Actemra (tocilizumab) is a preferred product and will only be considered for coverage under the medical or pharmacy benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**GIANT CELL ARTERITIS (GCA)**

For initial authorization:
1. Member must be 50 years of age or older; AND
2. Medication must be prescribed by a rheumatologist; AND
3. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
4. Member has a history of erythrocyte sedimentation rate (ESR) ≥50 mm/h or history of C-reactive protein (CRP) ≥2.45 mg/dL documented in chart notes; AND
5. At least one of the following:
   a) Unequivocal cranial symptoms of GCA (new onset localized headache, scalp or temporal artery tenderness, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication);
   b) Unequivocal symptoms of polymyalgia rheumatica (PMR), defined as shoulder and/or hip girdle pain associated with inflammatory stiffness; AND
6. At least one of the following:
   a) Temporal artery biopsy revealing features of GCA;
   b) Evidence of large-vessel vasculitis by angiography;
   c) Cross-sectional imaging (such as MRI, CTA or PET-CT); AND
7. Medication must be used in combination with a tapering course of glucocorticoids; AND
8. Member does not have ANY of the following:
   a) Actual or recent myocardial infarction (within the last 3 months);
   b) Significant cardiac disease (NYHA Class III and IV), or severe chronic obstructive pulmonary disease (COPD) (FEV1 < 50% predicted or Functional dyspnea > Grade 3 on the MRC Dyspnea Scale) or other significant pulmonary disease;
   c) Active infection of any kind, or any major episode of infection requiring hospitalization or treatment with intravenous anti-infectives within the past 4 weeks, or completion of oral anti-infectives within the past 2 weeks;
   d) History of deep space/tissue infection (e.g. fasciitis, abscess, osteomyelitis) within 52 weeks;
   e) Any surgical procedure, including bone/joint surgery, within the past 8 weeks;
   f) Body weight > 150 kg or BMI > 35.
9. **Dosage allowed:** 162 mg given once every other week as a subcutaneous injection in combination with a tapering course of glucocorticoids.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

**For reauthorization:**
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

### JUVENILE IDIOPATHIC ARTHRITIS (JIA) – systemic (SJIA) and polyarticular (PJIA)

**For initial authorization:**
1. Member must be 2 years of age or older with moderate to severe active PJIA or SJIA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have an inadequate response to methotrexate or inability to tolerate methotrexate. 
5. Member must have at least 6 months of active disease AND at least one of the following signs or symptoms:
   a) Four or fewer joints involved with an inadequate response to glucocorticoid injection AND methotrexate or leflunomide AND NSAID treatment for at least 12 weeks;
   b) Five or more joints involved AND an inadequate response to methotrexate or leflunomide for at least 12 weeks.
6. **Dosage allowed:** For PJIA intravenously every 4 weeks: body weight <30 kg - 10 mg per kg; body weight ≥30 kg - 8 mg per kg. For SJIA intravenously every 2 weeks: Body weight <30 kg - 12 mg per kg; body weight ≥30 kg - 8 mg per kg.

*If member meets all the requirements listed above, the medication will be approved for 12 months.*

**For reauthorization:**
1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

*If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

### RHEUMATOID ARTHRITIS (RA)

**For initial authorization:**
1. Member must be 18 years of age or older with moderate to severe active RA; AND
2. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with at least two non-biologic DMARDS (i.e. methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 12 weeks.
5. **Dosage allowed:** Subcutaneously: for body weight <100 kg - 162 mg every other week, followed by an increase to every week (based on clinical response); for body weight ≥100 kg - 162 mg every...
week. Intravenously: when used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response.

**If member meets all the requirements listed above, the medication will be approved for 12 months.**

For **reauthorization**:
1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

**If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.**

CareSource considers Actemra (tocilizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Adult-onset Still disease
- Ankylosing spondylitis
- Crohn's disease
- Neuromyelitis optica
- Psoriatic arthritis
- Relapsing polychondritis
- Systemic lupus erythematosus
- Systemic sclerosis-associated myopathy/polyarthritis
- Systemic vasculitis
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Uveitis

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/08/2017</td>
<td>New policy for Actemra created. Policy SRx-0042 archived. For diagnosis of JIA: length of active disease added. For diagnosis of RA: list of non-biologic DMARDS added. List of diagnoses considered not medically necessary added.</td>
</tr>
<tr>
<td>08/30/2017</td>
<td>New diagnosis of GCA was added. For diagnosis of JIA (PJIA and SJIA) leflunomide was added as a treatment option.</td>
</tr>
<tr>
<td>10/13/2017</td>
<td>Option to approve under the pharmacy benefit was added.</td>
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</table>

References:


Effective date: 10/27/2017
Revised date: 10/13/2017