UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Simponi - OHIO

Program	Prior Authorization
Medication	Simponi (golimumab) subcutaneous
Markets In Scope	Ohio

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 [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, contraindication, or intolerance to methotrexate

-AND-

d. Prescribed or recommended by a rheumatologist

-AND-

e. **One** of the following:

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

- Cimzia (certolizumab)
- Humira (adalimumab)
- 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 [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)]

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 [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. One of the following:

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

         (a) Cimzia (certolizumab)
         (b) Humira (adalimumab)
         (c) 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 [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)]

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 [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-

e. One of the following:

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

(a) Cimzia (certolizumab)
(b) Humira (adalimumab)
(c) 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 [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)]

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 (i.e., 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 [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-

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. **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)]

Authorization will be issued for 12 months.

3. References:

1. Simponi Prescribing Information. Janssen Biotech Inc., November 2013.
2. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care & Research. 2012;64(5):625-639.
3. Furst DE, Keystone EC, Braun J, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2011. Ann Rheum Dis. 2012;71(Supp II):i2–i45.

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.
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7. Inman RD, Davis Jr. JC, van der Heijde D, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis: Results of a randomized, double-blind, placebo-controlled, Phase III Trial. Arthritis Rheum. 2008; 58(11): 3402-3412.
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11. Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum. 1995;38:727-735.
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
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.