Actemra® (tocilizumab)
Effective 02/20/2019

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® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

Rheumatoid Arthritis (RA)
Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

Giant Cell Arteritis (GCA)
Adult patients with giant cell arteritis.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.

Systemic Juvenile Idiopathic Arthritis (SJIA)
Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.

Cytokine Release Syndrome (CRS)
Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.

Coverage Guidelines

Rheumatoid Arthritis (RA)

1. Member has a diagnosis of RA **AND**
2. Member is at least 18 years of age **AND**

3. Prescriber has provided documentation of ONE of the following*:
    a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, leflunomide, methotrexate, sulfasalazine)
    b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication

    AND
4. Dosing is appropriate (see appendix)

***Enbrel and Humira are the MH preferred products**

Juvenile Idiopathic Arthritis (JIA)
Actemra® IV Only

1. Member has a diagnosis of JIA **AND**
2. Member is at least 2 years of age **AND**
3. Member has had an inadequate response, adverse reaction or contraindication to methotrexate **AND**
4. Dosing is appropriate (see appendix)

**Requests for the subcutaneous formulation Actemra for children <18 years of age will be reviewed on a case by case basis.*

Giant Cell Arteritis (GCA)
Actemra® SQ Only

1. Member has a diagnosis of GCA **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber has provided documentation of ONE of each of the following categories:
    a. Glucocorticoids
        i. Inadequate response, adverse reaction, or contraindication to at least ONE systemic glucocorticoid*
        ii. Contraindication to ALL systemic glucocorticoids
    b. Systemic immunosuppressive therapy
        i. Inadequate response or adverse reaction to ONE systemic immunosuppressive therapy (e.g. methotrexate, cyclophosphamide)
        ii. Contraindication to ALL systemic immunosuppressive therapy

    AND
4. Dosing is appropriate (see appendix)

**Requests for members who satisfy the criteria except for the corticosteroid trial will be evaluated on a case-by-case basis as corticosteroids are not intended for long-term therapy.*

Continuation of Therapy
Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 1 year

Appendix

	Pediatric Dosing	Other Dosing
Actemra® (tocilizumab)	**Polyarticular Juvenile Idiopathic Arthritis:** IV: **Patients <30 kg:** 10 mg/kg every 4 weeks **Patients ≥30 kg:** 8 mg/kg every 4 weeks **Systemic Juvenile Idiopathic Arthritis:** IV: **Patients <30 kg:** 12 mg/kg every 2 weeks **Patients ≥30 kg:** 8 mg/kg every 2 weeks	**Rheumatoid Arthritis (mod-severe):** IV: **Initial/maintenance:** 4 mg/kg IV every 4 weeks as a 60-minute infusion. Dose may be increased to 8 mg/kg every 4 weeks; maximum: 800 mg per infusion. SQ: **Patients <100 kg:** 162 mg every other week, followed by every week dosing based on clinical response. **Patients ≥100 kg:** 162 mg every week; every other week dosing may be appropriate to manage dose-related laboratory changes **Giant Cell Arteritis** SQ: 162 mg every week

References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2018.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 26, 2017.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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
8. 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

Review History

11/22/2010: Reviewed
01/03/2011: Implemented
02/28/2011: Reviewed
06/06/2011: Reviewed & revised (SJIA indication)

02/27/2012: Reviewed & revised
02/25/2013: Reviewed & revised
02/24/2014: Reviewed & revised
02/23/2015: Reviewed
02/22/2016: Reviewed P&T Mtg
02/27/2017: Reviewed & revised (Adopted SGM & Step) P&T Mtg
03/01/2018: Reviewed & revised (Adopted MH RS);
02/20/2019: Reviewed & revised

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