UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1094-14
Program	Prior Authorization/Notification
Medication	*Simponi® (golimumab) *This program applies to the subcutaneous formulation of golimumab.
P&T Approval Date	1/2007, 6/2008 , 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 8/2012, 11/2012, 7/2013, 2/2014, 2/2015, 4/2015, 3/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021, 12/2021, 12/2022, 7/2023
Effective Date	10/1/2023; Oxford only: N/A

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 moderate to severe ulcerative colitis who have require continuous steroid therapy or who have had an inadequate response to or intolerance to prior treatment. 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, active
psoriatic arthritis, active ankylosing spondylitis, and active polyarticular juvenile idiopathic arthritis.

2. Coverage Criteria[a]:

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

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

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

      (1) Diagnosis of moderately to severely active rheumatoid arthritis

      -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.

2. **<u>Reauthorization</u>**

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

(1) Diagnosis of active psoriatic arthritis

-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.

2. **Reauthorization**

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

(1) Diagnosis of active ankylosing spondylitis

-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.

2. **Reauthorization**

a. **Simponi** will be approved based on **both** 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.

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 is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)
(b) History of inadequate response or failure to tolerate **one** of the following:

i. Oral aminosalicylates
ii. Oral corticosteroids
iii. Azathioprine
iv. 6-mercaptopurine

-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)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Simponi** will be approved based on **both** 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.

[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.

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 and/or Step Therapy 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.

Program	Prior Authorization/Notification – Simponi (golimumab)
Change Control	
2/2014	Extended reauthorization duration to 24 months.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated background and references.
4/2015	Changed initial UC authorization from 10 weeks to 12 weeks.
3/2016	Annual review. Updated background information. Added Otezla (apremilast) to the combination criteria for psoriatic arthritis. Updated statement regarding scope of the program. Added reference to the UHC drug policy for intravenous infusions. Updated references.

3/2017	Annual review with no changes to coverage criteria. Updated background and references.
3/2018	Annual review with no changes to coverage criteria. Updated references.
3/2019	Annual review. Added Olumiant (baricitinib) to list of medications that patient should not be receiving while on Simponi therapy for rheumatoid arthritis. Updated references.
3/2020	Annual review. Added Rinvoq (upadacitinib) to list of medications that patient should not be receiving while on Simponi therapy for rheumatoid arthritis. Updated references.
3/2021	Annual review. No changes to clinical criteria. Updated background.
12/2021	Updated initial authorization for UC to 12 months.
12/2022	Annual review with no change to coverage criteria. Added Rinvoq as a JAK inhibitor example. Updated reference and background. Added state mandate footnote.
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.