Medical Necessity Guidelines: 
Actemra® (tocilizumab)

Effective: January 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

Applies to:

Commercial Products
☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview
Food and Drug Administration (FDA) Approved Indications:
Actemra (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of:
• Rheumatoid Arthritis (RA)
• Giant Cell Arteritis (GCA)
• Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
• Polyarticular Juvenile Idiopathic Arthritis (PJIA)
• Systemic Juvenile Idiopathic Arthritis (SJIA)
• Cytokine Release Syndrome (CRS)

Clinical Guideline Coverage Criteria
The Plan may authorize coverage of Actemra (tocilizumab) when the following criteria are met:

Authorization Criteria- Rheumatoid Arthritis (RA)
1. The Member has a diagnosis of moderately to severely active rheumatoid arthritis (RA) AND
2. The Member is 18 years of age or older

Authorization Criteria- Giant Cell Arteritis (GCA)
1. The Member has a diagnosis of giant cell arteritis (GCA) AND
2. The Member is 18 years of age or older

Authorization Criteria - Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
1. The Member has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)
   AND
2. The Member is 18 years of age or older

Authorization Criteria - Polyarticular Juvenile Idiopathic Arthritis (PJIA)
1. The Member has a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA)
   AND
2. The Member is 2 years of age and older

Authorization Criteria - Systemic Juvenile Idiopathic Arthritis (SJIA)
1. The Member has a diagnosis of active systemic juvenile idiopathic arthritis (PJIA)
   AND
2. The Member is 2 years of age and older

Authorization Criteria - Cytokine Release Syndrome (CRS)
1. The Member has a diagnosis of chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome (CRS)
   AND
2. The Member is 2 years of age and older

Limitations
- The Plan considers Actemra (tocilizumab) as experimental/investigational and not medically necessary for all other indications.
- For the treatment of Cytokine Release Syndrome (CRS), Actemra will be approved for a period of 30 days

Codes
The following code(s) require prior authorization:

Table 1: HCPCS Codes

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<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>J3262</td>
<td>Injection, tocilizumab, 1 mg</td>
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References:

Approval And Revision History
September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information
Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update
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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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