Pharmacy Medical Necessity Guidelines: Actemra® (tocilizumab)

Effective: July 11, 2017

Prior Authorization Required ✓ Type of Review – Care Management
Not Covered ✓ Type of Review – Clinical Review

Pharmacy (RX) or Medical (MED) Benefit

SQ: RX / IV: MED

Department to Review RXUM/MED

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
☐ Tufts Health Direct – Health Connector
☒ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:
Subcutaneous Formulation
RXUM: 617.673.0988
Intravenous Formulation
MM: 888.415.9055

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS
Actemra (tocilizumab) is an interleukin-6 receptor inhibitor indicated for:
• Treatment of adult patients with giant cell arteritis,
• Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older,
• 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), and
• Treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older

COVERAGE GUIDELINES

Rheumatoid Arthritis
The plan may authorize coverage of Actemra (tocilizumab) for Members when all of the following criteria are met and limitations do not apply:
1. The Member has a documented diagnosis of rheumatoid arthritis
   AND
2. The prescription is written by a rheumatologist
   AND
3. The Member is 18 years of age or older
   AND
4. The Member tried and failed treatment with or the provider indicates clinical inappropriateness of Humira and Enbrel for the treatment of rheumatoid arthritis
   OR
5. The Member is new to the plan and has been stable on Actemra prior to enrollment

Giant Cell Arteritis
The plan may authorize coverage of Actemra (tocilizumab) injection for subcutaneous use only for Members when all of the following criteria are met:
1. The Member has a documented diagnosis of giant cell arteritis
   AND
2. The prescription is written by a rheumatologist
   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
Polyarticular or Systemic Juvenile Idiopathic Arthritis (PJIA or SJIA)
The plan may authorize coverage of Actemra (tocilizumab) injection for intravenous use only for Members when ALL of the following criteria are met:

1. The Member has a documented diagnosis of active polyarticular or 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 tried and failed treatment with, or the patient has a contraindication to corticosteroids (i.e., prednisone, hydrocortisone or methylprednisolone) AND methotrexate

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. Member must try and fail subcutaneous syringes prior to using the intravenous formulation unless the provider indicates clinical inappropriateness with using the subcutaneous syringes or the Member is a pediatric patient.
3. Coverage of Actemra (tocilizumab) injection, for subcutaneous use will be limited as follows:
   • Actemra 162 mg prefilled syringe – 4 syringes per 28 days.
4. Coverage of Actemra (tocilizumab) injection, for intravenous use in adults will be limited as follows:
   • Actemra 80 mg/4mL vials – 10 syringes per 28 days.
   • Actemra 200 mg/10mL vials – 4 vials per 28 days.
   • Actemra 400 mg/20mL vials – 2 vials per 28 days.
5. Coverage of Actemra (tocilizumab) injection, for intravenous use in pediatric patients will be limited as follows:
   • For pediatric patients weighing <30 kg (66 lbs), approve the minimum number of vials requested, not to exceed 12mg/kg for one treatment course every 14 days.
   • For pediatric patients weighing ≥30 kg (66 lbs), approve the minimum number of vials requested, not to exceed 8 mg/kg for one treatment course every 14 days.

CODES
The following HCPCS/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3262</td>
<td>Injection, tocilizumab, 1 mg</td>
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REFERENCES


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

Subsequent endorsement date(s) and changes made:
- November 4, 2014: Reviewed by the Pharmacy and Therapeutics Committee
- October 6, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- June 13, 2017: Updated criteria to include supplemental indication of treatment giant cell arteritis.
- 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.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink<sup>SM</sup> Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.