CIMZIA® UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Disease Modifying Anti-Rheumatic Drug (DMARD)
BRAND NAME:	Cimzia® (certolizumab pegol injection). 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 containing 200 mg certolizumab pegol for reconstitution, 2 vials containing diluent, syringes, needles, and alcohol swabs. (HICL = D6AB)

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.

BENEFIT DESIGN:

Coverage determined through coverage authorization criteria.

COVERAGE AUTHORIZATION CRITERIA:

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, **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.

PROVIDER EDUCATION:

1. Review appropriate method for administration (subcutaneous).
2. Injection site reactions, infection, and abdominal pain are some common adverse effects.
3. UCB Medical Information: 866-822-0068.

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 subcuataneous 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.

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:

- Concurrent administration of anakinra (Kineret) and TNF-blocking agents has been associated with an increased risk of serious infections, an increased risk of neutropenia, and no additional benefit compared to these agents alone.
- Live vaccines should not be given concurrently with Cimzia®. No data are available on the response to vaccinations or the secondary transmission of infection by live vaccines in patients receiving Cimzia®.

REFERENCES:

1. Cimzia (certolizumab pegol). Product Information. UCB, Inc. May 2009.
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 for Rheumatoid Arthritis. Arthritis & Rheumatism (Arthritis Care & Research). 2008; 59(6):762-784.

WARNINGS: RISK OF SERIOUS INFECTIONS

See full prescribing information for complete boxed warning.

- 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.