Actemra (tocilizumab)
Effective January 1, 2020

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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)

1. Authorization may be granted for members who are currently receiving treatment with Actemra, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
   OR
2. Authorization may be granted for treatment of moderately to severely active RA when one of the following criteria is met:
   a. The member has experienced an inadequate response or intolerance to all preferred products (Enbrel, Humira and Rinvoq)
   b. The member has a contraindication to all preferred products (Enbrel, Humira and Rinvoq) and meets one of the following:
      - The member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
      - The member has an intolerance or contraindication to methotrexate (see Appendix).

Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

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

OR

1. Authorization may be granted for treatment of active pJIA when BOTH of the following criteria is met:
   a. One of the following:
      - The member experienced an inadequate response to BOTH methotrexate AND an NSAID.
      - The member has experienced an intolerance or has a contraindication to BOTH methotrexate and NSAIDs. (see Appendix A)

   AND

   b. One of the following:
      - The member has experienced an inadequate response to at least TWO TNF inhibitors (e.g., Enbrel, Humira, or Remicade). A 3-month trial for each is required
      - The member has experienced an intolerance or has a contraindication to TNF inhibitors.

Active Systemic Juvenile Idiopathic Arthritis (sJIA)

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

   OR

2. Authorization of 24 months may be granted for treatment of active sJIA when any TWO of the following criteria are met:
   a. The member has an inadequate response to at least a 2-week trial of corticosteroids.
   b. The member has an inadequate response to at least a 3-month trial of methotrexate
   c. The member has an inadequate response to at least a 3-month trial with NSAIDS

Giant Cell Arteritis

Authorization may be granted for members diagnosed with Giant Cell Arteritis

Unicentric and Multicentric Castleman's Disease

Authorization may be granted for members diagnosed with of Unicentric or Multicentric Castleman's disease.

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.

Continuation of Therapy

1. Reauthorizations for all diagnoses, excluding CRS, will be granted when documented is submitted supporting improvement in member's condition
2. Reauthorization for CRS will not be granted

Limitations

1. Initial approvals 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.
3. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).
   a. Note: Members who have received Actemra or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.

Appendix

Examples of Contraindications to Methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

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

11/20/19 – Added Rinvoq as a trial for RA and Skyrizi for PS. Added started and stabilized criteria. Approval duration switched to 4 doses.

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