Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Actemra® (tocilizumab) Subcutaneous**

Effective: March 1, 2026

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 authorize coverage of Actemra Subcutaneous for Members when **ALL** of the following criteria are met:

Giant Cell Arteritis

Initial Authorization Criteria

1. Documented diagnosis of giant cell arteritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist or neurologist

AND

4. Documentation of history of failure to a systemic corticosteroid, unless contraindicated (*Note: document drug, date and duration of trial*)

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of giant cell arteritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist or neurologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Juvenile Idiopathic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of **one (1)** of the following:
    a. Active polyarticular juvenile idiopathic arthritis
    b. Active systemic juvenile idiopathic arthritis

AND

2. Patient is at least 2 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation of history of failure to **two (2)** of the following medications, unless contraindicated or clinically significant adverse effects are experienced (*Note: document drugs, dates, duration of trials*):
    a. Cimzia
    b. Enbrel
    c. Rinvoq
    d. Simlandi
    e. Xeljanz (polyarticular juvenile idiopathic arthritis only)

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of **one (1)** of the following:
    a. Active polyarticular juvenile idiopathic arthritis
    b. Active systemic juvenile idiopathic arthritis

AND

3. Patient is at least 2 years of age

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: document drug, date, and duration of trial)*

AND

5. Documentation of history of failure to **two (2)** of the following medications, unless contraindicated or clinically significant adverse effects are experienced (*Note: document drugs, dates, duration of trials):*
    a. Cimzia
    b. Enbrel
    c. Rinvoq
    d. Simlandi
    e. Simponi
    f. Xeljanz

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

3. Patient is at least 18 years of age or older

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Systemic Sclerosis-Associated Interstitial Lung Disease

Initial Authorization Criteria

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

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by a rheumatologist or pulmonologist

AND

4. Documentation of history of failure to **two (2)** of the following medications, unless contraindicated or clinically significant adverse effects are experienced *(Note: document drugs, dates, and duration of trials):*
    a. Azathioprine
    b. Cyclophosphamide
    c. Mycophenolate mofetil

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

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

AND

3. Patient is at least 18 years of age

AND

4. Prescribed by a rheumatologist or pulmonologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

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.
3. Authorizations will be provided in 12-month intervals.
4. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
5. Members new the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.

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; August 2025.
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).
- June 11, 2024: Updated biologic prerequisites for pJIA to include Rinvoq and Xeljanz (eff 7/1/24).
- June 10, 2025: Updated biologic prerequisites for pJIA to include Cimzia (eff 7/1/25).
- October 14, 2025: Approvals limited to 12 months with annual reauthorization coverage criteria added. Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Updated diagnosis requirements, updated Initial Authorization Criteria prerequisite language (no change in prerequisites), and removed previous treatment with a biologic agent indicated for the requested use and Actemra stability language (eff 1/1/26).
- December 9, 2025: Replaced Humira with Simlandi as Simlandi is the preferred adalimumab product (eff 3/1/26).

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.