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PHARMACY POLICY STATEMENT
Kentucky 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 **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 a rheumatologist; AND
3. 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
4. Member has a history of erythrocyte sedimentation rate (ESR) ≥ 50 mm/h or history of C - reactive protein (CRP) ≥ 2.45 mg/dL documented in chart notes OR if member received glucocorticoid (prednisone) therapy ESR ≥ 30 mm/h and CRP ≥ 1 mg/dL; AND
5. At least **one** of the following:
   a) Unequivocal cranial symptoms of GCA (new onset localized headache, scalp or temporal artery tenderness, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication);
   b) Unequivocal symptoms of polymyalgia rheumatica (PMR), defined as shoulder and/or hip girdle pain associated with inflammatory stiffness; AND
6. At least **one** of the following:
   a) Temporal artery biopsy revealing features of GCA;
   b) Evidence of large-vessel vasculitis by angiography;
   c) Cross-sectional imaging (such as MRI, CTA or PET-CT); AND
7. Medication must be used in combination with a tapering course of glucocorticoids; AND
8. Member does **not** have ANY of the following:
   a) Significant cardiac disease (NYHA Class III and IV), or severe chronic obstructive pulmonary disease (COPD) (FEV1 < 50% predicted or Functional dyspnea > Grade 3 on the MRC Dyspnea Scale) or other significant pulmonary disease;
   b) Active infection of any kind, or any major episode of infection requiring hospitalization or treatment with intravenous anti-infectives within the past 4 weeks, or completion of oral anti-infectives within the past 2 weeks;
   c) History of deep space/tissue infection (e.g., fasciitis, abscess, osteomyelitis) within 52 weeks;

d) Any surgical procedure, including bone/joint surgery, within the past 8 weeks (exception temporal artery biopsy or other biopsy related to diagnosing this condition);
e) Body weight > 150 kg or BMI > 35.

9. **Dosage allowed:** 162 mg given once every week as a subcutaneous injection in combination with a tapering course of glucocorticoids. A dose of 162 mg given once every other week as a subcutaneous injection, in combination with a tapering course of glucocorticoids, can be also prescribed based on clinical considerations.

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 (e.g., ESR and CRP normalized due to treatment response, etc.)

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 30 days;
   b) Five or more joints involved and an inadequate response to methotrexate or leflunomide for at least 30 days.
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.

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RHEUMATOID ARTHRITIS (RA)

For **initial** authorization:

1. Member must be 18 years of age or older with moderate to severe active RA; 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 tried and failed treatment with at least **two** non-biologic DMARDS (i.e., methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, cyclosporine and leflunomide) or must have documented contraindication to all non-biologic DMARDS. Treatment trial duration with each non-biologic DMARD agent must have been at least 30 days.
5. **Dosage allowed:** 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. Intravenously: when used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Actemra doses exceeding 800 mg per infusion are not recommended in RA.

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

For **reauthorization**:

1. Member must be 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.

CareSource considers Actemra (tocilizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Adult-onset Still disease
- Ankylosing spondylitis
- Crohn's disease
- Neuromyelitis optica
- Psoriatic arthritis
- Relapsing polychondritis
- Systemic lupus erythematosus
- Systemic sclerosis-associated myopathy/polyarthritis
- Systemic vasculitis
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Uveitis

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.

References:

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