UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Actemra -ARIZONA

Program	Prior Authorization
Medication	Actemra (tocilizumab) subcutaneous

1. Background:

Actemra is indicated for the treatment of adult patients with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

Actemra is also indicated in adult patients with giant cell arteritis.

Actemra IV is not a pharmacy benefit for the UnitedHealthcare Community Plan

2. Coverage Criteria:

A. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Diagnosis of moderately to severely active RA (eg, swollen, tender joints with limited range of motion)

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one non-biologic disease modifying anti-rheumatic drug (DMARD) [eg, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine]

-AND-

d. Patient is not receiving Actemra 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 Actemra therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Documentation of positive clinical response to Actemra therapy

-AND-

b. Patient is not receiving Actemra 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. Giant Cell Arteritis

1. Initial Authorization

a. Diagnosis of giant cell arteritis

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one glucocorticoid (e.g., prednisone)

-AND-

d. Patient is not receiving Actemra 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.

2. **Reauthorization**

a. Documentation of positive clinical response to Actemra therapy

-AND-

b. Patient is not receiving Actemra 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:

1. Actemra Prescribing Information. Genentech, Inc., May 2017.
2. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum.2008;59(6):762-784.
3. Jones G, Sebba A, Gu J, et al. Comparison of tocilizumab monotherapy versus methotrexate monotherapy in patients with moderate to severe rheumatoid arthritis: the AMBITION study. Ann Rheum Dis. 2010;69(1):88-96.
4. Data on file, Genentech, Inc.
5. Smolen JS, Beaulieu A, Rubbert-Roth A, et al. for the OPTION Investigators. Effect of interleukin-6 receptor inhibition with tocilizumab in patients with rheumatoid arthritis

(OPTION study): a double-blind, placebo-controlled, randomized trial. Lancet. 2008;371:987-97.
6. Genovese MC, McKay JD, Nasonov EL, et al. Interleukin-6 receptor inhibition with tocilizumab reduces disease activity in rheumatoid arthritis with inadequate response to disease-modifying antirheumatic drugs: The tocilizumab in combination with traditional disease-modifying antirheumatic drug therapy study. Arthritis Rheum. 2008;58(10):2968-80.
7. Emery P, Keystone E, Tony HP, et al. IL-6 receptor inhibition with tocilizumab improves treatment outcomes in patients with rheumatoid arthritis refractory to anti-tumour necrosis factor biologicals: results from a 24-hour week multicentre randomized placebo-controlled trial. Ann Rheum Dis. 2008;67:1516-1523.
8. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum. 2013;65(10):2499-512.
9. De Benedetti F, Brunner H, Ruperto N, et al. Tocilizumab in patients with systemic juvenile idiopathic arthritis: efficacy data from the placebo-controlled 12-week part of the phase 3 TENDER trial. Arthritis Rheum. 2010; 62. Presented at the ACR Annual Meeting; November 6-7, 2010; Atlanta, GA. Abstract #1434.
10. Per clinical consult with pediatric rheumatologist, August 2, 2011.
11. Per clinical consult with rheumatologist, June 30, 2011.
12. 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 Res. 2012;64(5):625-39.
13. Gabay C, Emery P, van Vollenhoven R, et al. Tocilizumab monotherapy versus adalimumab monotherapy for treatment of rheumatoid arthritis (ADACTA): a randomised, doubleblind, controlled phase 4 trial. Lancet. 2013;381(9877):1541-1550.
14. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011;63(4):465-82.

Program	Program type – Prior Authorization
Change Control	
Date	Change
August 2017	New policy specific to Arizona.
October 2017	Added review criteria for giant cell arteritis. Updated background and references.