

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 are not covered under the commercial prescription drug benefit. It is covered under the SummaCare medical benefit – please transfer requests for authorization under the SummaCare medical benefit to the Pharmacy Management Department (330-996-8805)

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 must be administered 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
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).

Duration of Authorization:

Initial authorization: 6 months.

Subsequent authorizations: 12 months thereafter.

Quantity Limit (syringes for self-administration):

Initial 4 weeks of therapy: 3 boxes containing 2 200mg syringes each OR 1 Cimzia starter kit

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

****Specialty Medication:** Walgreens Specialty Pharmacy shall be the preferred provider. Authorization Specialist shall attempt to steer requesting provider to Walgreens. Upon initial approval or extension of an approval, complete the Walgreen's Specialty Referral form and fax to 866-617-6685. Once received, Walgreen's Specialty will contact the prescriber and member to arrange delivery of the medication.

***Note:** Use of Walgreen's Specialty is mandatory for most SummaCare commercial plans, but is not required for drugs covered under the Medicare Part D benefit. Please refer to the BDS prior to authorizing therapy.

Appendix A

| Disease Manifestations – Rheumatoid Arthritis |
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| 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: |
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| Corticosteroids (prednisone) |
| Anti-inflammatories (mesalamine/5-ASA, sulfasalazine) |
| Immunosuppressants (mercaptopurine, methotrexate, azathioprine, or cyclosporine) |

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Revised: September 2, 2010
Reviewed:

References:

1. Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc. July 2010.