Mass General Brigham
Health Plan

Actemra® (tocilizumab)
Effective 06/30/2023

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 when obtained through the pharmacy benefit.		
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	Actemra IV will only be available under the medical benefit.		

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

Coverage Guidelines

Authorization may be reviewed on a case by case basis 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 if the member meets ALL following criteria and documentation has been submitted:

Rheumatoid Arthritis (RA)

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

1. Diagnosis of moderate to severe rheumatoid arthritis
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 (see Appendix C)
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. Diagnosis of cytokine release syndrome
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. Diagnosis of systemic juvenile idiopathic arthritis
2. **ONE** of the following:
    a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to **ALL** traditional DMARDs (see Appendix C)
    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)

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis
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 (see Appendix C)
    b. **If reviewing under Pharmacy Benefit:** 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. Diagnosis of systemic sclerosis-associated interstitial lung disease
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. Diagnosis of giant cell arteritis
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)

Off-Label Indications

Polymyalgia Rheumatica (PMR)

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

1. Diagnosis of polymyalgia rheumatica (PMR)
2. Paid claims or physician documented of inadequate response or adverse reaction to **ONE** systemic corticosteroid or contraindication to **ALL** systemic corticosteroids
3. Paid claims or physician documented of inadequate response, adverse reaction or contraindication to methotrexate

Scleritis

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

1. Diagnosis of scleritis
2. Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to **BOTH** of the following*:*
    a. ophthalmic (topical), oral or injectable glucocorticoids
    b. oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus, and cyclophosphamide)
3. **If reviewing under Pharmacy Benefit:** Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to Rituxan® (rituximab)

Uveitis

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

1. Diagnosis of uveitis
2. Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to **BOTH** of the following*:*
    a. Ophthalmic (topical), oral or injectable glucocorticoids
    b. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus, and cyclophosphamide)
3. **If reviewing under Pharmacy Benefit, ONE** of the following:
    a. Paid claims or physician documented of inadequate response, adverse reaction, or contraindication to Humira® (adalimumab)
    b. Clinical rationale for use of the requested agent instead of Humira® (adalimumab)

New members currently stable on Actemra® can be approved without documentation of failed trials with the conventional therapies.

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. Off-label indications: 3 months

c. All other indications: 6 months

2. Reauthorizations will be granted for 12 months.
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. Dosing

	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 repeat dose every 8 hours for up to 3 additional doses.	**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:** IV: 6 mg/kg IV every 4 weeks as a 60 minute infusion SQ: 162 mg every week **Systemic Sclerosis-Associated Interstitial Lung Disease:** 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

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. Examples of Traditional DMARDs

Traditional DMARDs*
azathioprine
cyclosporine
hydroxychloroquine*
leflunomide
methotrexate*
sulfasalazine*
thalidomide

References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
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.
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.
01/11/2023 – Reviewed and updated for Jan P&T. Appropriate diagnosis was replaced with a specific indication throughout. Added language regarding stability of requested medication for new members with a documented history of hospitalization. Added examples of traditional DMARDs and higher dosing criteria to appendix. Off-label indications added for: PMR, scleritis, uveitis. Effective 3/1/23.
06/14/23 – Reviewed and updated for P&T. Separated criteria into Rx vs MB. Removed preferred product criteria for requests reviewing under MB. Effective 6/30/23