UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2203-7
Program	Prior Authorization/Medical Necessity
Medication	*Simponi® (golimumab) *This program applies to the subcutaneous formulation of golimumab.
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 5/2022, 5/2023, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

1. Background:

Simponi (golimumab) is a tumor necrosis factor (TNF) blocker, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate (MTX).[1] Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).[1] It is also indicated for the treatment of adult patients with active ankylosing spondylitis (AS).[1] Simponi is also 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 ulcerative colitis, it is indicated 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.[1] An intravenous formulation of golimumab, Simponi Aria®, is also available. Simponi Aria® is indicated for adult patients with moderately to severely active rheumatoid arthritis in combination with methotrexate, active psoriatic arthritis in patients 2 years of age and older, adult patients with active ankylosing spondylitis, and active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older.

2. Coverage Criteria[a]:

A. <u>Rheumatoid Arthritis (RA)</u>

1. **<u>Initial Authorization</u>**

a. **Simponi** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) **<u>One</u>** of the following:

(a) History of failure to a 3 month trial of **<u>one</u>** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib)]

-OR-

(c) **Both** of the following:

i. Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

-AND-

(3) Patient is not receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Simponi therapy

-AND-

(2) Patient is not receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia

(abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

(2) **One** of the following:

(a) History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

-OR-

(c) **Both** of the following:

i. Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

-AND-

(3) Patient is not receiving Simponi in combination with another immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx

(secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Simponi therapy

-AND-

(2) Patient is not receiving Simponi in combination with another immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis (AS)

1. **Initial Authorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis

-AND-

(2) **One** of the following:

(a) History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Xeljanz/Xeljanz XR (tofacitinib), Rinvoq (upadacitinib)].

-OR-

(c) **Both** of the following:

i. Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

-AND-

(3) Patient is not receiving Simponi in combination with with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(4) Prescribed by or in consultation with a rheumatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Simponi therapy

-AND-

(2) Patient is not receiving Simponi in combination with with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

D. Ulcerative Colitis (UC)

1. **Initial Authorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) **One** of the following:

(a) Patient has had prior or concurrent inadequate response to a therapeutic course of oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)].

-OR-

(c) **Both** of the following:

i. Patient is currently on Simponi therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Jannsen sponsored CarePath Savings program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Simponi*

-AND-

(3) Patient is not receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia

(abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Jannsen sponsored CarePath Savings program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Simponi** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Simponi therapy

-AND-

(2) Patient is not receiving Simponi in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut business, only a 60-day trial will be required. For Kentucky and Mississippi business only a 30-day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- The intravenous infusion is typically covered under the medical benefit. Please refer to the United Healthcare Drug Policy for Simponi Aria

4. References:

1. Simponi [package insert]. Horsham, PA: Janssen Biotech Inc.; September 2019.
2. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
3. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Arthritis Rheum. 2016;68(1):1-26.

4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis -- Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65:137-174.
5. Yu D, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Accessed January 14, 2019.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.

Program	Prior Authorization/Medical Necessity - Simponi (golimumab)
Change Control	
5/2020	New program
5/2021	Annual review. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Removed drug documentation where only one drug is required. References and background updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis, psoriatic arthritis and ulcerative colitis with no change to clinical intent. Updated initial authorization duration to 12 months for ulcerative colitis. Updated CT/KY footnote.
5/2022	Added targeted synthetic DMARD to bypass criteria for AS and added Rinvoq and Xeljanz as a JAK inhibitor example where applicable. Added Mississippi to state mandate language.
5/2023	Annual review. Updated drug examples to mirror other pharmacy programs.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.