



## 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 Rheumatoid arthritis (RA), moderately to severely active
<b>Available dosage forms:</b>	Lyophilized powder for reconstitution; subcutaneous administration (200 mg vials) Prefilled syringe; containing 200mg(1 ml) of Cimzia.
<b>Usual dose:</b>	Crohn's: 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. RA: Initially 400 mg subcutaneously (2 x 200 mg at different sites) at Weeks 0, 2 and 4, followed by 200mg every other week; for maintenance dosing, 400 mg subcutaneously every 4 weeks can be considered.
<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
<b>Criteria for use</b> ( <i>bullet points below are all inclusive unless otherwise noted</i> ):	<ul style="list-style-type: none"><li>• The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.</li><li>• <i>Crohn's Disease/Fistulizing Crohn's disease</i><ul style="list-style-type: none"><li>▪ Clinically diagnosed with Crohn's disease.</li><li>▪ Prescribed by a GI specialist.</li><li>▪ Failed/intolerant to at least one corticosteroid.</li><li>▪ Failed/intolerant to Humira.</li><li>▪ Failed/intolerant to at least one of the following:<ul style="list-style-type: none"><li>• sulfasalazine (Azulfidine)</li><li>• mesalazine (Asacol, Pentasa).</li></ul></li></ul></li><li>• <i>Rheumatoid Arthritis:</i><ul style="list-style-type: none"><li>▪ Prescribed by a rheumatologist</li><li>▪ Clinically diagnosed rheumatoid arthritis.</li><li>▪ Failed/intolerant to Enbrel and Humira.</li><li>▪ Failed/intolerant to at least one of the following:<ul style="list-style-type: none"><li>• azathioprine (Imuran)</li></ul></li></ul></li></ul>

- 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 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:**

- If prefilled syringes are used, and patient self administers Cimzia then it is a pharmacy benefit and must be obtained through CaremarkConnect 1-800-237-2767.
- If the doctor administers Cimzia in his office then it would be a medical benefit and Cimzia must be obtained by MD.
- 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

Revised: 06/09/10, 03/14/12