

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

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	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 3200 units per 28 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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 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:** 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.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must demonstrate improvement such as absence of flare or relapse, normalization of CRP (<1 mg/dL), or reduced glucocorticoid dose.

***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)) 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. **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 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 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 moderately to severely active RA; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member must have a trial and failure of, or intolerance to methotrexate and **one** other non-biologic DMARD (i.e., hydroxychloroquine, sulfasalazine, and leflunomide) for 3 months per trial, either together or separately; AND  
*Note: only one non-biologic DMARD is required if member has a poor prognostic factor such as high swollen joint count, presence of early joint erosions, presence of autoantibodies (RF and/or ACPA).*
5. **Dosage allowed:**
  - a) 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.
  - b) Intravenously: the recommended starting dose is 4 mg/kg every 4 weeks, followed by an increase to 8 mg/kg every 4 weeks based on clinical response. Max dose is 800 mg per infusion.

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

For **reauthorization**:

1. Chart notes demonstrate improvement of RA signs and symptoms (e.g. fewer number of painful and swollen joints, achievement of remission, slowed progression of joint damage, etc.).

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

## SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of active systemic sclerosis; AND
4. Presence of interstitial lung disease has been confirmed by high-resolution computed tomography (HRCT); AND
5. Documentation of baseline forced vital capacity (FVC), which must be 55% or greater<sup>14</sup>; AND
6. Member's lung disease has progressed despite at least a 6 month trial of an immunosuppressant (e.g. cyclophosphamide, mycophenolate mofetil) unless contraindicated or intolerable; AND
7. Member is a non-smoker or has been educated regarding smoking cessation; AND
8. Member has tested negative for tuberculosis (TB) within the past 12 months.
9. **Dosage allowed:** 162mg subQ once weekly.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes must demonstrate a slowed rate of pulmonary function decline, as evidenced by stabilized FVC or repeat HRCT.

***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 diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
05/08/2017	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.
08/30/2017	New diagnosis of GCA was added. For diagnosis of JIA (PJIA and SJIA) leflunomide was added as a treatment option.
10/13/2017	Option to approve under the pharmacy benefit was added.
02/26/2019	Dosing changed for GCA, PJIA and SJIA. ESR and CRP rates expanded for members on glucocorticoid (prednisone) therapy. Actual or recent myocardial infarction (within the last 3 months) criterion removed from GCA. Exception of temporal artery biopsy or other biopsy related to diagnosing GCA was added in criterion on surgical procedures within 8 weeks. References updated. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.

11/23/2020	Updates for RA section: Removed repeat TB test. Updated references. Changed the trials to require methotrexate as one of the non-biologic DMARD trials; only one trial is needed if member has poor prognostic factors.
03/17/2021	Added criteria for new indication of SSc-ILD. <u>GCA</u> : Updated references. Re-ordered criteria. Removed list of restrictions. Added ultrasound as an option. Combined signs and symptoms into one general criterion addressing key features. Added glucocorticoid rule (per EULAR). Re-wrote renewal criteria and removed repeat TB test. Reduced initial approval to 6 months.

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