CareSource

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

Actemra (tocilizumab) is a **non-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), or a chest x-ray) within 6 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; 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) Actual or recent myocardial infarction (within the last 3 months);
   b) 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;
   c) 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;
   d) History of deep space/tissue infection (e.g. fasciitis, abscess, osteomyelitis) within 52 weeks;
   e) Any surgical procedure, including bone/joint surgery, within the past 8 weeks;
   f) Body weight > 150 kg or BMI > 35.

9. **Dosage allowed:** 162 mg given once every other week as a subcutaneous injection in combination with a tapering course of glucocorticoids.

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.

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), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have tried and failed treatment with Enbrel or Humira (for diagnosis of PJIA only); AND
5. Member must have an inadequate response to methotrexate or inability to tolerate methotrexate.
6. 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.
7. **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 SJIA intravenously every 2 weeks: Body weight <30 kg - 12 mg per kg; body weight ≥30 kg - 8 mg per kg.

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 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), or a chest x-ray) within 6 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 12 weeks.
5. Member must have tried and failed treatment with both Enbrel and Humira.

6. **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.

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 was added; trial of Humira or Enbrel was added. For diagnosis of RA: list of non-biologic DMARDS was added. TNF inhibitors Humira and Enbrel were listed as required trials. List of diagnoses considered not medically necessary was 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.

References:

1. Actemra [package insert]. South San Francisco, CA: Genetec, Inc.; May 2017. Accessed on August 2, 2017.
2. US Food and Drug Administration Drug Safety Data. http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125261s114lbl.pdf (October 14, 2014)
3. American College of Rheumatology Ad Hoc Committee on Clinical Guidelines. Guidelines for the management of rheumatoid arthritis: Arthritis Rheum. 1996;39(5):713-723.
4. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis. Recommendations for the Medical Therapy of Children With Systemic Juvenile Idiopathic Arthritis and Tuberculosis Screening Among Children Receiving Biologic Medications Vol. 65, No. 10, October 2013, pp 2499–2512.

5. Actemra. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed March 16, 2017.
6. Unizony SH, Dasgupta B, Fisheleva E, et al., “Design of the Tocilizumab in Giant Cell Arteritis Trial,” International Journal of Rheumatology, vol. 2013, Article ID 912562, 10 pages, 2013. doi:10.1155/2013/912562.
7. Hoffmann-La Roch. An Efficacy and Safety Study of Tocilizumab (RoActemra/Actemra) in Participants With Giant Cell Arteritis (GCA). Available from: https://clinicaltrials.gov/ct2/show/NCT01791153?term=WA28119&rank=2. NLM identifier: NCT01791153. Accessed August 2, 2017.

Effective date: 10/27/2017
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