Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Actemra® (tocilizumab) Subcutaneous

Effective: January 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – 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

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 – Approved Indications

Actemra (tocilizumab) subcutaneous injection is an interleukin-6 (IL-6) receptor antagonist indicated for:

Disease State	
Giant Cell Arteritis	X
Juvenile Idiopathic Arthritis	X
Rheumatoid Arthritis	X
Systemic Sclerosis-Associated Interstitial Lung Disease	X

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Actemra for Members when all of the following criteria are met:

Giant Cell Arteritis

1. Documented diagnosis of giant cell arteritis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist or neurologist

AND

4. Documentation of **one (1)** of one of the following:
   a. Inadequate response or adverse reaction to a systemic corticosteroid
   b. Contraindication to systemic corticosteroids
   c. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular or systemic juvenile idiopathic arthritis

AND

2. Patient is at least 2 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. Inadequate response or adverse reaction to one (1), or contraindication to all traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), or previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with or contraindication to Enbrel and Humira (for polyarticular juvenile idiopathic arthritis only)
    b. The patient is new to the plan and stable on Actemra and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One (1) of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2) or contraindication to all of the following: Cimzia, Enbrel, Humira, Rinvoq, Simponi, Xeljanz
    b. The patient is new to the plan and stable on Actemra and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

Systemic Sclerosis-Associated Interstitial Lung Disease

1. Documented diagnosis of systemic sclerosis-associated interstitial lung disease

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist or pulmonologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least two (2) of the following agents: Azathioprine, cyclophosphamide, or mycophenolate mofetil
    b. Contraindication to azathioprine, cyclophosphamide, and mycophenolate mofetil
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.

Codes

None

References

1. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. Ann Rheum Dis.2016;75(3):499-510.
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
3. Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. Ann Rheum Dis 2018; 77:808.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.
6. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech, Inc; Dec 2022.
7. Singh JA, Guyatt G, Ogdie A, et al. "Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis," Arthritis Rheumatol. 2019 Jan;71(1):5-32. DOI: 10.1002/art.40726. Epub 2018 Nov 30.
8. Smith E, Yazici Y. Treatment of Behçet's syndrome. In: Curtis M, ed. UpToDate. Waltham, Mass.: UpToDate, August 2019.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- September 2022 e-vote: Effective January 1, 2023, Enbrel added as a preferred agent.
- December 12, 2023: Removed the Limitations Documentation of a patient having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products and for plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy (effective 1/1/2024).

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.