Actemra (tocilizumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Dosing/Quantity Limit
Actemra (tocilizumab) 80 mg, 200 mg, 400 mg vial for intravenous infusion	8 mg/kg* as frequently as every 4 weeks
Actemra (tocilizumab) ACTPen prefilled autoinjector, prefilled syringe 162 mg/0.9 mL	4 autoinjectors/syringes per 28 days

Dosing Override Criteria

I. For polyarticular juvenile idiopathic arthritis (PJIA), may approve up to 10 mg/kg every 4 weeks for individuals weighing less than 30 kg.
II. For systemic juvenile idiopathic arthritis (SJIA), may approve up to 12 mg/kg every 2 weeks for patients weighing less than 30 kg and up to 8 mg/kg every 2 weeks for patients at or above 30 kg.
III. For cytokine release syndrome (CRS), may approve a total of up to four intravenous doses at least 8 hours apart; each dose up to 8 mg/kg for individuals weighing at or above 30 kg and up to 12 mg/kg in individuals weighing less than 30 kg;
IV. For Coronavirus Disease 2019 (COVID-19), may approve a total of up to two intravenous doses at least 8 hours apart; each dose up to 8 mg/kg*.

*For rheumatoid arthritis and CRS, and COVID-19 each dose should not exceed 800mg total. For giant cell arteritis, each dose should not exceed 600 mg total.

APPROVAL CRITERIA

Initial requests for Actemra (tocilizumab) may be approved for the following:

I. Giant cell arteritis (GCA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with GCA; **AND**
   B. Actemra (tocilizumab) is used in combination with a tapering course of corticosteroids (such as, prednisone);
   OR
   C. Actemra (tocilizumab) is used as a single agent following discontinuation of corticosteroids;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe RA;

AND

B. Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021);

OR

C. If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine);

AND

D. Individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred agents include – Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)] unless the following criteria are met Medication samples/coupons/discount cards are excluded from consideration as a trial.:

1. Individual has been receiving and is maintained on a stable dose of Actemra (tocilizumab);

OR

2. Individual is unable to use the preferred agents due to demyelinating disease or heart failure with documented left ventricular dysfunction

OR

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:

A. Individual is 2 years of age or older with moderate to severe PJIA;

AND

B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate)]; **AND**

C. Individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred b**i**ologics include – Enbrel (etanercept) and Humira (adalimumab)] unless the following criteria are met. Medication samples/coupons/discount cards are excluded from consideration as a trial.:

1. Individual has been receiving and is maintained on a stable dose of Actemra (tocilizumab);

OR

2. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction;

OR

IV. Still's disease (Adult-onset Still's Disease [AOSD] or Systemic juvenile idiopathic arthritis (SJIA) when the following is met:

A. Individual is 2 years of age or older with Still's Disease as either AOSD or SJIA;

OR

V. Multicentric Castleman Disease when each of the following criteria are met (NCCN 2A):

A. Individual with a diagnosis of relapsed/refractory of progressive multicentric Castleman disease; **AND**
B. Used as a single agent; **AND**
C. Human immunodeficiency virus (HIV)-negative; **AND**
D. Human herpes-8 negative; **AND**
E. No concurrent clinically significant infection (for example, Hepatitis B or C); **AND**
F. No concurrent lymphoma;

OR

VI. Cytokine Release Syndrome when the following criteria are met:
A. Individual 2 years of age or older with chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (Label, NCCN 2A);

OR

VII. Chronic Antibody-Mediated Renal Transplant Rejection when each of the following criteria are met (Choi 2017):
A. Individual has chronic active antibody-mediated rejection plus donor-specific antibodies and transplant glomerulopathy; **AND**
B. Individual has failed to respond to intravenous immune globulin (IVIG) plus rituximab therapy (with or without plasma exchange);

OR

VIII. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) when each of the following criteria is met:
A. Individual has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD); **AND**
B. Diagnosis has been confirmed through chest high resolution computed tomography (HRCT) scan showing ground glass opacification or fibrosis; **AND**
C. Documentation is provided that individual has confirmed pulmonary function tests showing Forced Vital Capacity (% FVC) greater than 55% of predicted (Khanna 2020).

OR

IX. Coronavirus Disease 2019 (COVID-19) when each of the following criteria are met:
A. Individual is 18 years of age or older; **AND**
B. Individual is currently hospitalized with COVID-19; **AND**
C. Individual is currently receiving systemic corticosteroids and requires supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Continuation requests for Actemra (tocilizumab) may be approved if the following criterion is met:

I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Actemra (tocilizumab) may **not** be approved for the following:

I. In combination with topical or oral JAK inhibitors, ozanimod, deucravacitinib, nintedanib, pirfenidone, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, other IL-6 inhibitors, rituximab, or natalizumab; **OR**

II. If initiating of therapy, for a diagnosis other than COVID-19 or CRS, individual has an absolute neutrophil count less than 2000/mm^3, platelet count less than 100,000/mm^3, or alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limit of normal; **OR**

III. Tuberculosis, or other active serious infections or a history of recurrent infections; **OR**

IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention-recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors) [in the setting of non-emergent use only)]; **OR**

V. Individual with SSc-ILD and concomitant class II or higher pulmonary arterial hypertension (Khanna 2020); **OR**

VI. When the above criteria are not met and for all other indications.

Note:
Actemra (tocilizumab) has a black box warning for risk of serious infections. Individuals treated with Actemra are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Actemra should be discontinued if an individual develops serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before tocilizumab use and during therapy. Treatment for latent TB should be initiated prior to use. Risks and benefits of tocilizumab should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection.

Key References:

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12. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 4, 2022.
13. Khanna D, Lin CJF, Furst DE, et al; focuSSced investigators. Tocilizumab in systemic sclerosis: a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2020 Oct;8(10):963-974. Erratum in: Lancet Respir Med. 2020 Oct;8(10):e75. Erratum in: Lancet Respir Med. 2021 Mar;9(3):e29.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.