Policy Number: RX.PA.048.MPC
Revision Date: 05/2023

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 signficant 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. Non-MPC PA Renewal

- Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 1 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Actemra; **AND**
- Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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, XeljanzDose does not exceed FDA approved label dosing for indication

The medication is prescribed by or in consultation with a rheumatologist.

iv. 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 signficant 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. Non-MPC PA Renewal
- Patient has not been receiving medication samples for Actemra; **AND**
- Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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 signficant 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. Non-MPC PA Renewal
- Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 3 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Actemra; **AND**
- Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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 TWOother 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 signficant 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. Non-MPC PA Renewal
- Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 4 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Actemra; **AND**
- Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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 least 3 months and has had a documented clinically signficant response, as determined by the provider
  Note: Examples of response include normalization of C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, albumin, and/or hemoglobin; resolution of constitutional symptoms; increased body mass index (BMI), and reduction in lymphadenopathy.
- 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. Non-MPC Renewal
- Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 5 (Initial Authorization Criteria); AND
- Patient has not been receiving medication samples for Actemra; **AND**

- Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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 signficant 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. Non-MPC PA Renewal
   - Patients who have previously been taking Actemra and are requesting a non-MPC renewal should be considered under criterion 6 (Initial Authorization Criteria); AND
   - Patient has not been receiving medication samples for Actemra; **AND**
   - Patient has been established on therapy for at least 3 months and has had a documented clinically signficant 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

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

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
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.	*03/25/2020*
Annual Revision **Polyarticular Juvenile Idiopathic Arthritis:** Criteria were clarified to state that previously tried agents must have been systemic therapies.	*03/31/2021*
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	*03/2023*

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)	*11/2022*
Annual review	*02/2023*
Selected Revision *SJIA: Addition of trial and failure requirement with Xeljanz for at least 3 months*	*05/2023*