Mass General Brigham
Health Plan

Tocilizumab Products:
Actemra (tocilizumab)
Tyenne (tocilizumab-aazg)
Tofidence (tocilizumab-bavi)
Effective 06/01/2025

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 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	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)

Tyenne and Tofidence are tocilizumab biosimilars. They are approved for the treatment of RA, giant cell arteritis, pJIA, and SJIA. Tyenne is also approved for the treatment of CRS. Actemra and Tyenne are the preferred tocilizumab products.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, 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. Member has had minimum duration of a 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. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira (Abbvie), Adalimumab-adaz, Adalimumab-fkjp, Hadlima, Amjevita (Nuvaila)
    d. Rinvoq
    e. Simponi
    f. Xeljanz or Xeljanz XR
3. **Tofidence:** Member must have had prior use, intolerance or contraindication to ONE of the following:
    a. Actemra
    b. Tyenne

Active Polyarticular Juvenile Idiopathic Arthritis (pJIA)

1. Diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA)
2. Minimum duration of a 6-week trial and failure, intolerance, or contraindication to ONE of the following conventional therapies at maximally tolerated doses
    a. Leflunomide
    b. Methotrexate
3. Member has trial and failure, contraindication or intolerance to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira (Abbvie), Adalimumab-adaz, Adalimumab-fkjp, Hadlima, Amjevita (Nuvaila)
    d. Xeljanz
    e. Rinvoq/Rinvoq LQ
4. **Tofidence:** Member must have had prior use, intolerance or contraindication to ONE of the following:
    a. Actemra
    b. Tyenne

Active Systemic Juvenile Idiopathic Arthritis (sJIA)

1. Diagnosis of active systemic juvenile idiopathic arthritis (sJIA)
2. The member has trial and failure, intolerance, or contraindication 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. **Tofidence:** Member must have had prior use, intolerance or contraindication to ONE of the following:
    a. Actemra
    b. Tyenne

Giant Cell Arteritis

1. The member has a diagnosis of Giant Cell Arteritis
2. **Tofidence:** Member must have had prior use, intolerance or contraindication to ONE of the following:
    a. Actemra

b. Tyenne

Cytokine Release Syndrome (CRS)- (Intravenous Use ONLY) (Actemra and Tyenne Only)

1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

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

1. Documented diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

Continuation of Therapy

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. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Only Actemra and Tyenne will be approved for the treatment of cytokine release syndrome (CRS).
2. Only Actemra will be approved for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD)
3. **CRS:** Initial approvals for CRS will be granted for a total of 4 doses.
4. **All Other Diagnoses:** Initial approvals and reauthorizations will be granted for 24 months, excluding CRS.
5. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Actemra ACTPen, Tyenne pen	4 pens per 28 days
Actemra syringe, Tyenne syrine	4 syringes per 28 days
Actemra 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, 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, Tyenne IV solution 80 mg/4 mL, Tofidence IV solution 80 mg/4 mL	10 vials per 14 days

References

1. Actemra (tocilizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; December 2022.
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. 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.
4. 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
5. Frey N, Porter D. Cytokine Release Syndrome with Chimeric Antigen Receptor T Cell Therapy. Biol Blood Marrow Transplant 2019; 25:e123
6. 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
7. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 26, 2017.
8. 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.
9. 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.
10. 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.
11. Tofidence (tocilizumab-bavi) [prescribing information]. Cambridge, MA: Biogen MA Inc.; December 2024.
12. 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.