



CERTOLIZUMAB PEGOL (CIMZIA®) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Disease Modifying Anti-Rheumatic Drug (DMARD)
BRAND NAME:	Cimzia (certolizumab pegol injection). <ul style="list-style-type: none">• Supplied as a kit that includes 2 single-use prefilled syringes, each containing 200 mg (1 ml) of certolizumab pegol.• Also available as a kit that includes 2 vials each containing 200 mg certolizumab pegol for reconstitution

FDA INDICATIONS:

- Crohn's Disease: Certolizumab pegol is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical remission in adult patients with moderately to severely active disease who have had inadequate response to conventional therapy.
- Rheumatoid Arthritis: Certolizumab pegol is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.

COVERAGE AUTHORIZATION CRITERIA:

* Coverage is provided for Crohn's disease or rheumatoid arthritis for patients who have **previously used either etanercept (Enbrel®) or adalimumab (Humira®)** and such drug was ineffective in treating the patient's condition or was not tolerated.

Coverage is provided for **Crohn's Disease** if:

- Patient has moderately to severely active Crohn's disease, AND
- Patient has had inadequate response to conventional therapy (e.g., corticosteroid, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate), AND
- The prescriber has considered and screened for the presence of latent tuberculosis (TB) infection.

Coverage is provided for **Rheumatoid Arthritis** if:

- Patient has moderately to severely active rheumatoid arthritis, AND
- Patient has experienced a therapeutic failure or inadequate response with methotrexate (MTX), or has a contraindication to methotrexate, OR
- Patient is being treated for rapidly progressive and advancing disease, AND
- The prescriber has considered and screened for the presence of latent tuberculosis (TB) infection.

* Coverage of Cimzia is not provided for use in combination with Kineret®, Orencia®, Remicade®, Enbrel, Simponi®, or Humira.

QUANTITY LIMITATIONS (effective 10/1/11)

The allowed quantity for maintenance doses is two 200 mg injections every 28 days. This corresponds to maintenance doses of 400 mg every 28 days or 200 mg every other week. (Maintenance quantity limits will not take effect until 30 days after initiation of therapy.)

DOSAGE AND ADMINISTRATION:

- For the treatment of **Crohn's Disease**, the recommended initial adult dose of Cimzia is 400 mg (given as two 200 mg subcutaneous injections) initially at week 0, week 2, and week 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.
- For the treatment of **Rheumatoid Arthritis**, 400 mg (given as two 200 mg subcutaneous injections) is given at week 0, week 2, and week 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every four weeks can be considered.

WARNING: RISK OF SERIOUS INFECTIONS

- Increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
- Cimzia should be discontinued if a patient develops a serious infection or sepsis.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Cimzia.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.
- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which Cimzia is a member. Cimzia is not indicated for use in pediatric patients.

WARNINGS AND PRECAUTIONS:

- Serious infections – do not start Cimzia during an active infection. If an infection develops, monitor carefully, and stop Cimzia if infection becomes serious.
- Malignancies – Cases of lymphoma and other malignancies have been observed among patients receiving TNF blockers.
- Anaphylaxis or serious allergic reactions may occur.
- Hepatitis B virus (HBV) reactivation – monitor HBV carriers during and several months after therapy. If reactivation occurs, stop Cimzia and begin anti-viral therapy.
- Demyelinating disease, exacerbation or new onset, may occur.
- Cytopenias, pancytopenia – advise patients to seek immediate medical attention if symptoms develop, and consider stopping Cimzia.
- Heart failure, worsening or new onset, may occur.
- Lupus-like syndrome – stop Cimzia if syndrome develops.

DRUG INTERACTIONS:

- Use with Biological DMARDs – increased risk of serious infections
- Live vaccines – do not give with CIMZIA
- Laboratory tests – may interfere with aPTT tests

REFERENCES:

1. Cimzia (certolizumab pegol). Product information. UCB, Inc. November 2011.
2. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 Recommendations for the Use of Nonbiologic and Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis. *Arthritis & Rheumatism (Arthritis Care & Research)*. 2008; 59(6):762-784.