Reference number(s)
2423-A

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)
7. Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)

B. Compendial Uses
1. Rheumatoid arthritis with no previous treatment failure
2. Unicentric Castleman disease
3. Multicentric Castleman disease
4. Immunotherapy-related inflammatory arthritis
5. Acute graft versus host disease
6. Cytokine release syndrome (other than severe or life-threatening CAR T-cell induced CRS)
7. Thyroid eye disease

Note: The criteria outlined in this policy is only applicable to coverage in the outpatient setting. Hospitalized members receiving Actemra for the treatment of COVID-19 will be managed according to the member's inpatient benefit.

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 disease
Authorization of 12 months may be granted for treatment of unicentric Castleman disease when all of the following criteria are met:
1. The member is HIV-negative.
2. The member is human herpesvirus-8-negative.
3. The requested medication will be used as a single agent.
4. The disease has progressed following treatment of relapsed/refractory disease.

F. Multicentric Castleman disease
Authorization of 12 months may be granted for treatment of multicentric Castleman disease when both of the following criteria are met:
1. The requested medication will be used as a single agent.
2. The disease has progressed following treatment of relapsed/refractory or progressive 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 systemic corticosteroids.

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. Thyroid Eye Disease
Authorization of 12 months may be granted for treatment of active Graves' orbitopathy that has not responded to corticosteroids.

IV. CONTINUATION OF THERAPY

A. Cytokine release syndrome, immunotherapy-related inflammatory arthritis, and acute graft versus host disease
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, systemic sclerosis-associated interstitial lung disease, and thyroid eye disease
All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 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 of 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.; December 2022.
2. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed January 12, 2023.
3. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. https://www.nccn.org. Accessed January 12, 2023.