | Inhibition of JAK pathways | RA, PJIA, PsA, UC |
| **Xeljanz® XR** (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC |
| **Zeposia®** (ozanimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |
| **Velsipity®** (etrasimod tablets) | Sphingosine 1 phosphate receptor modulator | UC |

* Not an all-inclusive list of indications. 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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