UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1128-13
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, 7/2019, 7/2020, 4/2021, 4/2022, 4/2023, 7/2023
Effective Date	10/1/2023; Oxford only: N/A

1. Background:

Actemra (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist, available in both an intravenous and a subcutaneous formulation. Both formulations 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] Both formulations are also indicated for giant cell arteritis in adult patients. Both formulations are also indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) and active systemic juvenile idiopathic arthritis (SJIA), in patients 2 years of age and older. The intravenous formulation 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] The subcutaneous formulation is also indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).[1]

2. Coverage Criteria[a]:

A. <u>Giant Cell Arteritis (GCA)</u>

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

a. **Actemra** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of giant cell arteritis

-AND-

(2) Patient is not receiving Actemra in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 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 active polyarticular juvenile idiopathic arthritis

      -AND-

      (2) Patient is not receiving Actemra in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      Authorization will be issued for 12 months.

D. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. **Initial Authorization**

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

      (1) Diagnosis of active systemic juvenile idiopathic arthritis

      -AND-

      (2) Patient is not receiving Actemra in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

      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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

E. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

1. **Initial Authorization**

a. **Actemra** will be approved based on the following criterion:

(1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)

-AND-

(2) Patient is not receiving Actemra in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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 another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization

management programs may apply.

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 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.; June 2022.
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.
7/2019	Annual review. Added coverage criteria for SJIA. Updated background and references.
7/2020	Annual review. Updated authorization issue to 12 months for renewal. Updated reference.
4/2021	Added coverage criteria for systemic sclerosis-associated interstitial lung disease. Updated background and references.
4/2022	Annual review. Updated background to reflect both formulations being approved for GCA. Updated references.
4/2023	Annual review with no change to coverage criteria. Updated listed examples from Humira to adalimumab and added Rinvoq as JAK-I example. Updated reference. Added state mandate footnote.

7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.