

**Cimzia®**

To Initiate a Coverage Review, call 1 800 753-2851

**Covered Medication**

- Certolizumab pegol (Cimzia®)

**What It Does and How It Is Used**

- Cimzia® is indicated for for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy and for the treatment of active rheumatoid arthritis.
- **Crohn's disease (CD)** is a chronic, episodic inflammatory condition of the gastrointestinal (GI) tract, which mostly occurs in persons between the ages of 15 and 35, and often presents with cramp-like pain in the lower right abdomen, diarrhea, rectal bleeding, and weight loss.
- Patients with CD are found to have elevated levels of tumor necrosis factor alpha (TNF-α), a substance that promotes damage to the GI tract. Consequently, patients may develop extensive intestinal wall injury leading to ulcers, bleeding, anemia, skin lesions, liver disease, and weight loss and growth failure due to nutritional deficiencies.
- Untreated, CD can lead to small bowel stricture or obstruction requiring surgery. Fistulas may also occur as a consequence of CD in the areas of most severe inflammation.
- Currently there is no cure for CD, however, symptomatic treatment often includes aminosalicylates (5-ASAs), corticosteroids (prednisone and methylprednisolone), immunomodulators (azathioprine or 6-mercaptopurine), biologic agents (Humira®, Remicade®, Cimzia®, and Tysabri®), and antibiotics to help control inflammation and heal fistulas.
- Humira® and Remicade® are indicated for the induction and maintenance of remission in patients with moderate to severe CD. Scores ranging from 220 to 450 on the Crohn's Disease Activity Index (CDAI) are indicative of moderate to severe disease and remission is measured by achieving a CDAI score of less than 150.
- Cimzia® is used to reduce the signs and symptoms and maintain clinical response in patients with moderate to severe CD. Clinical response is measured by a decrease from baseline of 70 to 100 points in CDAI score.
- Certolizumab pegol is a pegylated humanized antibody Fab' fragment that inhibits tumor necrosis factor (TNF) activity, as does Remicade®, Humira®, and Enbrel®. The pegylation allows it to be dosed less frequently, once per month.
- Cimzia® is administered via subcutaneous injection. Humira® can be self-administered subcutaneously once every other week and Remicade® is an intravenous infusion given every other month.
- Cimzia® is given three times the first month, at a dose of 400 mg at week 0, 2, and 4; In patients who demonstrate a response, therapy is continued at 400 mg at week 8 and every 4 weeks thereafter.
- **Rheumatoid arthritis (RA)** is a progressive chronic inflammatory disease that primarily affects large and small joints.
- The disease is characterized by joint deformities of the hands, wrists, neck, jaw, elbows, feet, and ankles.
- In addition to pain, patients can experience neuropathy (numbness or loss of feeling in hands or feet). Other conditions associated with RA include cardiac abnormalities, pulmonary fibrosis, and corneal defects.
- RA is associated with a significant amount of morbidity, which can lead to a higher risk of mortality.
- RA treatment is aggressive soon after diagnosis with the goal of treatment being to eliminate synovitis (joint swelling) and joint destruction. Joint erosion is due to the presence of inflammatory mediators which cause joint and cartilage destruction. These damaging substances include; prostaglandins, cytokines, and tumor necrosis factor.
- Initial treatment in the mild stages can include NSAIDs and then usually a conventional disease-modifying antirheumatic drug (DMARD). DMARDs decrease pain, slow disease progression, and retard development of joint erosions.
- Methotrexate is the most commonly used DMARD. It may be used alone or with a biologic agent.
- Cimzia® is given three times the first month, at a dose of 400 mg at week 0, 2, and 4; followed by maintenance dosing of either 200 mg every other week or 400 mg every 4 weeks.
- Cimzia® is administered via subcutaneous injection.

**Rationale for Coverage Authorization**

To reduce exposure to cost associated with uncovered uses of Cimzia® such as for the treatment of mild Crohn's disease and for situations where the use of other therapies may be an option.

**Benefit Design**

- Coverage for Cimzia® is determined through prior authorization for every claim.

**Coverage Authorization Criteria**

Coverage for certolizumab pegol (Cimzia®) is provided in accord with the following:

1. For patients ≥ 18 years of age
2. Coverage is provided in situations where the patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment with Cimzia®.
3. Coverage is not provided for use in combination with other biologics or TNF antagonists
4. For the treatment of rheumatoid arthritis.
5. Induction and maintenance treatment for moderate to severe Crohn's disease
  - In situations where the patient has experienced intolerance or failure to previous treatment with Humira® or Remicade®.

**Coverage duration:**

Coverage for CD is provided for 3 months initially and may be renewed for 12 months, in situations in which the patient has responded to therapy.

Coverage for RA is provided for 5 years and may be renewed in situations where the patient has responded to therapy.

**References**

- Cimzia® (certolizumab pegol). Prescribing information. Smyrna, GA: UCB, Inc., May 2009.
- Lichtenstein GR, Hanauer SB and Sandborn W. American College of Gastroenterology: Practice Guidelines Management of Crohn's disease in adults. Available from: <http://www.gi.org/physicians/guidelines/CrohnsDiseaseinAdults2009.pdf> . Accessed August 10, 2009.
- Pardi DS, Loftus EV, Camilleri M. Treatment of inflammatory bowel disease in the elderly: an update. *Drugs and Aging*. 2002; 19(5):355-363.
- Sandborn WJ, Feagan BG, Stoinov S, et al. Certolizumab Pegol for the Treatment of Crohn's Disease (PRECISE 1). *NEJM*. 2007;357:228-238.
- Schreiber SM, Khaliq-Kareemi M, Lawrance IC, et al. Maintenance Therapy with Certolizumab Pegol for Crohn's Disease (PRECISE 2). *NEJM*. 2007;357:239-250.