

Actemra® (tocilizumab)



When requesting Actemra® (tocilizumab) for non-oncology indications, the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-Oncology Indications

Actemra is 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).

Actemra is indicated for the treatment of giant cell arteritis (GCA) in adult patients.

Actemra is indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Approved Non-Oncology Off-Label Compendial Use(s)

None

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have an active infection including localized infection
- Actemra (tocilizumab) will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- For an initial authorization request, an individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting Actemra (tocilizumab)
- For a re-authorization request, an individual's condition has improved or stabilized with Actemra (tocilizumab) therapy

For rheumatoid arthritis:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Has moderately to severely active disease AND

- Had an inadequate response to at least 3 months of methotrexate therapy unless contraindicated or intolerant to methotrexate OR
- Had an inadequate response to at least 3 months of leflunomide or sulfasalazine unless contraindicated or intolerant to leflunomide or sulfasalazine

For polyarticular juvenile idiopathic arthritis:

- Had an inadequate response to at least one TNF-inhibitor (e.g., adalimumab, etanercept)

For systemic juvenile idiopathic arthritis:

- Had an inadequate response or intolerance to prior biologic agent OR
- Has an active systemic features (e.g., fever, evanescent erythematous rash, hepatomegaly, splenomegaly, or serositis) and had an inadequate response to corticosteroids OR
- Had an inadequate response or intolerance to methotrexate or leflunomide with no active systemic features unless contraindicated

For giant cell arteritis:

- Had an inadequate response to a maximum tolerated corticosteroid dose unless contraindicated or intolerant to corticosteroids

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Rheumatoid arthritis

Actemra may be administered as an intravenous infusion or as a subcutaneous injection.

Intravenous dosing regimen

The recommended starting dose is 4 mg/kg every 4 weeks followed by an increase to 8 mg/kg every 4 weeks based on clinical response.

Subcutaneous dosing regimen

- For patients weighing less than 100 kg, the recommended dose is 162 mg administered by subcutaneous injection every other week, followed by an increase to every week based on clinical response
- For patients weighing 100 kg or more, the recommended dose is 162 mg administered by subcutaneous injection every week.

Giant Cell Arteritis

The recommended dose is 162 mg administered by subcutaneous injection every week

Polyarticular juvenile idiopathic arthritis

- For patients weighing less than 30 kg, the recommended dose is 10 mg/kg administered by intravenous every 4 weeks

- For patients weighing 30 kg or more, the recommended dose is 8 mg/kg administered by intravenous every 4 weeks

Systemic juvenile idiopathic arthritis

- For patients weighing less than 30 kg, the recommended dose is 12 mg/kg administered by intravenous every 2 weeks
- For patients weighing 30 kg or more, the recommended dose is 8 mg/kg administered by intravenous every 2 weeks

References

1. Actemra prescribing information. South San Francisco, CA; Genentech, Inc. March 2018.
2. Singh JA, Saag KG, Bridges JR SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. 2015.
3. Smolen JS, Landewe R, Bijlsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis* Published Online First: [March 6, 2017] doi:10.1136/annrheumdis-2016-210715
4. 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. *Arthritis & Rheumatism*. 2013;65:2499-2512.
5. American College of Rheumatology. Giant Cell Arteritis. Available at: <https://www.rheumatology.org/lAm-A/Patient-Caregiver/Diseases-Conditions/Giant-Cell-Arteritis>