UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Simponi

Program	Prior Authorization
Medication	Simponi (golimumab) subcutaneous
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2015
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

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;
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate;
- Active ankylosing spondylitis (AS);
- Moderate to severe ulcerative colitis (UC) 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 inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, or achieving and sustaining clinical remission in induction responders.

2. Coverage Criteria:

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

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

<u>One</u> of the following:

(1) **<u>All</u>** of the following:

a. Diagnosis of moderately to severely active RA

-AND-

b. Patient is not receiving Simponi in combination with **<u>any</u>** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. **One** of the following:

(1) Patient is receiving concurrent therapy with methotrexate (e.g., Rheumatrex, Trexall)

-OR-

(2) History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

d. History of failure, contraindication, or intolerance to **three** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Kevzara (sarilumab)
- Olumiant (baricitinib)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

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

a. Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active RA

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Simponi therapy

-AND-

b. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of active psoriatic arthritis

-AND-

b. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. **Both** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

e. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

-OR-

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

a. Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of active psoriatic arthritis

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Simponi therapy

-AND-

b. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with **one** of the following:

(1) Rheumatologist
(2) Dermatologist

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of active ankylosing spondylitis

-AND-

b. History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. **Both** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)

-AND-

(2) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

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

a. Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of active ankylosing spondylitis

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Simponi therapy

-AND-

b. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

D. Ulcerative Colitis

1. **Initial Authorization**

One of the following:

(1) **All** of the following:

a. Diagnosis of moderately to severely active ulcerative colitis

-AND-

b. **One** of the following:

(1) Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

-OR-

(2) History of failure to **one** of the following conventional therapies at maximally indicated doses within the last 3 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

(a) Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
(b) 6-mercaptopurine (Purinethol)
(c) Azathioprine (Imuran)
(d) Aminosalicylates (e.g., mesalamine, sulfasalazine)

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. History of failure, contraindication, or intolerance to Humira (adalimumab)

-AND-

e. Prescribed by or in consultation with a gastroenterologist

-OR-

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

a. Patient is currently on Simponi therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active ulcerative colitis

-AND-

c. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Simponi therapy

-AND-

b. Patient is not receiving Simponi in combination with **any** of the following:

(1) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

c. Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

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.

4. References:

1. Simponi [package insert]. Horsham, PA: Janssen Biotech Inc.; June 2018.
2. 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.
3. 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.
4. 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.

Program	Program type – Prior Authorization
Change Control	
Date	Change
2/2015	New policy
3/2016	Changed trial requirement of traditional DMARDs to only methotrexate to align with the requirement of concurrent use of methotrexate. Added Enbrel to prerequisite therapy in the following initial therapy sections: rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Updated policy template
10/2016	Annual Review – no change
3/2017	Added Otezla to list of medications that should not be used with Simponi. Updated policy template.
9/2017	Added Otezla to preferred agents for psoriatic arthritis

2/2018	Updated step therapy medications in the rheumatoid arthritis section to a trial of two TNF inhibitors and Kevzara due to PDL changes effective 4/1/18. Changed number of trial products from three to two in the psoriatic arthritis section.
2/2019	Revised background to align with package insert. Clarified that ankylosing spondylitis requires a trial of two preferred products. Removed prescriber check. Updated references.
3/2019	Revised step therapy medications for RA. Revised AS and UC prerequisite medications.
11/2019	Revised PsA and AS step therapy medications. Updated references.
12/2019	Revised additional prerequisite therapies and added documentation of drug, date, and duration of trials. Separated continuation of therapy requirements for current users.
1/2020	Revised RA step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements.