ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Actemra IV (tocilizumab) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Actemra IV (tocilizumab)

Diagnosis (documentation supportive of diagnosis is required)

☐ Moderate to severe active Rheumatoid Arthritis
☐ Active systemic juvenile idiopathic arthritis (age ≥ 2 years)
☐ Polyarticular juvenile idiopathic arthritis (age ≥ 2 years)
☐ Other (please state):_____

Clinical Consideration for Rheumatoid Arthritis Only

☐ Patient tried and failed previous TNF inhibitor therapy. Please indicate which drug was tried and failed **(documentation of failed therapy from medical records is required)**:

- ☐ Patient has failed therapy with Enbrel
- ☐ Patient has failed therapy with Humira
- ☐ Patient has failed therapy with Remicade
- ☐ Patient has failed therapy with Simponi
- ☐ Patient has failed therapy with Cimzia

**Note: Concomitant use of Actemra with other biologic therapy is contraindicated*

Physician Specialty

☐ Rheumatology
☐ Other (please state):_____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

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.

Moderately to Severely Active Rheumatoid Arthritis (RA):

- Actemra IV is the first IL-6 inhibitor approved for RA.
- Actemra is indicated as monotherapy or in combination with methotrexate or other DMARDs in adults with moderately to severely active RA who have had an inadequate response to 1 or more DMARDs. Avoid the use of tocilizumab with biological DMARDs.
- Tocilizumab, as monotherapy, with methotrexate, or with other DMARDs, significantly improved clinical response in patients with rheumatoid arthritis who had an inadequate response to methotrexate or other DMARDs in 5 randomized trials, with the longest duration of 2 years.
- Long-term treatment with monthly tocilizumab improved all measures of response, including ACR criteria and disease activity score, in an open-label, 5-year extension trial (n=143).

Active Systemic Juvenile Idiopathic Arthritis:

- 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.
- Actemra IV is indicated as monotherapy or in combination with methotrexate for the treatment of active systemic juvenile idiopathic arthritis in children 2 years or older.
- 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 compared with placebo in a 12-week, randomized, double-blind study in pediatric patients with persistent systemic juvenile idiopathic arthritis unresponsive to NSAID and glucocorticoid therapy (n=112).
- Actemra IV was superior to placebo for the treatment of systemic-onset JIA in a randomized, double-blind, placebo-controlled trial with open-label lead-in and extension phases (n=56).

Polyarticular Juvenile Idiopathic Arthritis (JIA):

- Actemra IV is indicated as monotherapy or in combination with methotrexate for the treatment of polyarticular JIA in children 2 years or older. Tocilizumab therapy was associated with fewer JIA ACR 30 flares compared with placebo in a 40-week, 2-part study of children with polyarticular JIA intolerant to or with an inadequate response to methotrexate. Children with disease subtypes rheumatoid factor positive or negative polyarticular JIA or extended oligoarticular JIA were included if they had at least 6 months of active with at least 5 joints with active arthritis and/or at least 3 active joints with limited motion. Stable doses of methotrexate were allowed throughout the study. Part 1 (n=188) was a 16-week, open-label, lead-in phase during which patients weighing < 30 kg were randomized to receive either 10 mg/kg or 8 mg/kg IV every 4 weeks, while children weighing 30

mg/kg or more received 8 mg/kg IV every 4 weeks. An ACR30 response was achieved in 91% of those receiving concomitant methotrexate and in 83% of those receiving tocilizumab monotherapy. ACR50 and 70 responses were achieved in 84% and 64% of those with concomitant methotrexate, and in 80% and 55% of those receiving tocilizumab monotherapy, respectively. Part 2 (n=163) was a 24-week randomized, placebo-controlled, double-blinded phase during which patients were continued on their current dose of tocilizumab up to week 40 or switched to placebo. The proportion of patients experiencing a JIA ACR30 flare, defined as 3 or more of the 6 core variables worsening by at least 30% with no more than 1 of the remaining variables improving by more than 30% at week 40 relative to week 16, was the primary endpoint. A JIA ACR30 flare was reported in 26% (21 of 82) of those receiving tocilizumab compared with 48% (39 of 81) of those receiving placebo, for a 21% lower incidence in the tocilizumab group (95% CI, -35% to -8%).

- 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. Most common adverse reactions (incidence of at least 5%): upper respiratory tract infections, nasopharyngitis, headache, hypertension, increased ALT, injection site reactions.
- REMS program to inform healthcare providers about the serious risks associated with tocilizumab. Visit http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM202044.pdf.

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 all FDA-approved indications not otherwise excluded from Part D including 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.
- Polyarticular juvenile idiopathic arthritis in children 2 years or older as monotherapy or in combination with methotrexate.

For the subQ formulation for Rheumatoid Arthritis, use the Actemra SubQ prior authorization form.

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 (TNF) antagonist therapies:

- Initial dose: 4 mg/kg IV over 60 minutes, once every 4 weeks; doses exceeding 800 mg per infusion not recommended.
- Maintenance dose: Based on clinical response, may increase to tocilizumab 8 mg/kg IV once every 4 weeks; doses exceeding 800 mg per infusion not recommended.

Pediatric dosing (see product labeling for complete information):

- Do not initiate tocilizumab therapy in patients with an absolute neutrophil count below 2000 per mm^3, platelet count below 100,000 per mm^3, or ALT or AST above 1.5 times ULN.
- Safety and effectiveness are not established in pediatric patients under the age of 2 years for the treatment of active systemic juvenile idiopathic arthritis or polyarticular juvenile idiopathic arthritis.
- Since body weight may fluctuate, changes in pediatric doses should not be made based solely on weight measurement during a single visit

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

- Less than 30 kg: 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 once every 2 weeks.
- 30 kg or greater: 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 once every 2 weeks.
- Since body weight may fluctuate, changes in dose should not be made based solely on weight measurement during a single visit.

Polyarticular juvenile idiopathic arthritis in children 2 years or older:

- Less than 30 kg: recommended dose is 10 mg/kg IV infusion over 1 hour once every 4 weeks, either as monotherapy or in combination with methotrexate.
- 30 kg or greater: recommended dose is 8 mg/kg IV infusion over 1 hour once every 4 weeks, either as monotherapy or in combination with methotrexate.
- Do not make dose adjustments based on body weight changes at a single visit, as weight may fluctuate.

Safety and effectiveness are not established in pediatric patients younger than 2 years for the treatment of active systemic juvenile idiopathic arthritis or polyarticular juvenile idiopathic arthritis.

Dosing adjustments:

- See product labeling for specific dosing requirements.

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.

- These infections have included bacterial infection, tuberculosis, invasive fungal or other opportunistic infections. Patients should be closely monitored
- 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. Evaluate for latent tuberculosis and treat if necessary prior to initiation of therapy. Monitor patients receiving tocilizumab for signs and symptoms of infection, including tuberculosis, even if initial latent tuberculosis test is negative

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.
- Geriatric (65 years and older); higher frequency of serious infections have been reported.
- 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 active hepatic disease; use not recommended.
- Hepatic transaminase (AST and ALT) elevations have been reported; increased frequency and magnitude observed with concomitant use of hepatotoxic drugs. Monitoring is recommended and interruption, dose reduction, and discontinuation may be necessary.
- Hypersensitivity reactions, including anaphylaxis, have been reported and fatalities have been reported with IV administration; if an anaphylactic or hypersensitivity reaction occurs, permanently discontinue treatment.
- Lipid elevation, including total cholesterol, triglyceride, and LDL cholesterol, have occurred. Monitoring is recommended.
- Malignancies have been reported.

Billing/Coding information

CPT Coding:

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
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)

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
- AWP (May 2013): Actemra® 200mg/10ml vial for IV injection (1): $862.00

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 ≥ 2 years
January 3, 2012	Medical policy updated
May 2013	Medical policy updated

REFERENCES:

- DRUGDEX®, accessed 07/21/2010, 01/03/12, 5/20/13
- Product Information: ACTEMRA® solution for intravenous infusion, tocilizumab solution for intravenous infusion. Genentech, Inc., South San Francisco, California, 2010, 2013.