CareSource

PHARMACY POLICY STATEMENT
North Carolina 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 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. 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. 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; AND
   Note: If methotrexate is contraindicated, one of the following conventional DMARDs must be trialed instead: leflunomide, sulfasalazine, or hydroxychloroquine.
6. Member must have a trial and failure of, or intolerance to Humira (adalimumab).
7. **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 is 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[14]; 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

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. GCA: 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.
02/17/2022	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.

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