Mass General Brigham
Health Plan

Actemra (tocilizumab)
Effective 01/01/2024

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview
Actemra is an interleukin-6 (IL-6) receptor antagonist. Endogenous IL- is induced by inflammatory stimuli and mediates a variety of immunological responses. Inhibition of IL-6 receptors by Actemra leads to a reduction in cytokine and acute phase reactant production.

Coverage Guidelines

Moderately to severely active rheumatoid arthritis (RA)
Authorization may be granted for members new to the plan who are currently receiving treatment with Actemra, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when the following criteria is met:

1. The member has a diagnosis of moderate to severely active rheumatoid arthritis (RA)
1. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira, Adalimumab-adaz, Adalimumab-fkjp, or Hadlima
    d. Rinvoq
    e. Simponi
    f. Xeljanz or Xeljanz XR
2. Member has had minimum duration of a 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses.
    a. Methotrexate
    b. Leflunamide
    c. sulfasalazine

Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Authorization may be granted for members new to the plan who have previously received Actemra excluding when these products have been obtained via physician samples or patient assistant program

OR

Authorization may be granted when the following criteria is met:

1. The member has a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA)
2. Minimum duration of a 6-week trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. Methotrexate
3. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Enbrel
    b. Humira, Adalimumab-adaz, Adalimumab-fkjp, or Hadlima
    c. Xeljanz or Xeljanz XR

Active Systemic Juvenile Idiopathic Arthritis (sJIA)

Authorization may be granted for members new to the plan who have previously received Actemra excluding when these products have been obtained via physician samples or patient assistant program.

OR

Authorization may be granted for treatment of active sJIA when the following criteria are met:

1. The member has trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses
    a. Minimum duration of 3-month trial and failure of methotrexate
    b. Minimum duration of 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
    c. Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

Giant Cell Arteritis

Authorization may be granted for members diagnosed with Giant Cell Arteritis

Cytokine Release Syndrome (CRS)- (Intravenous Use ONLY)

Authorization be granted for treatment of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome when documentation of diagnosis is submitted.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

Authorization may be granted for the treatment of SSc-ILD when documentation of diagnosis is submitted.

<u>Continuation of Therapy</u>

Reauthorizations for all diagnoses will be granted when documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

- For diagnosis of Cytokine Release Syndrome (CRS): reauthorization will not be granted

Limitations

1. Initial approvals and reauthorizations for all diagnoses will be granted for 24 months, excluding CRS.
2. Initial approvals for CRS will be granted for a total of 4 doses.

References

1. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; June 2019

2. Abboud R, Keller J, Slade M, et al. Severe cytokine-release syndrome after T cell-replete peripheral blood haploidentical donor transplantation is associated with poor survival and anti-IL-6 therapy is safe and well tolerated. *Biol Blood Marrow Transplant.* 2016;22(10):1851-1860.
3. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 26, 2017.
4. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
5. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017; 0:1-18.
6. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care Res.* 2011;63(4):465-482.
7. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications. *Arthritis & Rheumatism.* 2013; 65:2499-2512.
8. Fitzgerald JC, Weiss SL, Maude SL, et al. Cytokine release syndrome after chimeric antigen receptor T cell therapy for acute lymphoblastic leukemia. *Crit Care Med.* 2017;45(2):e124-e131.[PubMed 27632680]10.1097/CCM.0000000000002053
9. Maude SL, Barrett D, Teachey DT, Grupp SA. Managing cytokine release syndrome associated with novel T cell-engaging therapies. *Cancer J*. 2014;20(2):119-122.[PubMed 24667956]10.1097/PPO.0000000000000035
10. Frey N, Porter D. Cytokine Release Syndrome with Chimeric Antigen Receptor T Cell Therapy. Biol Blood Marrow Transplant 2019; 25:e123

Review History

11/20/2019 – Added Rinvoq as a trial for RA and Skyrizi for PS. Added started and stabilized criteria. Approval duration switched to 4 doses.
11/18/2020 – Reviewed; Updated for 2021 strategy to be implemented 1/1/2021.
01/11/2023 – Reviewed and Updated for Jan P&T; removed requirement of Remicade for diagnoses of RA and pJIA. For diagnosis of pJIA, added requirement of Simponi Aria. Effective 03/01/2023.
11/15/2023 – Reviewed and Updated for Nov P&T; Removed TB requirement. Removed Appendix. RA – preferred agents required needing prior use of TWO of the following agents: Cimzia, Enbrel, Humira or biosimilars, Rinvoq, Simponi, Xeljanz/XR. Updated conventional therapies to include methotrexate, leflunamide, or sulfasalazine. pJIA – updated preferred agents to require prior use of TWO of the following: Enbrel, Humira or biosimilars, and Xeljanz/XR. Updated conventional therapies to include methotrexate and leflunamide. Added indication of systemic sclerosis-associated interstitial lung disease (SSc-ILD). Effective 1/1/2024