



Certolizumab pegol (Cimzia)

Policy Number: M-0024

Revision: 1

Last Update: 3/19/2013

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

FDA:

- 1. Crohn's disease
- 2. Rheumatoid arthritis, moderately to severe

Off-Label

- 1. Psoriasis

Coding Information:

HCPCS Code(s)

J0718	INJECTION CERTOLIZUMAB PEGOL, 1 MG
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ICD-9 Code(s)

555.0-555.2	REGIONAL ENTERITIS OF SMALL INTESTINE - REGIONAL ENTERITIS OF SMALL INTESTINE WITH LARGE INTESTINE
555.9	REGIONAL ENTERITIS OF UNSPECIFIED SITE
696.0	PSORIATIC ARTHROPATHY
696.1	OTHER PSORIASIS AND SIMILAR DISORDERS
714.0	RHEUMATOID ARTHRITIS
714.1	FELTY'S SYNDROME
714.2	OTHER RHEUMATOID ARTHRITIS WITH VISCERAL OR SYSTEMIC INVOLVEMENT
714.30-714.33	CHRONIC OR UNSPECIFIED POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS - MONOARTICULAR JUVENILE RHEUMATOID ARTHRITIS
714.4	CHRONIC POSTRHEUMATIC ARTHROPATHY
714.81	RHEUMATOID LUNG

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714.9	UNSPECIFIED INFLAMMATORY POLYARTHROPATHY
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Background:

Certolizumab pegol (CDP-870, Cimzia) is a unique anti-TNF biologic that contains a Fab fragment of a humanized antibody that is a potent neutralizer of TNF-alpha. Certolizumab is chemically attached to polyethylene glycol (PEG, Pegylated) and is administered subcutaneously every 2—4 weeks. Certolizumab is indicated for the treatment of moderately to severely active rheumatoid arthritis and for reducing the signs and symptoms of Crohn's disease and maintaining clinical response in adults with moderately to severely active disease who have had an inadequate response to conventional therapy. Certolizumab was FDA approved for Crohn's disease in April 2008 and for rheumatoid arthritis in May 2009.

Black Box Warning:**SERIOUS INFECTIONS**

Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death [see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. CIMZIA should be discontinued if a patient develops a serious infection or sepsis.

Reported infections include:

-Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before CIMZIA use and during therapy. Treatment for latent infection should be initiated prior to CIMZIA use.

-Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. 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. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.

-Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with CIMZIA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

1. Cimzia Package insert available at <http://www.cimzia.com/cimzia-medication-guide-prescribing-information.aspx>. Accessed July 19, 2012.
2. Clinical Pharmacology Website available at <http://clinicalpharmacology-ip.com.ezproxy.samford.edu/Forms/Monograph/monograph.aspx?cpnum=3473&sec=mondsc>. Accessed July 19, 2012.



3. Micromedex website available at http://www.thomsonhc.com.ezproxy.samford.edu/micromedex2/librarian/ND_T/evidencexpert/ND_PR/evidencexpert/CS/8982CE/ND_AppProduct/evidencexpert/DUPLICATIONSHIELDSYNC/A40C8E/ND_PG/evidencexpert/ND_B/evidencexpert/ND_P/evidencexpert/PFActionI/evidencexpert.DisplayDrugpointDocument?docId=929020&contentSetId=100&title=Certolizumab+Pegol&servicesTitle=Certolizumab+Pegol&topicId=blackBoxWarningSection&subtopicId=null. Accessed July 19, 2012.

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