Actemra® (tocilizumab)
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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.
- Uveitis and Scleritis: second-line immunomodulatory agents for the treatment of severe ocular inflammatory conditions including posterior uveitis, panuveitis, severe uveitis, and scleritis in patients requiring immunomodulation in patients who have failed or who are not candidates for traditional immunomodulation (see Appendix B)

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners 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 if the member meets ALL following criteria and documentation has been submitted:

Moderate to Severe Rheumatoid Arthritis (RA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    3. Paid claims or physician documented inadequate response or adverse reaction to at least ONE traditional DMARD or contraindication to traditional DMARDs
    4. Paid claims or physician documented inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication
3. Dosing is appropriate

Cytokine Release Syndrome (CRS) - Actemra® IV Only
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration)
3. Appropriate dosing

Systemic Juvenile Idiopathic Arthritis (SJIA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs
    b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing

Moderate to Severe Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to ONE traditional DMARD or contraindication to traditional DMARDs
    b. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
3. Appropriate dosing

Giant Cell Arteritis (GCA) - Actemra® SQ Only
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** systemic glucocorticoid
    b. Contraindication to **ALL** systemic glucocorticoids
3. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** systemic immunosuppressive therapy (e.g. methotrexate, cyclophosphamide)
    b. Contraindication to **ALL** systemic immunosuppressive therapy

4. Appropriate dosing

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Reauthorization for cytokine release syndrome will be reviewed on a case by case basis.

Limitations

1. Initial approvals will be granted for the following:
    a. Cytokine release syndrome: 1 month past anticipated date of CAR T-cell administration
    b. Uveitis and Scleritis: 3 months
    c. All other diagnosis: 6 months
2. Reauthorizations will be granted for 1 year for the following indications:
    a. Giant Cell Arteritis (GCA)
    b. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
    c. Systemic Juvenile Idiopathic Arthritis (SJIA)
    d. Rheumatoid Arthritis (RA)
    e. Uveitis and Scleritis
3. The following quantity limits apply:

Actemra Actpen autoinjector	4 autoinjectors (3.6 ml) per 28 days
Actemra injection 162/0.9 pre-filled syringe	162 mg per week (3.6 ml) per 28 days
Actemra 200mg/10mL & 400mg/20mL	40mL per 14 days
Actemra 80mg/4mL	20mL (4 vials) per 28 days

Appendix A:

	Pediatric Dosing	**Adult 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 **Cytokine release syndrome:** IV: **Patients <30 kg**: 12 mg/kg/dose once; if no clinical improvement after initial dose, may repeat dose every 8 hours for up to 3 additional doses. **Patients ≥30 kg**: 8 mg/kg/dose once; if no clinical improvement after initial dose, may	**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 **Cytokine release syndrome:** IV: Maximum dose: 800 mg per dose **Patients <30 kg**: 12 mg/kg **Patients ≥30 kg**: 8 mg/kg

	repeat dose every 8 hours for up to 3 additional doses.	

Appendix B: Off-Label Indications
Uveitis and Scleritis:
Paid claims or physician documented appropriate dosing and documentation of inadequate response, adverse reaction or contraindication to **ALL** of the following:

- Topical, oral or injectable glucocorticoids
- Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
- For Scleritis: Rituxan® (rituximab)
- Appropriate dosing: 8 mg/kg every four weeks

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
03/18/2020: Reviewed P&T Mtg (addition of Cytokine release syndrome criteria per MH and dosing); added QL (effective 6/1/20)
11/05/2020 – Reviewed and Updated; separated out Comm/Exch vs. MassHealth. Matched MassHealth Preferred Unified Formulary for implementation 1/1/2021

Disclaimer

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