

**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 Number:

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

**Complete the Clinical Assessment:**

Diagnosis	<input type="checkbox"/> Moderate to severely active Crohn's Disease in adults <input type="checkbox"/> Moderate to severely active Rheumatoid Arthritis in adults	<input type="checkbox"/> Other (please state): _____ _____ _____
Clinical Consideration	For Crohn's Disease (CD), patients should have had an inadequate response to conventional therapy, including either Remicade (infliximab) or Humira (adalimumab).  <input type="checkbox"/> For CD, please indicate prior therapy: _____ _____	
Physician Specialty	<input type="checkbox"/> Rheumatology <input type="checkbox"/> Gastroenterology	<input type="checkbox"/> Other (please state): _____ _____
<b>* There is no physician specialty requirement for Medicare Part D members</b>		
Diagnosis: ICD-9 Code # / Description / J Code (required):		
Please provide ALL of the information below: Cimzia <sup>®</sup> (certolizumab pegol) Indication and directions for use: _____ _____ _____		
<b>*Please attach all relevant medical records and test results*</b> <b>Incomplete forms will not be processed.</b>		

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

STEP  
3

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

\_\_\_\_\_  
 Date

STEP  
4

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

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

Pharmacy Technician initials: \_\_\_\_\_ Date: \_\_\_\_\_

**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. 01/09/12

## RMHP Formulary Coverage Policy

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

# Cimzia® (certolizumab)

## CLASSIFICATION

- Immune suppressant, Tumor Necrosis Factor Inhibitor

## DESCRIPTION

- Certolizumab pegol is a tumor necrosis factor (TNF) inhibitor, which acts by binding and selectively neutralizing TNF-alfa. It does not neutralize TNF-beta. The inhibition of TNF-alfa, which is strongly expressed in the bowel wall and feces of patients with Crohn's disease results in an interference in the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide.
- Approved for maintaining clinical response and reduction of signs and symptoms of moderate to severe Crohn's disease in adults who had inadequate response to conventional therapy.
- For Crohn's disease, efficacy in maintenance of remission was not established in clinical trials. Other TNF inhibitors (infliximab and adalimumab) have shown significant benefit in maintenance of remission in Crohn's disease.
- Indicated for treatment of adults with moderate to severe active rheumatoid arthritis. Certolizumab pegol may be used as monotherapy or concomitantly with non-biological disease modifying anti-rheumatic drugs (DMARDs). In clinical trials, certolizumab pegol treatment in combination with methotrexate and alone, demonstrated improvements in the symptoms of active rheumatoid arthritis, improvements in physical function and a decrease in the progression of structural damage compared with placebo.

## FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Tier 5

Commercial Formulary: Tier 6

Medicare Part D coverage: Tier 5

## COVERAGE CRITERIA

Cimzia® (certolizumab) meets the definition of **medical necessity** for the following:

- Crohn's disease, moderate to severely active disease after an inadequate response to conventional therapy
- Rheumatoid arthritis, moderately to severely active disease

Cimzia® (certolizumab) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported

Required Provider Specialty:

- Approval is limited to Rheumatology or Gastroenterology

## DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- Crohn's disease:
  - Initial: 400 mg subQ (as 2 subQ injections of 200 mg) once and then repeat at weeks 2 and 4 weeks
  - Maintenance: 400 mg subQ (as 2 subQ injections of 200 mg) once every 4 weeks
- Rheumatoid arthritis, moderately to severe:
  - Initial: 400 mg subQ (as 2 subQ injections of 200 mg) once and then repeat at weeks 2 and 4
  - Maintenance: 200 mg subQ once every 2 weeks or 400 mg (as 2 subQ injections of 200 mg) every 4 weeks

## PRECAUTIONS:

- **Black Box Warning**
  - Tuberculosis (TB), invasive fungal infections, bacterial, viral, and other opportunistic infections, some fatal, have been observed in patients receiving certolizumab pegol. Patients should be evaluated for TB risk factors and be tested for latent TB infection prior to initiating certolizumab pegol and during therapy. Treatment of latent TB infection should be initiated prior to therapy with certolizumab pegol. Monitor patients receiving certolizumab pegol for signs and symptoms of infection including TB in patients who tested negative for latent TB infection. Lymphoma and other malignancies, some fatal, have been reported in pediatric patients (not indicated in this population) treated with tissue necrosis factor blockers.
- Auto-antibody formation has occurred; may develop into lupus-like syndrome; discontinue therapy if symptoms of lupus-like syndrome occur.
- CNS demyelinating disorders; new onset or worsening of preexisting condition may occur.
- Concomitant use of biological disease-modifying antirheumatic drugs (e.g. abatacept, anakinra, natalizumab, rituximab), or live or attenuated vaccines is not recommended.
- Congestive heart failure, new-onset or worsening of preexisting disease, has been reported; monitoring recommended.
- Hematologic abnormalities have occurred, especially in patients with active or history of blood dyscrasias; may require discontinuation of therapy.
- Hepatitis B virus, chronic carriers; reactivation has occurred including several months after therapy termination; monitoring recommended; discontinuation and supportive treatment may be necessary.
- Hypersensitivity reactions including serum sickness-like reactions have been reported; discontinue therapy if such reaction occurs.
- Neurologic disorders including seizure disorder, optic neuritis, and peripheral neuropathy have been reported.

## Billing/Coding information

### CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
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## HCPCS Coding:

J0718	Injection, certolizumab pegol, 1mg
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## ICD-9 Diagnoses Codes That Support Medical Necessity:

555.0	Crohn's disease; small intestine
555.1	Crohn's disease, large intestine
555.2	Crohn's disease, small intestine with large intestine
555.9	Crohn's disease, unspecified site
714.0 – 714.9	Rheumatoid arthritis – unspecified inflammatory polyarthropathy

## COST

- AWP (April 2010): Cimzia® 200mg/ml subQ injection (1): \$1,755.19
- AWP (November 2011): Cimzia® 200mg/ml subQ injection (1): \$2,109.05

## COMMITTEE APPROVAL:

- August 2010

## GUIDELINE UPDATE INFORMATION:

April 2010	Medical Policy created
November 2011	Medical Policy updated

## REFERENCES:

- DRUGDEX®, accessed 04/05/2010
- Product Information: CIMZIA® lyophilized powder for solution, solution for subcutaneous injection, certolizumab pegol lyophilized powder for solution, solution for subcutaneous injection. UCB, Inc, Smyrna, GA, 2009.