### 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.

### Coverage Guidelines
**Rheumatoid Arthritis (RA)**
1. Member has a diagnosis of RA **AND**
2. Member is at least 18 years of age **AND**
3. Prescriber has provided documentation of ONE of the following*:
   a. Inadequate response, adverse reaction, or contraindication to at least ONE traditional DMARD (hydroxychloroquine, leflunomide, methotrexate, sulfasalazine)
   b. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for the requested indication **AND**
4. Dosing is appropriate (see appendix)

*Enbrel and Humira are the MH preferred products*
Cytokine Release Syndrome (CRS)
Actemra® IV Only
1. Member has a diagnosis of CRS AND
2. Member is at least 2 years of age AND
3. concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration) AND
4. Dosing is appropriate (see appendix)

Systemic Juvenile Idiopathic Arthritis (SJIA) and Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Actemra® IV Only
5. Member has a diagnosis of SJIA or PJIA AND
6. Member is at least 2 years of age AND
7. Member has had an inadequate response, adverse reaction or contraindication to methotrexate AND
8. Dosing is appropriate (see appendix)
*Requests for the subcutaneous formulation Actemra for children < 18 years of age will be reviewed on a case-by-case basis.

Giant Cell Arteritis (GCA)
Actemra® SQ Only
1. Member has a diagnosis of GCA AND
2. Member is at least 18 years of age AND
3. Prescriber has provided documentation of ONE of each of the following categories:
   a. Glucocorticoids
      i. Inadequate response or adverse reaction to at least ONE systemic glucocorticoid*
      ii. Contraindication to ALL systemic glucocorticoids
   b. Systemic immunosuppressive therapy
      i. Inadequate response or adverse reaction to ONE systemic immunosuppressive therapy (e.g. methotrexate, cyclophosphamide)
      ii. Contraindication to ALL systemic immunosuppressive therapy
4. Dosing is appropriate (see appendix)
*Requests for members who satisfy the criteria except for the corticosteroid trial will be evaluated on a case-by-case basis as corticosteroids are not intended for long-term therapy.

Continuation of Therapy
Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations
1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 1 year

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<tbody>
<tr>
<td>Actemra Actpen autoinjector</td>
<td>4 autoinjectors (3.6 ml) per 28 days</td>
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<tr>
<td>Actemra injection 162/0.9 pre-filled syringe</td>
<td>162 mg per week (3.6 ml) per 28 days</td>
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<tr>
<td>Actemra 200mg/10mL &amp; 400mg/20mL</td>
<td>40mL per 14 days</td>
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<tr>
<td>Actemra 80mg/4mL</td>
<td>20mL (4 vials) per 28 days</td>
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Appendix:

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

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