MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/15/11	**7/18/15**	**7/18/14**
Author		
Laura Walters, RPh, Tim Smith, RPh, Dr. Stephen Lucht		

CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Tocilizumab (Actemra)

B. POLICY

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Tocilizumab (Actemra) Prior Authorization (PA) Program is to encourage appropriate selection of therapy for patients with Rheumatoid Arthritis or Juvenile Iodiopathic Arthitis based on product labeling, clinical literature and established guidelines as well as to encourage use of preferred agents.

CareSource will approve the use of tocilizumab (Actemra) and consider its use as medically necessary when the following criteria have been met for:

- Rheumatoid arthritis
- Active systemic juvenile idiopathic arthritis
- Active Polyarticular Juvenile Idiopathic Arthritis

Rheumatoid Arthritis

Tocilizumab (Actemra) is indicated for the treatment of adult patients (18 years and older) with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.

Prior Authorization Criteria:

- Documented diagnosis of moderate to severe active rheumatoid arthritis
- Age 18 or older
- Prescribed by a rheumatologist or under recommendation of rheumatologist.

AND

- Failure of trial of 1 or more tumor necrosis factor (TNF) antagonist (Adalimumab, Etanercept, Golimumab, Infliximab)
  OR
- Unable to tolerate or has a medical contraindication of conventional therapies

Active Systemic Juvenile Idiopathic Arthritis and Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Tocilizumab (Actemra) is indicated for reducing signs and symptoms of active systemic juvenile idiopathic arthritis and Polyarticular Juvenile Idiopathic Arthritis in patients 2 years of age and older.

Prior Authorization Criteria:

- Documented diagnosis of active systemic juvenile idiopathic arthritis or polyarticular juvenile idiopathic arthritis
- Age 2 years or older
- Prescribed by a rheumatologist or under recommendation of rheumatologist.
- Inadequate response to non-steroidal anti-inflammatory drugs, corticosteroids, Methotrexate or other biologics
  OR
- has a medical contraindication of conventional therapies

NOTE: Tocilizumab may be used alone or in combination with methotrexate or other DMARDs.

NOTE: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

All other uses of tocilizumab (Actemra) are considered experimental/investigational and, therefore, may not be covered. Please refer to CareSource's Off Label Policy.

For Medicare

Please refer to the CareSource policy

National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD)

Conditions of Coverage

J-Code	J3262
Place Of Service	Office, Outpatient **Note:** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. ALL authorizations are subject to continued eligibility.

D. REVIEW / REVISION HISTORY

06/15/2011
12/13/2012
07/ 2014- new indication added PIJA

E. REFERENCES

Actemra [package insert]. South San Francisco, CA: Genentech Inc; October 2013.

Winifred S. Hayes, Inc. *Infliximab for Rheumatoid Arthritis*. www.hayesinc.com Published: April 29, 2004 (February 8, 2011)

FDA Approves New Drug for Rheumatoid Arthritis; Pharmacist's Letter; March 2010; Vol: 26

Rheumatoid arthritis: the role of DMARDs. Pharmacist's Letter/Prescriber's Letter July 2012;25(2):250210.

Sing Jasvinder, et al. American College of Rheumatology *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 & Rheumatology (Arthritis Care & Research), 64:5, 625-639, May 2012.

Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2014.

U.S. Food and Drug Administration. Actemra® Prescribing Information.2013. Retrieved 5/15/14 from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist

FDA Approves Actemra for the treatment of Systemic Juvenile Idiopathic Arthritis (SJIA); http://insciences.org/article.php?article_id=10062 (May 1, 2011)

2013 ACR Guidelines for JRA full manuscript http://www.rheumatology.org/Practice/Clinical/Guidelines/Juvenile_Idiopathic_Arthritis_(Members__Only)/ . Accessed May 15,2014

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

	7/20/2014
Chief Medical Officer	**Date**

	6/27/2014
Director of Specialty Pharmacy	**Date**

Independent Medical Review: 5/17/2011