

## Medical Affairs Policy & Procedure

**Title/Service:** Cimzia (certolizumab pegol)

<b>Revised</b>	11/18/11
<b>Reviewed</b>	11/21/08, 12/28/09, 01/14/11
<b>Developed</b>	
<b>Policy Committee Approval</b>	11/18/11

### **Description:**

Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker used in the treatment of certain inflammatory diseases.

### **Indications of Coverage:**

NOTE: Unless contraindicated, patient must try/fail both Enbrel and Humira for appropriate indications before coverage of Cimzia or Simponi will be considered.

Cimzia is indicated for reducing signs and symptoms of **Crohn's disease** and maintaining clinical response in adults (individuals greater than 18 years of age) with moderately to severely active disease who have had an inadequate response to conventional therapy (oral mesalamine, oral corticosteroids, and 6-mercaptopurine or azathioprine (6-MP/AZA).

Dosage: The recommended initial adult dose of Cimzia is 400mg (given as two [subcutaneous](#) injections of 200mg) initially, and at weeks two and four. In individuals who obtain a clinical response, the recommended maintenance [regimen](#) is 400mg every four weeks. Cimzia is supplied as a kit containing two 200mg injections.

Cimzia is indicated for treatment of adults (individuals greater than 18 years of age) with moderately to severely active **rheumatoid arthritis**, with a minimum of six painful joints and an erythrocyte sedimentation rate (ESR) greater than 27mm/hr, or a C-reactive protein (CRP) greater than .2mg/dL, or morning stiffness lasting for more than forty five minutes when the failure of prior treatment with disease modifying anti-rheumatic drugs (DMARDS) such as methotrexate or sulfasalazine is documented.

Dosage: The recommended initial adult dose of Cimzia is 400mg initially, and at weeks two and four, followed by 200mg every other week; or, for maintenance dosing, 400mg every four weeks.

If criteria are met, treatment may be approved for up to six months. Subsequent treatment may be approved in one year increments with review of continued therapeutic response and **consistent** prescription medication use.

Administration: Cimzia is a self-administered medication.

### **Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

### **Documentation Required:**

- Office notes
- Lab reports (if necessary)
- Procedure reports, pathology reports (for Crohn's)
- Prescription medication use data

### **Rationale:**

Cimzia has been shown to be effective in cases of excess TNF production that may lead to an inflammatory condition, such as Crohn's disease. Cimzia binds to TNF alpha, which is a substance in the body with a prominent role in inflammatory processes. The efficacy and safety of Cimzia was assessed in two double blind, placebo-controlled trials which demonstrated significant clinical response as measured by the Crohn's Disease Activity Index, and in several studies demonstrating the efficacy of Cimzia when used with methotrexate for the treatment of rheumatoid arthritis.

### **References:**

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3. Keystone E, Heijde D, Mason D Jr, Landewé R, Vollenhoven RV, Combe B, Emery P, Strand V, Mease P, Desai C, Pavelka K. Certolizumab pegol plus methotrexate is significantly more effective than placebo plus methotrexate in active rheumatoid arthritis: findings of a fifty-two-week, phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. [Arthritis Rheum](#). 2008 Nov; 58(11):3319-29.

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*Approved by the Medical Director*