

Policy Number: RX.PA.048.MPC
Revision Date: 02/2026

RX.PA.048.MPC Actemra IV

The purpose of this policy is to define the prior authorization process for Actemra IV.

Actemra[®] (tocilizumab) intravenous infusion, an interleukin-6 (IL-6) receptor inhibitor, is indicated for the following conditions:¹

- **Giant cell arteritis** in adults.
- **Polyarticular juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.
- **Rheumatoid arthritis**, for treatment of adults with moderate to severe active disease who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).
- **Systemic juvenile idiopathic arthritis**, for the treatment of active disease in patients ≥ 2 years of age.

PROCEDURE

A. Initial Authorization Criteria

I. CLINICAL CRITERIA (Use for ALL Drug Requests)

Must meet all of the criteria listed under the respective product:

- 1. Giant Cell Arteritis (GCA).** Approve for the duration noted if the patient meets the following criteria:

Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria

- The patient has tried at least one systemic corticosteroid for at 3 months or has a documented intolerance; or has relapsing GCA; AND
Note: An example of a systemic corticosteroid is prednisone.
- Actemra IV is prescribed by or in consultation with a rheumatologist.
- Dose does not exceed FDA approved label dosing for indication
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

Patients currently receiving Actemra IV. Approve for 1 year if the patient meets the following criteria:

A. MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion 1 (Initial Authorization Criteria); AND
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

2. Polyarticular Juvenile Idiopathic Arthritis. Approve for the duration noted if the patient meets all of the following criteria:

Initial Therapy. Approve for 3 months if the patient meets all of the following criteria: Patient meets all of the following conditions:

- Patient has tried at least one systemic therapy for this condition for at least 3 months or has a documented intolerance to at least two other agents;
Note: Examples of other systemic therapies include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID).
- Patient has aggressive disease, as determined by the prescriber; AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has a documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred JAK inhibitor, Xeljanz.
- Dose does not exceed FDA approved label dosing for indication

The medication is prescribed by or in consultation with a rheumatologist

- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

Patient is Currently Receiving Actemra Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal

- Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 2 (Initial Authorization Criteria); AND
- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion 2 (Initial Authorization Criteria)
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

3. Rheumatoid Arthritis. Approve for the duration noted if the patient meets all of the following criteria:

Initial Therapy. Approve for 3 months if the patient meets all of the following:

- Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months or has a documented intolerance to at least two DMARD agents; AND
- Note: Examples of conventional DMARDs include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine.
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
 - Dose does not exceed FDA approved label dosing for indication
 - Patient has a documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred JAK inhibitor, Xeljanz
 - The medication is prescribed by or in consultation with a rheumatologist.
 - Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

Patient is Currently Receiving Actemra Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant

response, as determined by the provider

- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion 3 (Initial Authorization Criteria); AND
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

4. Systemic Juvenile Idiopathic Arthritis. Approve for the duration noted if the patient meets all of the following:

Initial Therapy. Approve for 3 months if the patient meets the following criteria:

- The patient has tried at least TWO other systemic therapies for this condition for at least 3 months or has a documented intolerance to at least two systemic agents; AND

Note: Examples of other systemic therapies include a corticosteroid (oral, intravenous), a conventional synthetic disease-modifying antirheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine]

- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Patient has a documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred JAK inhibitor, Xeljanz
- Dose does not exceed FDA approved label dosing for indication
- The medication is prescribed by or in consultation with a rheumatologist.
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

Patient is Currently Receiving Actemra Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion 4 (Initial Authorization Criteria); AND
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

Other Uses with Supportive Evidence

5. Castleman's Disease. Approve for the duration noted if the patient meets all of the following conditions:

Initial Approval. Approve for 3 months if the agent is prescribed by or in consultation with an oncologist or hematologist.

- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

A) Patient is Currently Receiving Actemra Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal:

- Patient has received an MPC prior authorization and has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion 5 (Initial Authorization Criteria); AND
- Patient has been established on therapy for at least 3 months and has had

a documented clinically significant response, as determined by the provider

6. Still's Disease. Approve for the duration noted if the patient meets the following criteria:

Initial Therapy. Approve for 3 months if the patient meets ALL of the following:

- Patient has tried one corticosteroid for at least 3 months; AND
- Patient has tried at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) given for at least 3 months or was intolerant to at least two conventional synthetic DMARDs; AND
- Patient has documented intolerance, contraindication to, or failed treatment for at least 3 months with preferred TNF inhibitors, Enbrel (etanercept) and Humira (adalimumab)
- Dose does not exceed FDA approved labeling for indication
- The medication is prescribed by or in consultation with a rheumatologist.
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

Reauthorization Criteria:

Patient is Currently Receiving Actemra Intravenous. Approve for 1 year if the patient meets one of the following (A or B):

A. MPC Renewal

- Patient has received an MPC prior authorization and has been established on therapy for least 3 months and has had a documented clinically significant response, as determined by the provider
- Patient must not be concurrently using Actemra with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).

Note: Examples of biologics and DMARDs consist of infliximab products, Otezla, Rinvoq, Xeljanz, etc.

OR

B. Renewal from Previous Insurer:

- Patients who have received prior approval (from insurer other than MPC), or have been receiving medication samples should be considered under criterion 6 (Initial Authorization Criteria); AND
- Patient has been established on therapy for at least 3 months and has had a documented clinically significant response, as determined by the provider

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Actemra IV treatments will be considered investigational or experimental for any other use and will not be covered.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Same as initial

APPLICABLE CODES:	
CODE	DESCRIPTION
J3262	Injection, tocilizumab, 1mg

REFERENCES

1. Actemra® injection for intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; June 2019.
2. Schoels MM, van der Heijde D, Breedveld FC, et al. Blocking the effects of interleukin-6 in rheumatoid arthritis and other inflammatory rheumatic diseases: systematic literature review and meta-analysis informing a consensus statement. *Ann Rheum Dis*. 2013;72(4):583-589.
3. Yescarta™ suspension for intravenous infusion [prescribing information]. Santa Monica, CA: Kite Pharma; May 2019.
4. Kymriah™ suspension for intravenous infusion [prescribing information]. East Hanover, NJ: Novartis Oncology; June 2019.
5. Lee DW, Gardner R, Porter DL, et al. Current concepts in the diagnosis and management of cytokine release syndrome. *Blood*. 2014;124(2):188-195.
6. The NCCN Management of Immunotherapy-Related Toxicities Clinical Practice Guidelines in Oncology (Version 1.2021 – February 1, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 24, 2021.
7. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res (Hoboken)*. 2019;71(6):717-734.
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 Rheum*. 2013;65(10):2499-2512.
9. Singh J, Saag K, Bridges Jr. SL, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2016;68(1):1-25.
10. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 3.2021 – March 16, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 24, 2021.
11. Riera E, Olivé A, Narváez J, et al. Adult onset Still's disease: review of 41 cases. *Clin Exp Rheumatol*. 2011;29(2):331-336.
12. Puéchal X, de Bandt M, Berthelot JM, et al. Tocilizumab in refractory adult Still's disease. *Arthritis Care Res (Hoboken)*. 2011;63(1):155-159.
13. Perdan-Pirkmajer K, Praprotnik S, Tomšič M. A case of refractory adult-onset Still's disease successfully controlled with tocilizumab and a review of the literature. *Clin Rheumatol*. 2010;29(12):1465-1467.
14. Sabnis GR, Gokhale YA, Kulkarni UP. Tocilizumab in Refractory Adult-Onset Still's Disease with Aseptic Meningitis-Efficacy of Interleukin-6 Blockade and Review of the Literature. *Semin Arthritis Rheum*. 2011;40(4):365-368.
15. De Bandt M, Saint-Marcoux B. Tocilizumab for multirefractory adult-onset Still's disease. *Ann Rheum Dis*. 2009;68(1):153-154.
16. Yoshimura M, Makiyama J, Koga T, et al. Successful treatment with tocilizumab in a patient with refractory adult-onset Still's disease (AOSD). *Clin Exp Rheumatol*. 2010;28(1):141-142.

17. Nakahara H, Mima T, Yoshio-Hoshino N, et al. A case report of a patient with refractory adult-onset Still's disease who was successfully treated with tocilizumab over 6 years. *Mod Rheumatol*. 2009;19(1):69-72.
18. Matsumoto K, Nagashima T, Takatori S, et al. Glucocorticoid and cyclosporine refractory adult onset Still's disease successfully treated with tocilizumab. *Clin Rheumatol*. 2009;28(4):485-487.
19. Iwamoto M, Nara H, Hirata D, et al. Humanized monoclonal anti-interleukin-6 receptor antibody for treatment of intractable adult-onset Still's disease. *Arthritis Rheum*. 2002;46(12):3388-3389.
20. Rech J, Ronneberger M, Englbrecht M, et al. Successful treatment of adult-onset Still's disease refractory to TNF and IL-1 blockade by IL-6 receptor blockade. *Ann Rheum Dis*. 2011;70(2):390-392.
21. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
22. Xeljanz® tablets [prescribing information]. New York, NY: Pfizer Inc; February 2016.
23. Ito H, Takazoe M, Fukuda Y, et al. A pilot randomized trial of a human anti-interleukin-6 receptor monoclonal antibody in active Crohn's disease. *Gastroenterology*. 2004;126:989-996.
24. Centers for Disease Control and Prevention (Web site). Coronavirus (COVID-19). Updated March 22, 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/index.html/>. Accessed on March 23, 2020.
25. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2020 Mar 23]. Available from: <https://clinicaltrials.gov/ct2/results?cond=Coronavirus&term=tocilizumab&cntry=&state=&city=&dist=>. Search terms: coronavirus, tocilizumab.
26. Xu X, Han M, Li T, et al. Effective treatment of severe COVID-19 patients with tocilizumab. *Proc Natl Acad Sci U S A*. 2020;117(20):10970-10975.
27. Strohbehn GW, Heiss BL, Rouhani SJ, et al. COVIDOSE: A Phase II Clinical Trial of Low-Dose Tocilizumab in the Treatment of Noncritical COVID-19 Pneumonia. *Clin Pharmacol Ther*. 2021;109(3):688-696.
28. Dastan F, Saffaei A, Haseli S, et al. Promising effects of tocilizumab in COVID-19: A non-controlled, prospective clinical trial. *Int Immunopharmacol*. 2020;88:106869.
29. Galvan-Roman JM, Rodriguez-Garcia SC, Roy-Vallejo E, et al. IL-6 serum levels predict severity and response to tocilizumab in COVID-19: An observational study. *J Allergy Clin Immunol*. 2021;147(1):72-80.
30. Zhao H, Zhu Q, Zhang C, et al. Tocilizumab combined with favipiravir in the treatment of COVID-19: A multicenter trial in a small sample size. *Biomed Pharmacother*. 2021;133:110825.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<p>Annual Revision Cytokine Release Syndrome: This condition was clarified to specify that it must be Associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy to be reviewed under this condition for coverage. Examples of chimeric antigen receptor T-cell therapy were moved to a Note in the policy (previously listed as examples within the criteria). Polyarticular Juvenile Idiopathic Arthritis: For the exception applying to patients with aggressive disease, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). Examples of one other agent tried for Polyarticular Juvenile Idiopathic Arthritis were moved to a Note in the policy (previously listed as examples within the criteria). Examples of biologics for Polyarticular Juvenile Idiopathic Arthritis were moved to be included in the Appendix (previously listed in a Note in the criteria section). Examples of an absolute contraindication to methotrexate, sulfasalazine, or leflunomide were move to a Note in the policy (previously listed as examples within the criteria). Examples of a response to therapy were moved to a Note in the policy (previously listed as examples within the criteria). Rheumatoid Arthritis: Examples of conventional synthetic disease-modifying antirheumatic drugs were moved to a Note in the policy (previously listed as examples within the criteria). Examples of biologics for Rheumatoid Arthritis were moved to be included in the Appendix (previously listed in a Note in the criteria section). Examples of a response to therapy were moved to a Note in the policy (previously listed as examples within the criteria). Systemic Juvenile Idiopathic Arthritis: Examples of one other systemic agent tried for Systemic Juvenile Idiopathic Arthritis were moved to a Note in the policy (previously listed as examples within the criteria). Castleman's Disease: For the exception applying to patients currently receiving Actemra who have responded, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). Examples of a response to therapy were moved to a Note in the policy (previously listed as examples within the criteria). Inflammatory Arthritis Associated with Checkpoint Inhibitor Therapy: Examples of a steroid were moved to a Note in the policy (previously listed as examples within the criteria). Examples of a nonsteroidal anti-inflammatory agent were moved to a Note in the policy (previously listed as examples within the criteria). Examples of a response to therapy were moved to a Note in the policy (previously listed as examples within the criteria). Criteria requiring a previous therapy were clarified to specify systemic therapies must have been tried (i.e., systemic corticosteroid, systemic NSAID). Still's Disease: For the exception applying to patients currently receiving Actemra who have responded, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). Examples of a response to therapy were moved to a Note in the policy (previously listed as examples within the criteria). COVID-19: This off-label indication was added to the policy as an approval if the patient has cytokine release syndrome.</p>	<p>03/25/2020</p>
<p>Annual Revision Polyarticular Juvenile Idiopathic Arthritis: Criteria were clarified to state that previously tried agents must have been systemic therapies.</p>	<p>03/31/2021</p>
<p>Criteria Revisions Expanded upon required initial DMARD therapy for all indications and specified requirements for reauthorization for all indications. All indications require t/f with 1 conventional DMARD for 3 months or intolerance to at least 2 conventional DMARDS. Most indications require t/f with Humira and Enbrel. Added GCA</p>	<p>03/2023</p>

Policy Number: RX.PA.048.MPC
Revision Date: 02/2026

indication and required criteria for approval and reauthorization.	
Selected Revision Addition of trial and failure for at least 3 months with preferred JAK inhibitor, Xeljanz for the following indications: polyarticular juvenile idiopathic arthritis (JIA) and rheumatoid arthritis (RA)	<i>11/2022</i>
Annual review	<i>02/2023</i>
Selected Revision <i>SJIA: Addition of trial and failure requirement with Xeljanz for at least 3 months</i>	<i>05/2023</i>
Annual review Change in Non-MPC renewal to renewal from previous insurer Minor grammatical errors	<i>02/2024</i>
<i>Annual Review</i>	<i>02/2025</i>
<i>Annual Review</i>	<i>02/2026</i>