

Actemra® (tocilizumab)
Effective 08/01/2022

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> 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 the 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.
- **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):** Adult patients with systemic sclerosis-associated interstitial lung disease
- **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)

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:
 - a. Paid claims or physician documented inadequate response or adverse reaction to at least **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 (see Appendix for frequent or higher doses)

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 (see Appendix for frequent or higher doses)

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 (see Appendix for frequent or higher doses)

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) - Actemra® SQ Only

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Paid claims or physician documented inadequate response or adverse reaction to **ONE** of the following or contraindication to **ALL** of the following:
 - a. cyclophosphamide
 - b. mycophenolate
3. Appropriate dosing (see Appendix for frequent or higher doses)



Giant Cell Arteritis (GCA)

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. Appropriate dosing (see Appendix for frequent or higher doses)

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy and request can be recertified if dosing is appropriate.

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. Systemic Sclerosis-Associated Interstitial Lung Disease
 - e. Rheumatoid Arthritis (RA)
 - f. 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)	<p>Polyarticular Juvenile Idiopathic Arthritis: IV: Patients <30 kg: 10 mg/kg every 4 weeks</p> <p>Patients ≥30 kg: 8 mg/kg every 4 weeks</p> <p>Systemic Juvenile Idiopathic Arthritis: IV: Patients <30 kg: 12 mg/kg every 2 weeks</p> <p>Patients ≥30 kg: 8 mg/kg every 2 weeks</p>	<p>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.</p> <p>SQ: Patients <100 kg: 162 mg every other week, followed by every week dosing based on clinical response.</p> <p>Patients ≥100 kg: 162 mg every week; every</p>

	<p>Cytokine release syndrome: <u>IV:</u> 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.</p> <p>Patients ≥30 kg: 8 mg/kg/dose once; if no clinical improvement after initial dose, may repeat dose every 8 hours for up to 3 additional doses.</p>	<p>other week dosing may be appropriate to manage dose-related laboratory changes</p> <p>Giant Cell Arteritis: <u>IV:</u> 6 mg/kg IV every 4 weeks as a 60 minute infusion <u>SQ:</u> 162 mg every week</p> <p>Systemic Sclerosis-Associated Interstitial Lung Disease: <u>SQ:</u> 162 mg every week</p> <p>Cytokine release syndrome: <u>IV:</u> Maximum dose: 800 mg per dose Patients <30 kg: 12 mg/kg Patients ≥30 kg: 8 mg/kg</p>
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Appendix B: Requests for More Frequent or Higher Doses

Requests for more frequent or higher doses of injectable biologics, may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
 - a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication
 - b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

Appendix C: Off-Label Indications

Uveitis

Paid claims or physician documented inadequate response, adverse reaction, or contraindication to **ALL** of the following:

1. Ophthalmic (topical) or oral glucocorticoids
2. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
3. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to Humira® (adalimumab)
 - b. Clinical rationale for use of Actemra® (tocilizumab)

Scleritis

Paid claims or prescriber provides appropriate dosing and documentation of inadequate response, adverse reaction, or contraindication to **ALL** of the following:

1. Topical, oral, or injectable glucocorticoids
2. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus, and cyclophosphamide)
3. Rituxan® (rituximab)



References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
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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.

06/22/2022 – Reviewed and updated for June P&T; matched MH UPPL. Added FDA approved indication and criteria: Systemic Sclerosis-Associated Interstitial Lung Disease. Criteria for GCA updated to clarify that both SC and IV dosing may be used. Continuation of therapy language was updated. Appendices added for "Request for More Frequent or Higher Doses". Actemra (tocilizumab) was added to the appendix for uveitis and scleritis. Updated References. Effective 08/01/2022.

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