UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Simponi -ARIZONA

Program	Prior Authorization
Medication	Simponi (golimumab) Subcutaneous

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 in combination with methotrexate. Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active psoriatic arthritis. It is also indicated for the treatment of adult patients with active ankylosing spondylitis. 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. An intravenous formulation of golimumab, Simponi Aria™, is also available. It is only indicated for adult patients with moderately to severely active rheumatoid arthritis.

Simponi Aria (IV) is not a pharmacy benefit for the UnitedHealthcare Community Plan

2. Coverage Criteria:

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

1. <u>Initial Authorization</u>

a. Diagnosis of moderately to severely active RA

-AND-

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

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, 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 (eg, Rheumatrex, Trexall)

-OR-

(2) History of failure, contraindication, or intolerance to methotrexate

-AND-

d. Prescribed or recommended by a rheumatologist

-AND-

e. One of the following:

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

(a) Humira (adalimumab)
(b) Enbrel (etanercept)

-OR-

(2) For continuation of prior Simponi therapy

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

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. **Initial Authorization**

a. Diagnosis of active psoriatic arthritis

-AND-

b. Prescribed or recommended by a rheumatologist or dermatologist

-AND-

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

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

-AND-

d. One of the following:

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

(a) Humira (adalimumab)
(b) Enbrel (etanercept)

-OR-

(2) For continuation of prior Simponi therapy

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 [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]

(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis

1. Initial Authorization

a. Diagnosis of ankylosing spondylitis

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to two or more NSAIDs

-AND-

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

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

-AND-

e. One of the following:

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

(a) Humira (adalimumab)
(b) Enbrel (etanercept)

-OR-

(2) For continuation of prior Simponi therapy

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

Authorization will be issued for 12 months.

D. Ulcerative Colitis

1. Initial Authorization

a. Diagnosis of moderately to severely active ulcerative colitis

-AND-

b. One of the following:

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

-OR-

(2) History of failure, contraindication, or intolerance to one of the following therapies:
(a) Oral aminosalicylates
(b) Oral corticosteroids
(c) Azathioprine
(d) 6-mercaptopurine

-AND-

c. Prescribed or recommended by a gastroenterologist

-AND-

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

(1) Biologic DMARD [eg, 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-

e. One of the following:

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

-OR-

(2) For continuation of prior Simponi therapy

Authorization will be issued for 10 weeks.

2. <u>Reauthorization</u>

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

Authorization will be issued for 12 months.

3. References:

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12. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. Arthritis Rheum. 1993; 36 (6): 729-740.
13. Per clinical consult with rheumatologist, June 30, 2011.
14. van der Heijde, Sieper J, Maksymowych WP, et al. 2010 update of the international ASAS recommendations for the use of anti-TNF agents in patients with axial spondyloarthritis. Ann Rheum Dis. 2011;70:905-908.
15. Kornbluth A, Sachar DB, and Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2010;105(3):501-23.
16. Simponi Aria Prescribing Information. Janssen Biotech, Inc., September 2013.
17. Xeljanz Prescribing Information. Pfizer, Inc., November 2013.

Program	Program type – Prior Authorization
Change Control	
Date	Change
August 2017	New policy specific to Arizona.