Certolizumab (Cimzia®) Prefilled Syringe

Policy #: Rx.01.11

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

Certolizumab (Cimzia®) is indicated for reducing the 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. Certolizumab (Cimzia®) is also indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.

The use of certolizumab (Cimzia®) requires prior authorization (i.e., clinical pharmacist and/or Medical Director review).

Description:

Certolizumab (Cimzia®) is a tumor necrosis factor (TNF) blocker. Certolizumab (Cimzia®) selectively neutralizes both membrane associated and soluble human TNFα. TNFα is a key pro-inflammatory cytokine with a central role in inflammatory processes such as Crohn’s disease and Rheumatoid arthritis. At this time no studies are available showing Certolizumab (Cimzia) to have superior efficacy to Enbrel, Humira, or Remicade.

Policy:

Certolizumab (Cimzia) is approved when EITHER of the following inclusion criteria are met:

1. Documentation of a diagnosis of moderately to severely active Crohn’s disease and ALL of the following:
   a. Documentation medication is being recommended by a gastroenterologist
   b. Documentation of age ≥18 years
   c. Documentation of inadequate response or inability to tolerate Adalimumab (Humira)
   d. Patient is not on concurrent therapy with other tumor necrosis factor antagonists

2. Documentation of a diagnosis of moderately to severely active Rheumatoid Arthritis or Active Ankylosing Spondylitis and ALL of the following:
   a. Documentation of age ≥18 years
   b. Medication is being recommended by a rheumatologist
   c. Patient had an inadequate response or inability to tolerate both Humira and Enbrel
d. Patient is not on concurrent therapy with other tumor necrosis factor antagonists

**Black Box Warning:**

Serious infections:
Patients treated with certolizumab are at an increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. Discontinue certolizumab if a patient develops a serious infection or sepsis. Reported infections include the following:
- Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before certolizumab use and during therapy. Initiate treatment for latent infections prior to certolizumab use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral, and other infections caused by opportunistic pathogens, including Legionella and Listeria.

Carefully consider the risks and benefits of treatment with certolizumab prior to initiating therapy in patients with chronic or recurrent infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with certolizumab, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

Malignancy: Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, of which certolizumab is a member. Certolizumab is not indicated for use in children.

**Guidelines:**

Refer to the specific manufacturer’s prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

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<thead>
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<th>Brand name</th>
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<tr>
<td>Cimzia</td>
<td>certolizumab</td>
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**Cross References:**

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<td>P&amp;T Approval Date:</td>
<td>July 11, 2013</td>
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<td>March 01, 2014</td>
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