PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Actemra (tocilizumab)
BILLING CODE	For medical - J3262 (1 unit = 1 mg) For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Actemra is an interleukin-6 (IL-6) receptor antagonist. It is supplied as IV and subQ formulations. IL-6 is a pro-inflammatory cytokine produced by a variety of cell types.

Actemra (tocilizumab) will be considered for coverage when the following criteria are met:

Giant Cell Arteritis (GCA)

For **initial** authorization:

1. Member must be 50 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a diagnosis of GCA based on at least one of the following:
   a) Temporal artery biopsy revealing features of GCA;
   b) Evidence of large-vessel vasculitis by angiography;
   c) Imaging (i.e. ultrasound, MRI, CT or PET-CT); AND
4. Member demonstrates typical signs and symptoms of active GCA such as elevated erythrocyte sedimentation rate (ESR) or C - reactive protein (CRP), new-onset persistent localized headache, visual symptoms, polymyalgia rheumatica, claudication, weight loss or fever; AND
5. Member has developed or has an increased risk of glucocorticoid side effects OR member has relapsed on glucocorticoids; AND
6. Actemra will be used in adjunct with a tapering course of glucocorticoids; AND
7. Member has tested negative for tuberculosis (TB) within the past 12 months.
8. **Dosage allowed/Quantity limit:** 162 mg subQ once weekly in combination with a tapering course of glucocorticoids. A dose of 162 mg subQ every other week in combination with a tapering course of glucocorticoids may also be considered.
   Limit: 4 syringes/autoinjectors per 28 days

If

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)) within 12 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; AND
5. Member must have 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. Member must have a trial and failure of or intolerance to Humira (adalimumab).
7. **Dosage allowed/Quantity limit:** For PJIA intravenously every 4 weeks: body weight < 30 kg - 10 mg per kg; body weight ≥ 30 kg - 8 mg per kg. For PJIA subcutaneously: body weight < 30 kg - 162 mg once every three weeks; body weight ≥ 30 kg - 162 mg once every two weeks. For SJIA intravenously every 2 weeks: Body weight < 30 kg - 12 mg per kg; body weight ≥ 30 kg - 8 mg per kg. For SJIA subcutaneously: body weight < 30 kg - 162 mg every two weeks; body weight ≥ 30 kg - 162 mg every week.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1.