

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

**If Applicable:** Pharmacy Name: \_\_\_\_\_  
Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

**Please attach all relevant medical records and test results.**

STEP  
2

Diagnosis	<input type="checkbox"/> Moderate to severe active Rheumatoid Arthritis	<input type="checkbox"/> Other (please state): _____
Physician Specialty	<input type="checkbox"/> Rheumatology	<input type="checkbox"/> Other (please state): _____
Clinical Consideration	Patient must have tried and failed previous TNF antagonist therapy. Medical records required if no claims history.*	Failures of which medication(s): _____ _____
<i>*Note: Concomitant use of Actemra with other biologic therapy is contraindicated</i>		
Supporting Documentation	Diagnosis: ICD-9 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Actemra <sup>®</sup> (tocilizumab)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<b>We will not process incomplete forms. If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>		

STEP  
3

**I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date).**

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

STEP **Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034**  
4

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/06/12

## RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

### Actemra® (tocilizumab)

#### CLASSIFICATION

- Immunological Agent, IL-6 receptor inhibitor

#### DESCRIPTION

- An interleukin-6 receptor inhibitor indicated in adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one of more tumor necrosis factor (TNF) antagonist therapies.
- IL-6 is involved in processes such as T-cell activation, induction of immunoglobulin secretion, initiation of hepatic acute phase protein synthesis, and stimulation of hematopoietic precursor cell proliferation and differentiation. IL-6 is produced by a variety of cell types including T- and B-cells, lymphocytes, monocytes, and fibroblasts as well as by synovial and endothelial cells leading to local production of IL-6 in joints affected by inflammatory processes such as rheumatoid arthritis.
- May be used as monotherapy or may be combined with methotrexate or other disease-modifying antirheumatic drugs (DMARDs).
- Its safety and efficacy for the treatment of RA was demonstrated in five randomized, double-blind, multicenter trials involving more than 4000 patients, most of whom had failed prior anti-TNF therapy.
- Its safety and efficacy for the treatment of active systemic juvenile idiopathic arthritis in children age 2 years and older was established in a 12-week, randomized, double-blind study (n=112). Treatment with tocilizumab resulted in a greater proportion of patients achieving at least a juvenile idiopathic arthritis American College of Rheumatology 30% (JIA ACR30) response without fever in the preceding 7 days, compared with placebo, in pediatric patients treated with or without concurrent methotrexate. Tocilizumab is indicated as monotherapy or in combination with methotrexate for the treatment of active systemic juvenile idiopathic arthritis in children age 2 years and older.
- The first IL-6 inhibitor approved for RA.
- Should not be used concurrently with other biologic therapies.
- Same adverse effects and boxed warnings as other biologics for RA, but with the added risk of gastrointestinal perforations (especially in patients with diverticulitis), decreases in absolute neutrophil count (ANC) and platelet count, as well as elevations in lipid levels and liver enzymes.
- Further long term data are needed to fully determine its safety profile, especially in terms of serious events. Actemra's place in therapy will continue to evolve with more clinical research and experience. As it is indicated, reserve for patients who have inadequately responded to TNF-antagonists.

#### FORMULARY COVERAGE

Prior authorization: Yes

Good Health Formulary: Tier 6

Commercial Formulary: Tier 6

Medicare Part D coverage: Tier 5

#### COVERAGE CRITERIA

Actemra® (tocilizumab) meets the definition of **medical necessity** for the following:

- Rheumatoid arthritis (moderate to severe): Patient must have tried and failed previous TNF antagonist therapy. Medical records required if no claims history.

- Active systemic juvenile idiopathic arthritis: In pediatric patients (2 years and older) as monotherapy or in combination with methotrexate.

Actemra® (tocilizumab) is considered **experimental** for the following:

- Any condition or diagnosis *not* FDA approved or Compendia supported.

Required Provider Specialty:

- Approval is limited to Rheumatology

## DOSAGE/ADMINISTRATION:

Adult Dosing:

Rheumatoid arthritis (Moderate to Severe), in patients who had an inadequate response to one or more tumor-necrosis-factor antagonist therapies

- The recommended starting dose when used in combination with (non-biologic) disease-modifying antirheumatic drugs (DMARDs) or as monotherapy is tocilizumab 4 milligrams/kilogram (mg/kg) administered once every 4 weeks as a 60-minute intravenous infusion.
- Based on clinical response, the dose may be increased to 8 mg/kg every 4 weeks.
- Doses exceeding 800 mg per infusion are not recommended.

Pediatric dosing:

Active systemic juvenile idiopathic arthritis in children 2 years of age and older:

- In children 2 years of age and older with body weight *less than 30 kg*, the recommended dose of tocilizumab as monotherapy or in combination with methotrexate for the treatment of active systemic juvenile idiopathic arthritis is 12 mg/kg IV infusion over 1 hour every 2 weeks.
- In children 2 years of age and older with body weight of *30 kg or greater*, the recommended dose of tocilizumab as monotherapy or in combination with methotrexate for the treatment of active systemic juvenile idiopathic arthritis is 8 mg/kg IV infusion over 1 hours every 2 weeks.
- Since body weight may fluctuate, changes in dose should not be made based solely on weight measurement during a single visit.
- Safety and effectiveness has not been established in pediatric patients under the age of 2 years for the treatment of active systemic juvenile idiopathic arthritis.
- Doses exceeding 800 mg per infusion are not recommended.

Dosing adjustments:

- See product information for specific dosing requirements for different levels of hematologic or hepatic toxicity that may develop during therapy
- Renal impairment:
  - Mild: No dose adjustment required
  - Moderate to severe: No studies have been done
- Hepatic impairment: if alanine transaminase (ALT) or aspartate aminotransferase (AST) elevations 1.5 times upper limit of normal (ULN), tocilizumab should not be initiated.
- Hematologic impairment: if absolute neutrophil count (ANC) below 2000 per cubic milliliter (mm<sup>3</sup>) or platelet count below 100,000/mm, tocilizumab should not be initiated.

## PRECAUTIONS:

- **Black Box Warning: Risk of Serious Infections**
  - Patients treated with tocilizumab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
  - If a serious infection develops, interrupt tocilizumab until the infection is controlled.
  - The risks and benefits of treatment with tocilizumab should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
  - Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with tocilizumab, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating.
- Contraindications
  - Hypersensitivity to tocilizumab.
- Precautions
  - Serious infections (e.g. tuberculosis, invasive fungal infections, and other opportunistic infections), including fatalities, have been reported, especially with concomitant immunosuppressant use; do not initiate therapy in patients with active infections (including chronic or localized infections); discontinue therapy if a serious infection develops
  - Tuberculosis (TB), reactivation or new onset, may occur; increased risk in patients with potential exposure due to travel or residence in endemic areas or close personal contact with active TB or with history of latent or active disease
  - Demyelinating disorders (e.g. multiple sclerosis, chronic inflammatory demyelinating polyneuropathy); new onset or worsening of preexisting condition may occur
  - Concomitant use with live vaccines is not recommended
  - Concomitant use with biological disease-modifying antirheumatic drugs, such as tumor necrosis factor (TNF) antagonists, interleukin-1R antagonists, anti-CD20 monoclonal antibodies and selective co-stimulation modulators should be avoided
  - Gastrointestinal perforation has been reported
  - Hematologic abnormalities (e.g. neutropenia and thrombocytopenia) have been reported; monitoring recommended; reduction of dose or interruption of therapy may be necessary
  - Hepatic impairment or hepatic disease, active; use not
  - Hypersensitivity reactions, including anaphylaxis may occur
  - Lipid elevation, including total cholesterol, triglyceride, and LDL cholesterol have occurred; monitoring recommended
  - Malignancies have been reported
  - Serum transaminase (AST and ALT) elevations have been reported; increased frequency and magnitude observed with concomitant use of hepatotoxic drugs; monitoring recommended; reduction of dose or interruption of therapy may be necessary

## Billing/Coding information

### CPT Coding:

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Each additional hour (list separately in addition to code for primary)

### HCPCS Coding:

J3262	Injection, tocilizumab 1mg (for billing prior to 1/1/11 use J3590 or C9264)
J9250-260	Methotrexate sodium, 5 mg/ 50mg

## ICD-9 Diagnoses Codes That Support Medical Necessity:

714.0 – 714.9	Rheumatoid arthritis
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### COST

- AWP (July 2010): Actemra® 200mg/10ml vial for IV injection (1): \$1,533.60
- AWP (January 2012): Actemra® 200mg/10ml vial for IV injection (1): \$796.00

### COMMITTEE APPROVAL:

- August 18, 2010

### GUIDELINE UPDATE INFORMATION:

July 2010	Medical Policy created
August 18, 2010	Approved at RMHP Pharmacy and Therapeutics Committee
April 15, 2011	New FDA approved indication for active systemic juvenile idiopathic arthritis in pediatric patients $\geq 2$ years
January 3, 2012	Medical policy updated

### REFERENCES:

- DRUGDEX®, accessed 07/21/2010, 01/03/12
- Product Information: ACTEMRA® solution for intravenous infusion, tocilizumab solution for intravenous infusion. Genentech, Inc, South San Francisco, California, 2010.