PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Actemra (tocilizumab)
BILLING CODE	J3262 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital/Office
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** 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.

JUVENILE IDIOPATHIC ARTHRITIS (JIA) – only for 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 an inadequate response to methotrexate or inability to tolerate methotrexate.
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 AND NSAID treatment for at least 12 weeks;
   b) Five or more joints involved AND an inadequate response to methotrexate.
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 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. **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
- Polymyalgia rheumatica
- Psoriatic arthritis
- Relapsing polychondritis
- Systemic lupus erythematosus
- Systemic sclerosis-associated myopathy/polyarthritis
- Systemic vasculitis
- Takayasu arteritis
- Tumor nerosis factor receptor associated periodic syndrome (TRAPS)
- Uveitis

DATE	ACTION/DESCRIPTION
05/15/2017	New policy for Actemra created. 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.

References:

1. Actemra [package insert]. South San Francisco, CA: Genetec, Inc.; March 2017. Accessed on May 1, 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.

Effective date: 10/01/2017
Revised date: 05/15/2017