CareSource

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	Outpatient/Office/Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 3200 units per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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[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:** 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. 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.

References:

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