

# STANDARD MEDICARE PART B MANAGEMENT

## ACTEMRA (tocilizumab)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs
2. Adult patients with giant cell arteritis
3. Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis
4. Patients 2 years of age and older with active systemic juvenile idiopathic arthritis
5. Adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) for slowing the rate of decline in pulmonary function.
6. 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 (CRS).

##### B. Compendial Uses

1. Rheumatoid arthritis with no previous treatment failure
2. Unicentric Castleman's disease
3. Multicentric Castleman's disease
4. Refractory/severe immunotherapy-related inflammatory arthritis not responding to corticosteroids and anti-inflammatory agents
5. Acute graft versus host disease
6. Cytokine release syndrome (other than severe or life-threatening CAR T-cell induced CRS)
7. Severe coronavirus disease 2019 (COVID-19) pneumonia

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. DOCUMENTATION

The following documentation must be available, upon request, for systemic sclerosis-associated interstitial lung disease: For initial requests: Results of a chest high-resolution computed tomography (HRCT) study

#### III. CRITERIA FOR INITIAL APPROVAL

##### A. **Rheumatoid arthritis**

Authorization of 12 months may be granted for treatment of rheumatoid arthritis.

**B. Juvenile idiopathic arthritis**

Authorization of 12 months may be granted for treatment of polyarticular or systemic juvenile idiopathic arthritis.

**C. Giant cell arteritis**

Authorization of 12 months may be granted for treatment of giant cell arteritis.

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

Authorization of 12 months may be granted for treatment of sclerosis-associated interstitial lung disease when the diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

**E. Unicentric Castleman's disease**

Authorization of 12 months may be granted for treatment of relapsed or refractory unicentric Castleman's disease.

**F. Multicentric Castleman's disease**

Authorization of 12 months may be granted for treatment of relapsed, refractory, or progressive multicentric Castleman's disease.

**G. Cytokine release syndrome**

1. Authorization of 1 month may be granted for treatment of chimeric antigen receptor (CAR) T cell-induced cytokine release syndrome (CRS).
2. Authorization of 1 month may be granted for treatment of cytokine release syndrome in members with refractory CRS related to blinatumomab therapy.

**H. Immunotherapy-related inflammatory arthritis**

Authorization of 12 months may be granted for treatment of refractory or severe immunotherapy-related inflammatory arthritis that has not responded to corticosteroids and anti-inflammatory agents.

**I. Acute graft versus host disease**

Authorization of 12 months may be granted for treatment of acute graft versus host disease when either of the following criteria is met:

1. Member has experienced an inadequate response to systemic corticosteroids.
2. Member has an intolerance or contraindication to corticosteroids.

**J. Severe coronavirus disease 2019 (COVID-19) pneumonia**

Authorization of 1 month may be granted for treatment of severe coronavirus disease 2019 (COVID-19) pneumonia when the member is part of a clinical trial.

**IV. CONTINUATION OF THERAPY**

**A. Cytokine release syndrome, immunotherapy-related inflammatory arthritis, acute graft versus host disease, and severe COVID-19 pneumonia**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**B. Rheumatoid arthritis, juvenile idiopathic arthritis, giant cell arteritis, and systemic sclerosis-associated interstitial lung disease**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

<b>Reference number(s)</b>
2423-A

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Actemra.
2. The member is receiving benefit from therapy.

**C. All other diagnoses**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Actemra.
2. Actemra is being used to treat an indication enumerated in Section III.
3. The member is receiving benefit from therapy. Benefit is defined as:
  - i. No evidence of unacceptable toxicity while on the current regimen AND
  - ii. No evidence of disease progression while on the current regimen

**V. REFERENCES**

1. Actemra [package insert]. South San Francisco, CA: Genetech, Inc.; March 2021.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed January 12, 2021.
3. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <https://www.nccn.org>. Accessed January 12, 2021.