MAGELLAN PHARMACY SOLUTIONS | iCORE HEALTHCARE	**Actemra® (tocilizumab) (IV and SC)**

Last Review Date: 03/25/2014 **Date of Origin**: 09/21/2010				**Dates Reviewed:** 12/2010, 03/2011, 05/13/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/19/2012, 09/06/2012, 09/25/2012, 11/01/2012, 12/06/2012, 03/07/2013, 06/06/2013, 09/05/2013, 11/07/2013, 12/05/2013, 03/25/2014
Prior Auth Available:	√	**Post-service edit:**	√	**Medical Necessity Criteria Number**: IC-0002

The medical necessity criteria were developed by ICORE Healthcare for the purpose of making clinical review determinations for requests for medications commonly used in various diseases. The clinical disciplines of oncology, hematology, rheumatology, neurology, internal medicine, pharmacy and nursing were consulted as part of the criteria development. The development followed an extensive literature search pertaining to established clinical guidelines and accepted prescribing patterns for each individual drug. The indications for the medications are consistent with FDA approved indications, CMS coverage guidelines, National Comprehensive Cancer Network (NCCN) guidelines and/or other published peer reviewed research literature.

I. Medication Description:

Tocilizumab (Actemra) is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody that is approved to reduce the signs and symptoms of moderate to severe rheumatoid arthritis in adults who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). Patients with rheumatoid arthritis have elevated IL-6 concentrations both in serum and in synovial fluid. Furthermore, IL-6 concentrations correlate with disease activity and joint damage.

II. Length of Authorization:

Coverage will be provided for 6 months and may be renewed

III. Review Criteria:

Coverage is provided in the following conditions:

Rheumatoid Arthritis†

- Adult patient (18 years or older); **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Documented moderate to severe active disease; **AND**
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava;**AND**
- May be used alone or in combination with MTX

Systemic Juvenile Idiopathic Arthritis (SJIA)†

- Patient is over the age of 2; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**

- Patient has active SJIA; **AND**
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava; **AND**
- May be used alone or in combination with MTX; **AND**
- Only approved for intravenous (IV) formulation (will NOT be approved for subcutaneous (SC) formulation (Actemra 162 mg/0.9 ml pre-filled syringe))

Polyarticular Juvenile Idiopathic Arthritis (PJIA)†

- Patient is over the age of 2; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient has active PJIA; **AND**
- Patient has had at least a 3 month trial and failed previous therapy with ONE oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, Imuran, Ridaura, Plaquenil, Cuprimine, Azulfidine, Arava; **AND**
- May be used alone or in combination with MTX; **AND**
- Only approved for intravenous (IV) formulation (will NOT be approved for subcutaneous (SC) formulation (Actemra 162 mg/0.9 ml pre-filled syringe))

†FDA Approved Indication(s)

IV. Renewal Criteria:

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- Ongoing monitoring for TB

V. Dosage/Administration:

Indication	Dose
Adult Rheumatoid Arthritis (IV)	4 mg/kg – 8 mg/kg IV every 4 weeks
Adult Rheumatoid Arthritis (SC) (wt<100kg)	162 mg administered subcutaneously every other week, followed by an increase to every week based on clinical response
Adult Rheumatoid Arthritis (SC) (wt≥100kg)	162 mg administered subcutaneously every week
Polyarticular Juvenile Idiopathic Arthritis (IV) (wt≥30 kg)	8 mg/kg IV every 4 weeks
Polyarticular Juvenile Idiopathic Arthritis (IV)	10 mg/kg IV every 4 weeks

(wt<30kg)	
Systemic Juvenile Idiopathic Arthritis(IV) (wt≥30kg)	8 mg/kg IV every 2 weeks
Systemic Juvenile Idiopathic Arthritis (IV) (wt<30kg)	12 mg/kg IV every 2 weeks

VI. Billing/Code Information :

Jcode:

J3262 – Actemra (Genentech) 80 mg, 200 mg, 400 mg IV Injection: 1 billable unit = 1mg

NDC:

Actemra 80 mg/ 4 ml vial – 50242-0135-xx (Genentech)
Actemra 200 mg/10 ml vial – 50242-0136-xx (Genentech)
Actemra 400 mg/20 ml vial - 50242-0137-xx (Genentech)
Actemra 162 mg/0.9 ml pre-filled syringe – 50242- 0138- xx (Genentech)

Max Units (per dose and over time):

Rheumatoid Arthritis
Male: 800 billable units every 28 days
Female : 800 billable units every 28 days

Systemic Juvenile Idiopathic Arthritis
Male: 800 billable units every 14 days
Female : 800 billable units every 14 days

Polyarticular Juvenile Idiopathic Arthritis
Male: 800 billable units every 28 days
Female : 800 billable units every 28 days

Quantity Limits:

Actemra 162 mg/0.9 ml pre-filled syringe : 4 syringes every 28 days

Covered Diagnosis:

ICD-9 Codes	Diagnosis
714.0	Rheumatoid arthritis
714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement

714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified
714.31	Polyarticular juvenile rheumatoid arthritis, acute
714.32	Pauciarticular juvenile rheumatoid arthritis
714.33	Monoarticular juvenile rheumatoid arthritis
714.4	Chronic postrheumatic arthropathy
714.81	Rheumatoid lung
714.89	Other specified inflammatory polyarthropathies
714.9	Unspecified inflammatory polyarthropathy

VII. Centers for Medicare and Medicaid Services (CMS):

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

VIII. Criteria Exclusions:

- Treatment for diagnoses not FDA approved
- All indications not described in Section III Review criteria are not covered and may be considered experimental or investigational.

IX. Black Box Warnings/Contraindications:

Black Box Warning:

- Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial, invasive fungal, viral, and other opportunistic infections have occurred in patients receiving Actemra
- If a serious infection develops, interrupt Actemra until the infection is controlled.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Actemra.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

Contraindications

- Actemra should not be administered to patients with known hypersensitivity to Actemra

X. References:

1. Actemra [package insert]. South San Francisco, CA; Genentech, Inc; October 2013. Accessed March 2014.

2. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.
3. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum 2008;59:762-84.
4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res (Hoboken). 2011 Apr;63(4):465-82.

XI. Appendix:

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E	CA,HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC