

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

<b>DRUG NAME</b>	<b>Actemra (tocilizumab)</b>
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:**  
SubQ route: 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  
IV route: 6 mg per kg every 4 weeks in combination with a tapering course of glucocorticoids. Max dose of 600 mg per infusion.

***If all the above requirements are met, 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 all the above requirements are met, 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/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. 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 all the above requirements are met, 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; AND
2. Medication is prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of moderately to severely active RA; AND
4. Member has had a negative tuberculosis test within the past 12 months; AND
5. Member must have a trial and failure of, or intolerance to methotrexate for at least 3 months;  
*Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine.*
6. **Dosage allowed/Quantity limit:**  
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. (Limit 4 syringes/autoinjectors per 28 days)

**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 of 800 mg per infusion.

***If all the above requirements are met, 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 all the above requirements are met, 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/Quantity limit:** 162mg subQ once weekly. (4 syringes/autoinjectors per 28 days)

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

## Cytokine Release Syndrome (CRS) treatment for CAR-T therapy patients

Any cancer related request must be submitted through [NantHealth/Eviti](#) portal.

**CareSource considers Actemra (tocilizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

**DATE**

**ACTION/DESCRIPTION**

<b>05/08/2017</b>	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.
<b>08/30/2017</b>	New diagnosis of GCA was added. For diagnosis of JIA (PJIA and SJIA) leflunomide was added as a treatment option.
<b>10/13/2017</b>	Option to approve under the pharmacy benefit was added.
<b>02/26/2019</b>	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.
<b>11/23/2020</b>	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.
<b>03/17/2021</b>	Added criteria for new indication of SSx-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.
<b>02/17/2022</b>	Transferred to new template. Added section for CRS. RA: Added new reference. Edited the terminology “non-biologic” DMARD to “conventional” DMARD. Changed from requiring 2 csDMARD to just 1.
<b>05/17/2022</b>	Added IV dosing for GCA indication.

References:

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