UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Actemra

Program	Prior Authorization
Medication	Actemra (tocilizumab) subcutaneous
Markets in Scope	California, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2015
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Actemra is an interleukin-6 (IL-6) receptor antagonist 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), adult patients with giant cell arteritis, patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis, and patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

Actemra contains a black boxed warning for risk of serious infection. See full prescribing information for additional details.

2. Coverage Criteria:

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

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

<u>One</u> of the following:

(1) **<u>All</u>** of the following:

a. Diagnosis of moderately to severely active RA

-AND-

b. History of failure to a 3 month trial of **<u>one</u>** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

c. Patient is not receiving Actemra 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. History of failure, contraindication, or intolerance to **three** of the following:

- Cimzia (certolizumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Kevzara (sarilumab)
- Olumiant (baricitinib)

-AND-

e. Prescribed by or in consultation with a rheumatologist

-OR-

(2) **All** of the following:

a. Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

b. Diagnosis of moderately to severely active RA

-AND-

c. Patient is not receiving Actemra 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. Prescribed by or in consultation with a rheumatologist

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 [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. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

B. Giant Cell Arteritis

1. **Initial Authorization**

a. Diagnosis of giant cell arteritis

-AND-

b. **One** of the following:

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

-OR-

(2) Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

c. Patient is not receiving Actemra 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. Prescribed by or in consultation with a rheumatologist

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 [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. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

C. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. **Initial Authorization**

a. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-

b. **One** of the following:

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

- Humira (adalimumab)
- Enbrel (etanercept)

-OR-

(2) Patient is currently on Actemra therapy as documented by claims history or medical records (document drug, date, and duration of therapy)

-AND-

c. Patient is not receiving Actemra 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. Prescribed by or in consultation with a rheumatologist

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 [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. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

D. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Initial Authorization

a. Diagnosis of active systemic juvenile idiopathic arthritis

-AND-

b. Patient is not receiving Actemra 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. Prescribed by or in consultation with a rheumatologist

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 [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. Prescribed by or in consultation with a rheumatologist

Authorization will be issued for 12 months.

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 may be in place.

4. References:

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
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	Program type – Prior Authorization
Change Control	
Date	Change
2/2015	New policy
3/2016	Initial therapy section: Added Enbrel to list of preferred drugs that require history of failure, contraindication, or intolerance Added technician note indicating Actemra as a non-preferred drug and listing the preferred alternatives Annual Review- Updated policy template
10/2016	Annual Review – no change
3/2017	Updated “Community & State” to “Community Plan” in background. Added Otezla to list of medications not to be used with Actemra. Updated policy template.
4/2017	Added hydroxychloroquine to example list of non-biologic DMARDs
10/2017	Added review criteria for giant cell arteritis. Updated background and references.
2/2018	Updated step therapy medications in the rheumatoid arthritis section to a trial of two TNF inhibitors and Kevzara due to PDL changes effective 4/1/18.
7/2018	Updated background and criteria for polyarticular juvenile

	idiopathic arthritis. Updated references.
3/2019	Removed prescriber check to align with other programs. Revised step therapy requirement for RA section. Added criteria for systemic juvenile idiopathic arthritis. Removed non-biologic DMARD requirement for PJIA section. Updated background and references.
11/2019	Annual review. Updated reference.
12/2019	Revised RA non-biologic DMARD requirement. Separated continuation of therapy requirements for current users.
1/2020	Updated RA step therapy medications due to PDL changes.
5/2020	Added prescriber requirement. Minor update to DMARD requirement. Updated references.