### Overview
ACTEMRA® (tocilizumab) is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of:

- **Rheumatoid Arthritis (RA):** Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
- **Giant Cell Arteritis (GCA):** Adult patients with giant cell arteritis.
- **Polyarticular Juvenile Idiopathic Arthritis (PJIA):** Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
- **Systemic Juvenile Idiopathic Arthritis (SJIA):** Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.
- **Cytokine Release Syndrome (CRS):** Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.
- **Uveitis and Scleritis:** Second-line immunomodulatory agents for the treatment of severe ocular inflammatory conditions including posterior uveitis, panuveitis, severe uveitis, and scleritis in patients requiring immunomodulation in patients who have failed or who are not candidates for traditional immunomodulation (see Appendix B).

### Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Actemra excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**
Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

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**Actemra® (tocilizumab)**
**Effective January 1, 2021**

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☒ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☒ Quantity Limit</th>
<th>☐ Step Therapy</th>
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</thead>
<tbody>
<tr>
<td>Benefit</td>
<td>☒ Pharmacy Benefit</td>
<td>☒ Medical Benefit (NLX)</td>
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</table>

**Specialty Limitations**
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
</tr>
<tr>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
</tr>
<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
</tr>
<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
</tr>
</tbody>
</table>

**Medical Specialty Medications (NLX)**
| All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |

| Exceptions | N/A |
Moderate to Severe Rheumatoid Arthritis (RA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   3. Paid claims or physician documented inadequate response or adverse reaction to at least **ONE** traditional DMARD or contraindication to traditional DMARDs
   4. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Dosing is appropriate

Cytokine Release Syndrome (CRS) - Actemra® IV Only
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration)
3. Appropriate dosing

Systemic Juvenile Idiopathic Arthritis (SJIA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs
   b. Paid claims or physician documented inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication
3. Appropriate dosing

Moderate to Severe Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs
   b. Paid claims or physician documented inadequate response, adverse reaction or contraindication to Humira® (adalimumab)
3. Appropriate dosing

Giant Cell Arteritis (GCA) - Actemra® SQ Only
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** systemic glucocorticoid
   b. Contraindication to **ALL** systemic glucocorticoids
3. **ONE** of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to **ONE** systemic immunsuppressive therapy (e.g. methotrexate, cyclophosphamide)
   b. Contraindication to **ALL** systemic immunsuppressive therapy
4. Appropriate dosing

Continuation of Therapy
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Reauthorization for cytokine release syndrome will be reviewed on a case by case basis.

Limitations

1. Initial approvals will be granted for the following:
   a. Cytokine release syndrome: 1 month past anticipated date of CAR T-cell administration
   b. Uveitis and Scleritis: 3 months
   c. All other diagnosis: 6 months

2. Reauthorizations will be granted for 1 year for the following indications:
   a. Giant Cell Arteritis (GCA)
   b. Polyarticular Juvenile Idiopathic Arthritis (PJIA)
   c. Systemic Juvenile Idiopathic Arthritis (SJIA)
   d. Rheumatoid Arthritis (RA)
   e. Uveitis and Scleritis

3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Product</th>
<th>Pediatric Dosing</th>
<th>Adult Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra Actpen autoinjector</td>
<td>4 autoinjectors (3.6 ml) per 28 days</td>
<td>Rheumatoid Arthritis (mod-severe):</td>
</tr>
<tr>
<td>Actemra injection 162/0.9 pre-filled syringe</td>
<td>162 mg per week (3.6 ml) per 28 days</td>
<td>IV: Initial/maintenance: 4 mg/kg IV every 4 weeks as a 60-minute infusion. Dose may be increased to 8 mg/kg every 4 weeks; maximum: 800 mg per infusion.</td>
</tr>
<tr>
<td>Actemra 200mg/10mL &amp; 400mg/20mL</td>
<td>40mL per 14 days</td>
<td>SQ: Patients &lt;100 kg: 162 mg every other week, followed by every week dosing based on clinical response.</td>
</tr>
<tr>
<td>Actemra 80mg/4mL</td>
<td>20mL (4 vials) per 28 days</td>
<td>Patients ≥100 kg: 162 mg every week; every other week dosing may be appropriate to manage dose-related laboratory changes</td>
</tr>
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</table>

Appendix A:

<table>
<thead>
<tr>
<th>Actemra® (tocilizumab)</th>
<th>Pediatric Dosing</th>
<th>Adult Dosing</th>
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<tbody>
<tr>
<td>Polyarticular Juvenile Idiopathic Arthritis:</td>
<td></td>
<td>Rheumatoid Arthritis (mod-severe):</td>
</tr>
<tr>
<td>IV:</td>
<td></td>
<td>IV:</td>
</tr>
<tr>
<td>Patients &lt;30 kg: 10 mg/kg every 4 weeks</td>
<td></td>
<td>Initial/maintenance: 4 mg/kg IV every 4 weeks as a 60-minute infusion. Dose may be increased to 8 mg/kg every 4 weeks; maximum: 800 mg per infusion.</td>
</tr>
<tr>
<td>Patients ≥30 kg: 8 mg/kg every 4 weeks</td>
<td></td>
<td>SQ:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patients &lt;100 kg: 162 mg every other week, followed by every week dosing based on clinical response.</td>
</tr>
<tr>
<td>Systemic Juvenile Idiopathic Arthritis:</td>
<td></td>
<td>Patients ≥100 kg: 162 mg every week; every other week dosing may be appropriate to manage dose-related laboratory changes</td>
</tr>
<tr>
<td>IV:</td>
<td></td>
<td>Giant Cell Arteritis:</td>
</tr>
<tr>
<td>Patients &lt;30 kg: 12 mg/kg every 2 weeks</td>
<td></td>
<td>SQ: 162 mg every week</td>
</tr>
<tr>
<td>Patients ≥30 kg: 8 mg/kg every 2 weeks</td>
<td></td>
<td>Cytokine release syndrome:</td>
</tr>
<tr>
<td>Cytokine release syndrome:</td>
<td></td>
<td>IV: Maximum dose: 800 mg per dose</td>
</tr>
<tr>
<td>IV:</td>
<td></td>
<td>Patients &lt;30 kg: 12 mg/kg</td>
</tr>
<tr>
<td>Patients &lt;30 kg: 12 mg/kg/dose once; if no clinical improvement after initial dose, may repeat dose every 8 hours for up to 3 additional doses.</td>
<td></td>
<td>Patients ≥30 kg: 8 mg/kg</td>
</tr>
<tr>
<td>Patients ≥30 kg: 8 mg/kg/dose once; if no clinical improvement after initial dose, may</td>
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</table>
Appendix B: Off-Label Indications

Uveitis and Scleritis:
Paid claims or physician documented appropriate dosing and documentation of inadequate response, adverse reaction or contraindication to ALL of the following:

- Topical, oral or injectable glucocorticoids
- Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
- For Scleritis: Rituxan® (rituximab)
- Appropriate dosing: 8 mg/kg every four weeks

References

Review History
11/22/2010: Reviewed
01/03/2011: Implemented
02/28/2011: Reviewed
06/06/2011: Reviewed & revised (SJIA indication)
02/27/2012: Reviewed & revised
02/25/2013: Reviewed & revised
02/24/2014: Reviewed & revised
02/23/2015: Reviewed
02/22/2016: Reviewed P&T Mtg
02/27/2017: Reviewed & revised (Adopted SGM & Step) P&T Mtg
03/01/2018: Reviewed & revised (Adopted MH RS);
02/20/2019: Reviewed & revised
03/18/2020: Reviewed P&T Mtg (addition of Cytokine release syndrome criteria per MH and dosing);
added QL (effective 6/1/20)
Preferred Unified Formulary for implementation 1/1/2021

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or
exclude people on the basis of race, color, national origin, age, disability, or sex