Mass General Brigham
Health Plan

Tocilizumab Products:
Actemra (tocilizumab)
Avtozma (tocilizumab-anoh)
Tyenne (tocilizumab-aazg)
Tofidence (tocilizumab-bavi)
Effective 01/01/2027

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.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

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

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
- Adults with giant cell arteritis
- Slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA)
- Patients 2 years of age and older with active systemic juvenile idiopathic arthritis (SJIA)
- Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced or life-threatening cytokine release syndrome (CRS)

Avtozma, Tyenne and Tofidence are biosimilars of Actemra. Avtozma and Tyenne are the preferred tocilizumab formulations.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following diagnosis-specific criteria is met:

Moderately to severely active rheumatoid arthritis (RA)

1. Diagnosis of moderately to severely active rheumatoid arthritis (RA)
2. Minimum duration of 3-month trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:

    a. Methotrexate
    b. Leflunomide
    c. Sulfasalazine
3. Trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    d. Rinvoq
    e. Simponi
4. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to BOTH of the following:
    a. Avtozma
    b. Tyenne

Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)
2. Minimum duration of 6-week trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. Methotrexate
3. Trial and failure, contraindication, or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Adalimumab-aaty, adalimumab-adaz, or Hadlima
    d. Rinvoq or Rinvoq LQ
4. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to BOTH of the following:
    a. Avtozma
    b. Tyenne

Active Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Diagnosis of active systemic juvenile idiopathic arthritis (sJIA)
2. Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies at maximally tolerated doses:
    a. Minimum duration of 3-month trial and failure of methotrexate
    b. Minimum duration of 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
    c. Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)
3. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to BOTH of the following:
    a. Avtozma
    b. Tyenne

Giant Cell Arteritis (GCA)

1. Diagnosis of Giant Cell Arteritis
2. Trial and failure, contraindication, or intolerance to a glucocorticoid (e.g., prednisone)
3. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to both of the following:
    a. Avtozma
    b. Tyenne

Cytokine Release Syndrome (CRS)- (Intravenous Use ONLY)

1. Submission of medical records (e.g., chart notes) documenting a diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome
2. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to both of the following:
    a. Avtozma
    b. Tyenne

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (SC use ONLY)

1. Submission of medical records (e.g., chart notes) documenting a diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
2. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to both of the following:
    a. Avtozma
    b. Tyenne

<u>Continuation of Therapy</u>

Reauthorization for the diagnosis of Cytokine Release Syndrome (CRS) will not be granted

All Other Diagnoses:

Requests for reauthorization for all other diagnoses will be granted when the following criteria are met:

1. Submission of medical records (e.g., chart notes) demonstrating an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition
2. **Actemra, Tofidence:** Trial and failure, contraindication, or intolerance to both of the following:
    a. Avtozma
    b. Tyenne

Limitations

1. **CRS:** Initial approvals for CRS will be granted for a total of 4 doses.
2. **All Other Diagnoses:** Initial approvals and reauthorizations will be granted for 24 months, excluding CRS.
3. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Actemra ACTPen Avtozma autoinjector Tyenne pen	4 pens per 28 days
Actemra syringe Avtozmasyringe Tyenne syringe	4 syringes per 28 days
Actemra IV solution 200 mg/10 mL, Avtozma IV solution 200 mg/10 mL Tyenne IV solution 200 mg/10 mL, Tofidence IV solution 200 mg/10 mL	4 vials per 14 days
Actemra IV solution 400 mg/20 mL, Avtozma IV solution 400 mg/20 mL Tyenne IV solution 400 mg/20 mL, Tofidence IV solution 400 mg/20 mL	2 vials per 14 days
Actemra IV solution 80 mg/4 mL, Avtozma IV solution 80 mg/4 mL Tyenne IV solution 80 mg/4 mL,	10 vials per 14 days

Tofidence IV solution 80 mg/4 mL	

References

1. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; August 2025.
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. Avtozma (tocilizumab-anoh) [prescribing information]. Jersey City, NJ: Celltrion US; July 2025.
4. 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.
5. 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
6. Frey N, Porter D. Cytokine Release Syndrome with Chimeric Antigen Receptor T Cell Therapy. Biol Blood Marrow Transplant 2019; 25:e123
7. 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
8. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 26, 2017.
9. 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.
10. 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.
11. 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.
12. Tofidence (tocilizumab-bavi) [prescribing information]. Cambridge, MA: Biogen MA Inc.; December 2024.
13. Tyenne (tocilizumab-aazg) [prescribing information]. Lake Zurich, IL: Fresenius Kabi, USA; February 2025.

Review History

11/20/2019 – Added Rinvoq as a trial for RA and Skyrizi for PS. Added started and stabilized criteria. Approval duration switched to 4 doses.
11/18/2020 – Reviewed; Updated for 2021 strategy to be implemented 1/1/2021.
01/11/2023 – Reviewed and Updated for Jan P&T; removed requirement of Remicade for diagnoses of RA and pJIA. For diagnosis of pJIA, added requirement of Simponi Aria. Effective 03/01/2023.
11/15/2023 – Reviewed and Updated for Nov P&T; Removed TB requirement. Removed Appendix. RA – preferred agents required needing prior use of TWO of the following agents: Cimzia, Enbrel, Humira or biosimilars, Rinvoq, Simponi, Xeljanz/XR. Updated conventional therapies to include methotrexate, leflunamide, or sulfasalazine. pJIA – updated preferred agents to require prior use of TWO of the following: Enbrel, Humira or biosimilars, and Xeljanz/XR. Updated conventional therapies to include methotrexate and leflunomide. Added indication of systemic sclerosis-associated interstitial lung disease (SSc-ILD). Effective 1/1/2024
09/11/2024 – Reviewed and updated at September P&T. Added Rinvoq and Rinvoq LQ as previous treatment options for diagnosis of pJIA. Updated SJIA criteria to include line for diagnosis. Effective 11/1/2024.

10/09/2024 – Reviewed and updated for October P&T. For diagnoses of RA and pJIA added Amjevita (Nuvaila) as a preferred adalimumab product. Specified pJIA diagnosis is “active.” Removed Xeljanz XR as a biologic step option for pJIA. Added Cimzia as a preferred biologic step option for pJIA. Effective 1/1/2025.
12/11/2024 – Reviewed and updated for December P&T. Added the biosimilars Tyenne and Tofidence to policy. Both products will require step through with Actemra. Effective 3/1/2025.
03/12/2025 – Reviewed and updated for March P&T. Updated policy to include Tyenne as one of two preferred tocilizumab products for the treatment of RA, CRS, GCA, sJIA, and pJIA. Updated policy to only allow approval of Actemra for the treatment of SScILD and only allow approval of Actemra and Tyenne for CRS. Effective 06/01/2025.
09/10/2025 – Reviewed and updated for September P&T. Updated criteria for giant cell arteritis to require trial and failure with a corticosteroid. Effective 12/1/2025.
10/08/2025 – Reviewed and updated for October P&T. Effective 12/1/2025: Updated approval language for Tofidence to require trial and failure, intolerance or contraindication with either Actemra or Tyenne. Effective 1/1/2026: Added Avtozma to the policy. Updated policy to indicate that Tyenne is the preferred tocilizumab product. For all diagnoses listed in the policy approval of Actemra, Avtozma or Tofidence requires trial and failure with Tyenne, including in renewal criteria. Updated policy to reflect that Humira, Hadlima, Simlandi and Yuflyma are the preferred adalimumab trial options. Updated policy to indicate it no longer applies to the medical benefit.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 - Reviewed and updated at April P&T. Added Avtozma self-injectable formulations to the policy as nonpreferred tocilizumab products. Effective 08/16/2026.
07/15/2026 – Reviewed and updated at July P&T. Updated initial criteria for SSc-ILD to clarify that only the SC formulation will be approved, for FDA-approved package labeling. Effective 10/01/2026.
09/09/2026 – Reviewed and updated at September P&T. Updating initial and reauthorization criteria for Actemra and Tofidence to require trial and failure with Avtozma and Tyenne. Updating preferred adalimumab products throughout policy. Effective 01/01/2027.
10/14/2026 – Reviewed and updated at October P&T. Removing Xeljanz/tofacitinib as a previous trial option. Effective 01/01/2027.