# Pharmacy Medical Necessity Guidelines: Actemra® (tocilizumab)

*Effective: October 22, 2018*

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|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | SC: RX<br>IV: MED | Department to Review | RXUM/<br>PRECERT/<br>MM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**
*Intravenous injection*
All plans except Tufts Health Direct:
PRECERT: 617.972.9409

Tufts Health Direct:
MM: 888.415.9055

*Self-administered formulations (subcutaneous injection)*
RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Actemra (tocilizumab) is an interleukin-6 receptor inhibitor indicated for:

**Cytokine Release Syndrome**
- Treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older

**Giant Cell Arteritis**
- Treatment giant cell arteritis in adults

**Polyarticular Juvenile Idiopathic Arthritis**
- Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older

**Rheumatoid Arthritis**
- 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

**Systemic Juvenile Idiopathic Arthritis**
- Treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older

## COVERAGE GUIDELINES

**Actemra (tocilizumab) – subcutaneous**

The plan may authorize coverage of **Actemra** (tocilizumab) injection for subcutaneous use for Members when **all** the following criteria are met:

**Giant Cell Arteritis**

1. The Member has a documented diagnosis of giant cell arteritis

**AND**

2. The prescription is written by a rheumatologist or neurologist

**AND**

3. The Member has tried and failed treatment or has a documented contraindication to at least one of the following therapies:
   a) Glucocorticoids (e.g., prednisone, methylprednisolone)
   b) In Members who cannot tolerate glucocorticoids, methotrexate OR cyclophosphamide

**Systemic Juvenile Idiopathic Arthritis**

1. The Member has a documented diagnosis of active systemic juvenile idiopathic arthritis

**AND**

2. The prescription is written by a rheumatologist

**AND**

3. The Member is over 2 years of age

**AND**

4. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate
   a) methotrexate

   **OR**

   b) both of the following types of drugs
      - nonsteroidal anti-inflammatory drugs (NSAIDS)
      - corticosteroids

**Rheumatoid Arthritis**

1. The Member has a documented diagnosis of rheumatoid arthritis

**AND**

2. The prescription is written by a rheumatologist

**AND**

3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with at least two of the following agents:
   a) Humira (adalimumab)
   b) Enbrel (etanercept)
   c) Simponi (golimumab)

**OR**

4. The Member is new to the plan and has been stable on Actemra (tocilizumab) prior to enrollment

**Actemra (tocilizumab) – intravenous**

The plan may authorize coverage of **Acterma intravenous injection** for Members when all of the following criteria are met:

**Cytokine release syndrome**

1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

**Polyarticular Juvenile Idiopathic Arthritis**

1. The Member has a documented diagnosis of active polyarticular juvenile idiopathic arthritis with
   a) History of at least 6 months of active disease
   b) At least five joints with active arthritis (swollen or limitation of movement accompanied by pain and/or tenderness) and/or at least 3 active joints having limitation of motion.

**AND**

2. The prescription is written by a rheumatologist

**AND**

3. The Member is over 2 years of age

**AND**

4. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate
   a) methotrexate

   **OR**

   b) both of the following types of drugs
      - nonsteroidal anti-inflammatory drugs (NSAIDS)
      - corticosteroids

**Rheumatoid Arthritis**

1. The Member has a documented diagnosis of rheumatoid arthritis

**AND**

2. The prescription is written by a rheumatologist

**AND**

3. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with Remicade® (infliximab) or Simponi Aria® (golimumab)

**OR**

4. The Member is new to the plan and has been stable on Actemra (tocilizumab) prior to enrollment.

**Systemic Juvenile Idiopathic Arthritis**

5. The Member has a documented diagnosis of active systemic juvenile idiopathic arthritis

**AND**

6. The prescription is written by a rheumatologist

**AND**

7. The Member is over 2 years of age

**AND**

8. The Member has a documented inadequate response after three months at optimal doses or an inability to tolerate
   c) methotrexate

   **OR**

   d) both of the following types of drugs
      - nonsteroidal anti-inflammatory drugs (NSAIDS)
      - corticosteroids

## LIMITATIONS

1. Samples, free goods or similar offerings of Actemra (tocilizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Coverage of Actemra (tocilizumab) injection for subcutaneous use will be limited as follows:
   - Actemra 162 mg prefilled syringe – 4 syringes per 28 days.

## CODES

The following HCPCS/CPT code(s) are:

| Code | Description |
|---|---|
| J3262 | Injection, tocilizumab, 1 mg |

**Note:** Medical billing codes may not be used for Actemra (tocilizumab) injection for subcutaneous use. This formulation must be obtained via the Member's pharmacy benefit.

## REFERENCES


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18. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech Inc.; 2016 January.
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## APPROVAL HISTORY

July 13, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2011: Removed temporary code C9264 and replaced with code J3262
2. May 10, 2011: Added criteria for coverage of Systemic Juvenile Idiopathic Arthritis
3. April 10, 2012: No changes
4. March 12, 2013: No changes
5. June 11, 2013: Added criteria for coverage of Polyarticular Juvenile Idiopathic Arthritis. Added methotrexate as a prerequisite option for Systemic Juvenile Idiopathic Arthritis.
6. December 10, 2013: Added coverage guidelines for Actemra (tocilizumab) injection, for subcutaneous use.
7. October 7, 2014: No changes
8. October 6, 2015: No changes
9. January 1, 2016: Administrative change to rebranded template.
10. September 13, 2016: Effective 1/1/2017: Coverage of Actemra (tocilizumab) injection, for subcutaneous use requires trial and failure of treatment with, contraindication to or clinical inappropriateness of treatment with at least two of the following agents where indicated: Humira, Enbrel, Simponi. Coverage of Actemra (tocilizumab) injection, for intravenous use for the diagnosis

of rheumatoid arthritis requires trial and failure of treatment with, contraindication to or clinical inappropriateness of treatment with Remicade or Simponi Aria. Added exception language for Members new to the plan and stable on Actemra (tocilizumab) prior to enrollment.
11. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
12. June 13, 2017: Updated criteria to include supplemental indication of treatment of giant cell arteritis.
13. July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Actemra (tocilizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
14. October 15, 2018: Added coverage criteria for Actemra intravenous injection based on updated indication for cytokine release syndrome. Added Actemra subcutaneous injection to the approval criteria for systemic juvenile idiopathic arthritis.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.