UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1128-7
Program	Prior Authorization/Notification
Medication	*Actemra® (tocilizumab) *This program applies to the subcutaneous formulation of tocilizumab.
P&T Approval Date	2/2014, 2/2015, 3/2016, 3/2017, 7/2017, 7/2018
Effective Date	10/1/2018; Oxford only: 10/1/2018

1. Background:

Actemra (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist, available in both an intravenous and a subcutaneous formulation. Both forms of Actemra are 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).[1] Examples of DMARDs commonly used in the treatment of rheumatoid arthritis include methotrexate, leflunomide, and sulfasalazine.[2,3] The subcutaneous formulation is also indicated for giant cell arteritis in adult patients. Both formulations are also indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA), while the intravenous formulation, is indicated only for active systemic juvenile idiopathic arthritis (SJIA), in patients 2 years of age and older. The intravenous form is also indicated for the treatment of adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.[1]

2. Coverage Criteria:

A. Giant Cell Arteritis (GCA)

1. Initial Authorization

a. Actemra will be approved based on **all** of the following criteria:

(1) Diagnosis of giant cell arteritis

-AND-

(2) Patient is not receiving Actemra in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Actemra therapy

-AND-

(2) Patient is not receiving Actemra in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 24 months.

B. Rheumatoid Arthritis (RA)

1. Initial Authorization

a. Actemra will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient has had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) (e.g., methotrexate, leflunomide, sulfasalazine)

-AND-

(3) Patient is not receiving Actemra in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Actemra therapy

-AND-

(2) Patient is not receiving Actemra in combination with **either** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)][1]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 24 months.

C. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. Initial Authorization

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

(1) Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-

(2) Patient is not receiving Actemra in combination with **either** of the following:
(a) Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Actemra therapy

-AND-

(2) Patient is not receiving Actemra in combination with **either** of the following:
(a) Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]

Authorization will be issued for 24 months.

3. Additional Clinical Rules:

- 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 Actemra.

4. References:

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; May 2018.
2. Pavy S. Constantin A, Pham T, et al. Methotrexate therapy for rheumatoid arthritis: clinical practice guidelines based on published evidence and expert opinions. Joint Bone Spine 2006;73(4):388-95.
3. 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.

Program	Prior Authorization/Notification - Actemra (tocilizumab)
Change Control	
2/2014	New program.
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 references.
3/2016	Annual review with no change to the coverage criteria. Updated background. Updated statement regarding scope of the program. Added reference to UHC drug policy for intravenous infusions. Updated references.
3/2017	Annual review with no change to the coverage criteria. Updated background and references.
7/2017	Added coverage criteria for giant cell arteritis. Updated background and references.
7/2018	Annual review. Added coverage for PJIA. Updated references.