Medication Description:

Tocilizumab (Actemra) is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody that is approved to reduce the signs and symptoms of moderate to severe rheumatoid arthritis in adults who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). Patients with rheumatoid arthritis have elevated IL-6 concentrations both in serum and in synovial fluid. Furthermore, IL-6 concentrations correlate with disease activity and joint damage.

Length of Authorization:

Coverage will be provided for 6 months and may be renewed.

Review Criteria:

Coverage is provided in the following conditions:

Rheumatoid Arthritis†

- Adult patient (18 years or older); AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Documented moderate to severe active disease; AND
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava; AND
- May be used alone or in combination with MTX

Systemic Juvenile Idiopathic Arthritis (SJIA)†

- Patient is over the age of 2; AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
Patient has active SJIA; AND
Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava; AND
May be used alone or in combination with MTX; AND
Only approved for intravenous (IV) formulation (will NOT be approved for subcutaneous (SC) formulation (Actemra 162 mg/0.9 ml pre-filled syringe))

Polyarticular Juvenile Idiopathic Arthritis (PJIA)†
Patient is over the age of 2; AND
Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
Patient has active PJIA; AND
Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava; AND
May be used alone or in combination with MTX; AND
Only approved for intravenous (IV) formulation (will NOT be approved for subcutaneous (SC) formulation (Actemra 162 mg/0.9 ml pre-filled syringe))

†FDA Approved Indication(s)

IV. Renewal Criteria:
Coverage can be renewed based upon the following criteria:
Patient continues to meet criteria identified in section III; AND
Disease response; AND
Absence of unacceptable toxicity from the drug; AND
Ongoing monitoring for TB

V. Dosage/Administration:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Rheumatoid Arthritis (IV)</td>
<td>4 mg/kg – 8 mg/kg IV every 4 weeks</td>
</tr>
<tr>
<td>Adult Rheumatoid Arthritis (SC) (wt&lt;100kg)</td>
<td>162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response</td>
</tr>
<tr>
<td>Adult Rheumatoid Arthritis (SC) (wt≥100kg)</td>
<td>162 mg administered subcutaneously every week</td>
</tr>
<tr>
<td>Polyarticular Juvenile Idiopathic Arthritis (IV) (wt≥30 kg)</td>
<td>8 mg/kg IV every 4 weeks</td>
</tr>
<tr>
<td>Polyarticular Juvenile Idiopathic Arthritis (IV)</td>
<td>10 mg/kg IV every 4 weeks</td>
</tr>
</tbody>
</table>
VI. Billing/Code Information:

**Jcode:**
J3262 – Actemra (Genentech) 80 mg, 200 mg, 400 mg IV Injection: 1 billable unit = 1mg

**NDC:**
Actemra 80 mg/4 ml vial – 50242-0135-xx (Genentech)
Actemra 200 mg/10 ml vial – 50242-0136-xx (Genentech)
Actemra 400 mg/20 ml vial - 50242-0137-xx (Genentech)
Actemra 162 mg/0.9 ml pre-filled syringe – 50242-0138-xx (Genentech)

**Max Units (per dose and over time):**
Rheumatoid Arthritis
Male: 800 billable units every 28 days
Female: 800 billable units every 28 days

Systemic Juvenile Idiopathic Arthritis
Male: 800 billable units every 14 days
Female: 800 billable units every 14 days

Polyarticular Juvenile Idiopathic Arthritis
Male: 800 billable units every 28 days
Female: 800 billable units every 28 days

**Quantity Limits:**
Actemra 162 mg/0.9 ml pre-filled syringe: 4 syringes every 28 days

**Covered Diagnosis:**

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>714.0</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>714.1</td>
<td>Felty's syndrome</td>
</tr>
<tr>
<td>714.2</td>
<td>Other rheumatoid arthritis with visceral or systemic involvement</td>
</tr>
</tbody>
</table>
VII. Centers for Medicare and Medicaid Services (CMS):
Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):
N/A

VIII. Criteria Exclusions:
- Treatment for diagnoses not FDA approved
- All indications not described in Section III Review criteria are not covered and may be considered experimental or investigational.

IX. Black Box Warnings/Contraindications:
**Black Box Warning:**
- Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving Actemra
- If a serious infection develops, interrupt Actemra until the infection is controlled.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Actemra.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

**Contraindications**
- Actemra should not be administered to patients with known hypersensitivity to Actemra

X. References:


XI. Appendix:

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
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</thead>
<tbody>
<tr>
<td>E</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Administrative Services (NAS)</td>
</tr>
<tr>
<td>F</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Administrative Services (NAS)</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services (NGS)</td>
</tr>
<tr>
<td>H</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service (WPS)</td>
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<td>9 (N)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options</td>
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<td>10 (J)</td>
<td>TN, GA, AL</td>
<td>Cahaba Government Benefit Administrators</td>
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<td>Palmetto GBA</td>
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<td>12 (L)</td>
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<td>Novitas Solutions</td>
</tr>
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<td>K</td>
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<td>National Government Services (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
</tr>
</tbody>
</table>