



Prior Authorization Guidelines

Cimzia® (certolizumab pegol) Pre-filled Syringes

Commercial Coverage: Cimzia® prefilled syringes for self-administration are covered under the prescription drug benefit. Cimzia® lyophilized vials for reconstitution require administration by a healthcare provider and are therefore covered under the medical benefit.

Medicare Coverage: Coverage for Cimzia® is subject to B vs. D determination. Cimzia® prefilled syringes for self-administration will usually be covered under the Med D prescription drug benefit. Cimzia® lyophilized vials for reconstitution require administration by a healthcare provider and should therefore be covered under the medical benefit (Part B).

Criteria for coverage (Commercial and Medicare):

Coverage of Cimzia® will be authorized when the following apply:

1. The patient is under the care of a rheumatologist. **AND**
2. The patient has a diagnosis of rheumatoid arthritis based on the criteria developed by the American College of Rheumatology with disease manifestations (as listed in **Appendix A**) and disease progression despite optimized therapy with the agents listed in **Appendix B. AND**
OR
3. The patient is under the care of a gastroenterologist. **AND**
4. The patient has a diagnosis of moderately to severely active Crohn's disease and has an inadequate response to conventional therapy (**Appendix C**).

To achieve optimal response when Cimzia® is prescribed for the treatment of rheumatoid arthritis, the concurrent use of methotrexate is recommended.

Duration of Authorization:

Coverage of Cimzia® will initially be authorized for 6 months. If continued response is exhibited at 6 months, authorization will be required every 12 months thereafter.

Quantity Limit:

Initial 4 weeks of therapy: 3 boxes containing 2 200mg syringes each

All subsequent therapy: 1 box containing 2 200mg syringes per 30 days.

****Specialty Medication:** A Specialty Pharmacy is the preferred provider of Cimzia. The Authorization Specialist shall attempt to steer requesting provider to Specialty. Upon initial approval or extension of an approval, complete the Specialty Referral form and fax to 877.301.8207. Once received, the Specialty pharmacy will contact the prescriber and member to arrange delivery of the medication.

***Note:** Use of Diplomat Specialty is mandatory for most SummaCare commercial plans. SummaCare Medicare Part D enrollees may choose not to use Diplomat Specialty Pharmacy. Please refer to the BDS prior to authorizing therapy.

Appendix A

Disease Manifestations – Rheumatoid Arthritis
ESR > 28 mm/hr or CRP > 2.0 mg/dl
Greater than 6 inflamed or tender joints

Appendix B

First Line Agents for Rheumatoid Arthritis	
NSAIDs	Ibuprofen, naproxen, etc
COXII inhibitors	Celebrex®
DMARD (trials or treatment failures of at least one)	Plaquenil®, oral/injectable gold salts, methotrexate, azathioprine, d-penicillamine, sulfasalazine, Arava® (leflunomide)

Appendix C

Conventional Therapy for Crohn’s Disease:
Corticosteroids (prednisone)
Anti-inflammatories (mesalamine/5-ASA, sulfasalazine)
Immunosuppressants (mercaptopurine, methotrexate, azathioprine, or cyclosporine)

References:

UCB, Inc. *Prescribing Information for Cimzia*. Smyrna, GA. May 2009