



## Prior Authorization Approval Criteria

### *Cimzia (certolizumab pegol)*

<b>Generic name:</b>	Certolizumab pegol
<b>Brand name:</b>	Cimzia
<b>Medication class:</b>	TNF-alpha blocker <ul style="list-style-type: none"><li>• Recombinant humanized monoclonal antibody (FAB fragment)</li><li>• Immune suppressant</li></ul>
<b>FDA-approved uses:</b>	Crohn's disease: in patients who are refractory to conventional therapy
<b>Available dosage forms:</b>	Lyophilized powder for reconstitution; subcutaneous administration (200 mg vials)
<b>Usual dose:</b>	Initially 400 mg subcutaneously (2 x 200 mg at different sites) at Weeks 0, 2 and 4, then 400 mg subcutaneously every 4 weeks if clinical response achieved
<b>Approximate yearly cost:</b>	\$23,186.52 (based on AWP 2009) – includes the 3 loading doses within the first month and the once monthly administration thereafter
<b>Duration of therapy:</b>	Indeterminate

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed with Crohn's disease
- Failed/intolerant to at least one corticosteroid.
- Failed/intolerant to at least one of the following:
  - sulfasalazine (Azulfidine)
  - mesalazine (Asacol, Pentasa).
- Failed/intolerant to at least one of the following:
  - azathioprine (Imuran)
  - 6-mercaptopurine (Purinethol)
  - methotrexate.

**Criteria for continuation of therapy:**

- Achievement of clinical response

**Caution:**

- Caution in patients at high risk of infection
- Caution in patients with a past history of TB or in those who are deemed to be at high risk
- Caution in patients who are or may be chronic carriers of hepatitis B virus (HBV)
- Caution in patients with CNS demyelinating disorders
- Caution in patients with congestive heart failure (CHF)
- Patients may be at an increased risk for developing blood dyscrasias
- Patients may be at increased risk of developing malignancies

**Monitoring:**

- Decrease in signs and symptoms of Crohn's disease
- Signs of active infection
  - TB
  - Opportunistic infections
  - Fungal infections
- Congestive heart failure (new onset or worsening of pre-existing condition)
- Hematological abnormalities
- Hypersensitivity reactions
- Adverse effects:
  - Arthralgias (common)
  - Urinary tract infections (common)
  - Upper respiratory infections (common)
  - Other less common but severe ADE's include cardiovascular deterioration, bowel obstruction, lupus erythematosus, seizure, and renal failure/nephrotic syndrome

**Contraindication:**

- Hypersensitivity to Cimzia or any of its active components
- Active infections
- Do not administer live or attenuated vaccines concomitantly with Cimzia

**Not approved if:**

- Patient is treatment naïve to conventional Crohn's therapy
- See below for "special considerations"

**Special considerations:**

- Pregnancy Category B: no controlled studies have been conducted in women; use only if benefit outweighs the risk
- Breast feeding: unclear if excreted in breast milk; best to avoid use or choose to discontinue breast feeding the infant while taking medication
- Pediatrics: safety and efficacy has not been established
- Geriatrics: use with caution in this population as they are at greater risk of infection
- Drug-drug Interactions:
  - Anakinra (increased risk for serious infections)
  - Live and attenuated vaccines

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 03/11/09