Pharmacy Medical Necessity Guidelines: Actemra® (tocilizumab)

Effective: October 22, 2018

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	SC: RX IV: MED	Department to Review	RXUM/ 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
Tufts Health Together:
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

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:
The Member has a documented diagnosis of rheumatoid arthritis

AND

1. The prescription is written by a rheumatologist

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with or has a documented contraindication to at least one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate (MTX), penicillamine, sulfasalazine, cyclosporine or leflunomide

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

Systemic Juvenile Idiopathic Arthritis
The plan may authorize coverage of Actemra (tocilizumab) injection for Members when all of the following criteria are met:
1. The Member has a documented diagnosis of systemic juvenile idiopathic arthritis

AND

2. The prescription is written by a rheumatologist

AND

3. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate

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 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

Cytokine release syndrome
The plan may authorize coverage of Actemra (tocilizumab) injection **for intravenous use only** for Members when all of the following criteria are met:
1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

Polyarticular Juvenile Idiopathic Arthritis
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 polyarticular 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. For rheumatoid arthritis and systemic juvenile idiopathic arthritis, 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:

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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APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:
1. November 4, 2014: Reviewed by the Pharmacy and Therapeutics Committee
2. October 6, 2015: No changes
3. January 1, 2016: Administrative change to rebranded template.
4. September 13, 2016: No changes
5. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria for rheumatoid arthritis to require previous treatment with or contraindication to a nonbiologic DMARD.
6. June 13, 2017: Updated criteria to include supplemental indication of treatment giant cell arteritis.
7. 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.
8. 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. Added the following language to the Code section: "**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." Updated Limitation 1 to specify that it applies to rheumatoid arthritis and 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.

Provider Services