

Reference number
1959-A

SPECIALTY GUIDELINE 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. Moderately to severely active rheumatoid arthritis
2. Active polyarticular juvenile idiopathic arthritis
3. Active systemic juvenile idiopathic arthritis
4. Giant cell arteritis

B. Compendial Uses

1. Unicentric Castleman's disease
2. Multicentric Castleman's disease

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 24 months may be granted for members who have received Actemra or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Actemra.
2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when any of the following criteria is met:
 - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
 - b. Member has an intolerance or contraindication to methotrexate (see Appendix).

B. **Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

1. Authorization of 24 months may be granted for members who have received Actemra or Orencia in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Actemra.
2. Authorization of 24 months may be granted for treatment of active pJIA when any of the following criteria is met:
 - a. Member has experienced an inadequate response to at least a 3-month trial of a TNF inhibitor (e.g., Enbrel, Humira, or Remicade).
 - b. Member has experienced an intolerable adverse event or has contraindication to a TNF inhibitor.

C. **Active Systemic Juvenile Idiopathic Arthritis (sJIA)**

1. Authorization of 24 months may be granted for members who have received Actemra or Kineret in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Actemra.

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2. Authorization of 24 months may be granted for treatment of active sJIA when any of the following criteria is met:
 - a. Member has an inadequate response to at least a 2-week trial of corticosteroids.
 - b. Member has an inadequate response to at least a 3-month trial of methotrexate or leflunomide.

D. Giant Cell Arteritis

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

E. Unicentric and Multicentric Castleman's Disease

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

III. CONTINUATION OF THERAPY

A. Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis and Systemic Juvenile Idiopathic Arthritis

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Actemra as evidenced by low disease activity or improvement in signs and symptoms of the condition.

B. Giant Cell Arteritis

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

C. Unicentric and Multicentric Castleman's Disease

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

IV. OTHER

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB)

Note: Members who have received Actemra or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) in a paid claim through a pharmacy or medical benefit within the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

Actemra for subcutaneous administration is not FDA-approved for pJIA or sJIA and will not be authorized for these conditions.

V. APPENDIX: Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

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VI. REFERENCES

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; May 2017.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed September 6, 2016.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
4. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update. *Ann Rheum Dis*. 2014;73:492-509.
5. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res*. 2011;63(4):465-482.
6. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism*. 2013;65:2499-2512.