Policies Repository

Independence Blue Cross

Policy Title	Certolizumab (Cimzia®) Prefilled Syringe
Policy Number	FS.CLIN.74

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy

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 (ie, clinical pharmacy and/or Medical Director review).

Policy 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 diease and Rheumatoid arthritis. At this time no studies are available showing Certolizumab (Cimzia) to have superior efficacy to Enbrel, Humira, or Remicade.

Policy Guideline Inclusion

Crohn's disease
Certolizumab (Cimzia®) is approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of moderately to severely active Crohn's disease
- Documentation medication is being prescribed by a gastroenterologist
- Documentation of age ⩾18 years
- Documentation of a trial and failure to one of the following:
  - Infliximab (Remicade®)
  - One drug from any TWO of the following groups OR contraindication to ALL of the following groups:
    - Corticosteroids: Budesonide (Entocort® EC), Prednisone, Hydrocortisone, Methylprednisolone
    - Aminosalicylates: Sulfasalazine, Mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®), Olsalazine (Dipentum®), Balsalazide (Colazal™)
    - Immunomodulators: Azathioprine, 6-mercaptopurine, Cyclosporine,

Methotrexate
- Antibiotics: Metronidazole or Fluoroquinolones

- Documentation of a trial and failure/contraindication/intolerance/allergy to Adalimumab (Humira)
- Patient is not on concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
- Patient does not have an active infection
- Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis

Rheumatoid Arthritis
Certolizumab (Cimzia®) is approved when all of the following inclusion criteria are met:
- Documentation of a diagnosis of moderately to severely active rheumatoid arthritis
- Documentation of age ⩾18 years
- Medication is being prescribed by a rheumatologist
- Patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
  - Methotrexate
  - Hydroxychloroquine
  - Leflunomide
  - Azathioprine
  - Sulfasalazine
- Documentation of a trial and failure/contraindication/intolerance/allergy to Etanercept (Enbrel)
- Documentation of a trial and failure/contraindication/intolerance/allergy to Adalimumab (Humira)
- Patient is not on concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
- Patient does not have an active infection
- Patient has been evaluated (i.e. tuberculin skin test) and does not have active or latent tuberculosis

Policy Guideline Exclusion

Crohn's disease
Certolizumab (Cimzia) is denied when any of the following exclusion criteria are present:
- No documentation of a diagnosis of moderately to severely active Crohn's disease
- No documentation medication is being prescribed by a gastroenterologist
- Age <18 years
- No documentation of a trial and failure to one of the following:
  - Infliximab (Remicade®)
  - One drug from any TWO of the following groups OR contraindication to ALL of the following groups:
    - Corticosteroids: Budesonide (Entocort® EC), Prednisone, Hydrocortisone, Methylprednisolone
    - Aminosalicylates: Sulfasalazine, Mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®), Olsalazine (Dipentum®), Balsalazide (Colazal™)
    - Immunomodulators: Azathioprine, 6-mercaptopurine, Cyclosporine, Methotrexate
    - Antibiotics: Metronidazole or Fluoroquinolones
- No documentation of a trial and failure/contraindication/intolerance/allergy to Adalimumab (Humira)

- Patient is on concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
- Patient has an active infection
- Patient has not been evaluated (i.e. tuberculin skin test) for tuberculosis or does have active or latent tuberculosis

Rheumatoid Arthritis
Certolizumab (Cimzia) is denied when any of the following exclusion criteria are present:

- No documentation of a diagnosis of moderately to severely active rheumatoid arthritis
- Age <18 years
- No documentation medication is being prescribed by a rheumatologist
- No documentation patient had at least a 30 day trial and failure with ONE of the following disease-modifying anti-rheumatic drugs (DMARDs) OR contraindication to ALL of the following DMARDs:
    - Methotrexate
    - Hydroxychloroquine
    - Leflunomide
    - Azathioprine
    - Sulfasalazine
- No documentation of a trial and failure/contraindication/intolerance/allergy to Etanercept (Enbrel)
- No documentation of a trial and failure/contraindication/intolerance/allergy to Adalimumab (Humira)
- Patient is on concurrent therapy with biological DMARDs or other tumor necrosis factor antagonists
- Patient has an active infection
- Patient has not been evaluated (i.e. tuberculin skin test) for tuberculosis or does have active or latent tuberculosis

Policy List of Applicable Drugs

Brand Name	Generic Name
Cimzia	Certolizumab

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

American Gastroenterological Association Institute Medical Position Statement on Corticosteroids, Immunomodulators and Infliximab in Inflammatory Bowel Disease. Gastroenterology. 2006; 130:935-939.

Cimzia [package insert]. Smyrna; GA: UCB Inc. 2009.

Facts and Comparisons website [Cimzia]. Available at www.factsandcomparisons.com. Accessed June 11, 2009.

Knutson D, Greenberg G, Cronau H, et al. Management of Crohn's Disease a practical approach. American Family Physician. 2003:68:707-713.

Micromedex website [Cimzia]. Available at www.micromedex.com. Accessed June 11, 2009.

Policy Link to Related Policies

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