



## Certolizumab Pegol

### DESCRIPTION

Certolizumab pegol, a tumor necrosis factor (TNF) inhibitor, binds and selectively neutralizes TNF- $\alpha$ . TNF- $\alpha$  is a pro-inflammatory cytokine that plays a key role in the inflammatory process by stimulating the production of downstream inflammatory mediators, such as interleukin-1, prostaglandins, platelet activating factor, and nitric oxide.

An example of a preparation of certolizumab pegol is (Cimzia<sup>®</sup>)

### REFER TO DECISION SUPPORT TREE

### POLICY

- Certolizumab pegol for the treatment of Crohn's disease is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Certolizumab pegol for the treatment of rheumatoid arthritis is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Certolizumab pegol for the treatment of other conditions/diseases is considered **investigational**.

### MEDICAL APPROPRIATENESS

- Certolizumab pegol is considered **medically appropriate** for **ANY ONE** of the following conditions:
  - Crohn's disease with **ALL** of the following:
    - The individual is 18 years of age or older
    - Has moderately to severely active disease
    - Has had an inadequate response to conventional therapy (e.g., 5-aminosalicylates [e.g., Asacol, Pentasa, Salofalk, Dipentum], or immunosuppressive drugs [e.g., azathioprine and 6-mercaptopurine], or corticosteroids)
  - Rheumatoid arthritis with **ALL** of the following:
    - The individual is 18 years of age or older
    - Has moderately to severely active rheumatoid arthritis
    - The agent is used as monotherapy or in combination with methotrexate

### APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

### ADDITIONAL INFORMATION



For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

No controlled studies were found in the published literature that validate the use of certolizumab pegol for the treatment of other conditions/diseases.

## SOURCES

Drugs for rheumatoid arthritis. (2009, May). *Treatment Guidelines from The Medical Letter*, 7 (Issue 81), 1-15.

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U. S. Food and Drug Administration. (2009, May). Center for Drug Evaluation and Research. FDA Approval Letter. *BL 125271/0*. Retrieved June 18, 2009 from [http://www.accessdata.fda.gov/drugsatfda\\_docs/appltr/2009/125271s000ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appltr/2009/125271s000ltr.pdf).

U. S. Food and Drug Administration. (2009, May). Center for Drug Evaluation and Research. *Cimzia (certolizumab pegol)*. Retrieved June 18, 2009 from [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/125271s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/125271s000lbl.pdf).

**EFFECTIVE DATE**      12/12/2009

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**BlueCross BlueShield  
of Tennessee**

## Pharmaceutical Decision Support Tree

### **Certolizumab Pegol (Cimzia®)**

1. Does the individual have a diagnosis of Crohn's disease and **ALL** of the following?
  - The individual is 18 years of age or older
  - Has moderately to severely active Crohn's disease
  - Has had an inadequate response to conventional therapy (e.g., 5-aminosalicylates [e.g., Asacol, Pentasa, Salofalk, Dipentum], or immunosuppressive drugs [e.g., azathioprine and 6-mercaptopurine], or corticosteroids)

If yes, this does not meet medical necessity and/or medical appropriateness criteria  
If no, go to question #2

2. Does the individual have a diagnosis of rheumatoid arthritis and **ALL** of the following?
  - The individual is 18 years of age or older
  - Has moderately to severely active rheumatoid arthritis
  - The agent is used as monotherapy or in combination with methotrexate

If yes, this satisfies medical necessity and medical appropriateness criteria  
If no, this does not meet medical necessity and/or medical appropriateness criteria