BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Actemra (tocilizumab) Subcutaneous

Policy Number: 9.113
Version Number: 1.1
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Actemra SQ Injection

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	1. Use of Actemra in combination with a biologic DMARD (e.g. Humira, Enbrel, Cimzia, etc.) 2. Use of Actemra in combination with a Janus kinase inhibitor (e.g. Xeljanz)
Required Medical Information	Diagnosis of one of the following: 1. Giant cell arteritis (GCA); ***AND*** a. An inadequate response, or adverse reaction to at least one glucocorticoid.

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

2. Polyarticular juvenile idiopathic arthritis (pJIA); ***AND***
    a. 5 or more joints with active arthritis; ***AND***
    b. Baseline 10-joint clinical juvenile arthritis disease activity score (cJADAS-10) has been performed; ***AND***
    c. One of the following:
        i. Patient has tried one other systemic therapy for this condition; ***OR***
        Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID). A biologic also counts as a trial of one systemic therapy;
        ii. Patient will be starting on Actemra subcutaneous concurrently with methotrexate, sulfasalazine, or leflunomide; ***OR***
        iii. Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; ***OR***
        iv. Patient has aggressive disease, as determined by the prescriber; ***AND***
    d. Patient meets one of the following (i or ii):
        i. An inadequate response or adverse reaction to a trial of Humira or a contraindication to Humira **OR**
        ii. According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

3. Moderate to severe rheumatoid arthritis (RA); ***AND***
    a. One of the following:
        i. An inadequate response, intolerance or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira; ***OR***
        ii. According to the prescriber, the patient has heart failure or a previously treated lymphoproliferative disorder.

4. Systemic juvenile idiopathic arthritis (sJIA); ***AND***
    a. One of the below:
        i. An inadequate response, or adverse reaction to a minimum of at least a 3 consecutive month trial of one non-biologic DMARD (oral or injectable), or concurrently receiving methotrexate; ***OR***
        ii. An inadequate response, or adverse reaction to a minimum of a one month trial of one nonsteroidal anti-inflammatory drug; ***OR***
        iii. An inadequate response, or adverse reaction to a minimum of a two week trial of one glucocorticoid; ***OR***
        iv. An inadequate response, or adverse reaction to a biologic DMARD FDA approved for systemic juvenile idiopathic arthritis.

	5. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) ***AND*** a. Diagnosis is confirmed by high-resolution computed tomography; AND b. An inadequate response, or adverse reaction to at least ONE of the following agents or a contraindication to treatment with ALL three: i. Mycophenolate mofetil ii. Cyclophosphamide iii. Azathioprine
Age Restrictions	PJIA, SJIA,: 2 years of age and older RA, GCA, SSc-ILD: 18 years of age and older
Prescriber Restriction	GCA: Prescribed by or in consultation with a rheumatologist or neurologist SJIA, PJIA, RA: Prescribed by or in consultation with a rheumatologist SSc-ILD: Prescribed by or in consultation with a rheumatologist or pulmonologist
Coverage Duration	Initial and reauthorization: 12 months
Other criteria	Reauthorization: 1. Member has met initial criteria. ***AND*** 2. Clinical condition has improved or stabilized.

Applicable Coding:

Code	Medication
J3262	Actemra® (tocilizumab injection)

Clinical Background Information and References

1. Actemra (tocilizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; Accessed July 2021.
2. American College of Rheumatology 2008 Recommendations for the use of nonbiologics and biologics disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008; 59(6):762-84.
3. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis: 2002 Update. Arthritis Rheum. 2002; 46(2):328-46.
4. Bykerk VP, Ostör AJ, Alvaro-Gracia J et al. Tocilizumab in patients with active rheumatoid arthritis and inadequate responses to DMARDs and/or TNF inhibitors: a large, open-label study close to clinical practice. Ann Rheum Dis. 2012 Dec; 71(12):1950-4.
5. De Benedetti F, Brunner HI, Ruperto N et al. Randomized trial of tocilizumab in systemic juvenile idiopathic arthritis. N Engl J Med. 2012 Dec 20;367(25):2385-95.

6. Emery P, Keystone E, Tony HP et al. IL-6 receptor inhibition with tocilizumab improves treatment outcomes in patients with rheumatoid arthritis refractory to anti-tumor necrosis factor biologicals: results from a 24-week multicenter, randomized placebo-controlled trial. Ann Rheum Dis 2008; 67:1516-23.
7. Fleischmann RM, Halland AM, Brzosko M, et al. Tocilizumab inhibits structural joint damage and improves physical function in patients with rheumatoid arthritis and inadequate responses to methotrexate: LITHE study 2-year results. J Rheumatol. 2013 Feb; 40(2):113-26.
8. Food and Drug Administration. FDA approves Actemra to treat rare form of juvenile arthritis. URL: fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm251572.htm. Available from Internet. Accessed 2011 April 20. 2324464 3 Pharmacy Medical Necessity Guidelines: Actemra® (tocilizumab)
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10. Hunder GG. Treatment of giant cell (temporal) arteritis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on May 25, 2017).
11. Imagawa T, Yokota S, Mori M et al. Safety and efficacy of tocilizumab, an anti-IL-6-receptor monoclonal antibody, in patients with polyarticular-course juvenile idiopathic arthritis. Mod Rheumatol. 2012 Feb;22(1):109-15.
12. Jones G, Sebba A, Gu J et al. Comparison of tocilizumab monotherapy versus methotrexate monotherapy in patients with moderate to severe rheumatoid arthritis; the AMBITION study. Ann Rheum Dis 2010; 69:88-96.
13. Kaufmann J, Feist E, Roske AE, Schmidt WA. Monotherapy with tocilizumab or TNF-alpha inhibitors in patients with rheumatoid arthritis: efficacy, treatment satisfaction, and persistence in routine clinical practice. Clin Rheumatol. 2013 May 24
14. Nishimoto N, Amano K, Hirabayashi Y et al. Retreatment efficacy and safety of tocilizumab in patients with rheumatoid arthritis in recurrence (RESTORE) study. Mod Rheumatol. 2013 May 17.
15. Singh JA, Furst DE, Bharat A et al. Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. Vol. 64, No. 5, May 2012, pp 625–639.
16. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2016 Jan;68(1):1-26.
17. Smolen JS, Beaulieu A, Rubbert-Roth A et al. Effect of interleukin-6 receptor inhibition with tocilizumab in patients with rheumatoid arthritis (OPTION study): a double-blind, placebocontrolled, randomized trial. Lancet 2008; 371:987-97.
18. Strand V, Burmester GR, Ogale S et al. Improvements in health-related quality of life after treatment with tocilizumab in patients with rheumatoid arthritis refractory to tumour necrosis factor inhibitors: results from the 24-week randomized controlled RADIATE study. Rheumatology (Oxford). 2012 Oct; 51(10):1860-9.
19. Yazici Y, Curtis JR, Ince A et al. Efficacy of tocilizumab in patients with moderate to severe active rheumatoid arthritis and a previous inadequate response to disease-modifying antirheumatic drugs: the ROSE study. Ann Rheum Dis. 2012 Feb; 71(2):198-205.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.176 Actemra Policy retired, new policy created	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review: Created two separate policies for IV and SQ formulations; Addition of additional diagnostic criteria and trial requirements for PJIA; Addition of trial requirements and time periods of trial drugs for all indications; Addition of diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) and associated clinical criteria and the reauthorization criteria that the member must meet initial criteria.	1/1/2022	P&T Committee
1/20/2022	Updated policy to realign with ESI ICCV policy	3/1/2022	P&T Committee

Next Review Date

8/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.