MEDICAL POLICY STATEMENT		
Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/15/2011	**06/15/2012**	**06/15/2011**
Author		
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CareSource

CSMG Medical Policy Statements are derived from literature based and supported clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services are those health care services or supplies which are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative and are not provided mainly for the convenience of the member or provider.

A. SUBJECT

Certolizumab pegol (Cimzia) Injection

B. BACKGROUND

Certolizumab pegol (Cimzia) is a TNF blocker. Biological activities ascribed to TNFα include the upregulation of cellular adhesion molecules and chemokines, upregulation of major histocompatibility complex (MHC) class I and class II molecules, and direct leukocyte activation. TNFα stimulates the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide. Elevated levels of TNFα have been implicated in the pathology of Crohn's disease and rheumatoid arthritis. certolizumab pegol (Cimzia) binds to TNFα, inhibiting its role as a key mediator of inflammation. After treatment with certolizumab pegol (Cimzia), patients with Crohn's disease demonstrated a decrease in the levels of C-reactive protein (CRP). Increased TNFα levels are found in the synovial fluid of rheumatoid arthritis patients and play an important role in the joint destruction that is a hallmark of this disease.

The patient selection criteria outlined was derived from the FDA-approved prescribing information for certolizumab pegol (Cimzia), the studies that were presented to the FDA in support of the pre-market approval application, and studies in the peer-reviewed published medical literature. The FDA label indications found in the manufacturer prescribing information and described below are rheumatoid arthritis and Crohn's disease. Coverage decisions for conditions other than the above FDA approved indications will be reviewed on a case-by-case basis if proven effective through research documentation. The requesting provider will need to support his exception request with the appropriate literature.

C. POLICY

CareSource will approve the use of certolizumab pegol (Cimzia), and consider its use as medically necessary when the following criteria have been met for:

- Rheumatoid arthritis
- Crohn's disease

All other uses of certolizumab pegol (Cimzia) are considered experimental/ Investigational, and therefore, not covered.

Crohn's Disease

Certolizumab pegol (Cimzia) is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients (18 years or older) with moderate to severe active disease who have had an inadequate response to conventional therapy.

Prior Authorization Criteria:

- Documented diagnosis of active Crohn's Disease
- Prescribed by a gastroenterologist or under the recommendations of a gastroenterologist
- Failure of at least one of the conventional therapies after a trial:
    - 5-ASA products (e.g., mesalamine (Asacol, Pentasa), sulfasalazine (Azilfidine)
    - methotrexate (e.g., Rheumatrex)
    - Systemic corticosteroids (e.g., budesonide (Entocort)
    - Immunosuppressants (e.g., 6-mercaptopurine (Purinethol)
    - Azathioprine (Imuran), or cyclosporine (Neoral, Sandimmune, Gengraf)

      OR
    - Unable to tolerate or has a medical contraindication of conventional therapies

Rheumatoid Arthritis

Certolizumab pegol (Cimzia) is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderate to severe active rheumatoid arthritis who have had a documented inadequate response or inability to tolerate the DMARD (disease-modifying anti-inflammatory drugs).

Prior Authorization Criteria:

- Documented diagnosis of moderate to severe active rheumatoid arthritis
- Prescribed by a rheumatologist or under the recommendations of a rheumatologist
- Failure of a trial of one non-biological DMARD in combination with methotrexate (In the event the member has contraindications or intolerance to methotrexate, the member must have failed to respond to other DMARDs)

  OR
    - Unable to tolerate or has a medical contraindication of conventional therapies

Note: Documented diagnosis must be confirmed by portions of the individual's medical record, which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

Safety

CareSource will only review requests for **certolizumab pegol (Cimzia)** if the patient has **none** of the following contraindications:

- Patient has Tuberculosis (active, untreated or reactivation of latent TB), or contact with person with active TB or traveled to countries with high incidence of TB, or other active

serious infections, or a history of recurrent infections including invasive fungal infections, bacterial, viral and other infections caused by opportunistic pathogens, or has other respiratory disorders including Chronic Obstructive Pulmonary Disease (COPD)
- Patient has not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis
- Patient is not up to date with all immunizations in agreement with current immunization guidelines prior to initiating the therapy (patient may not be given live vaccines concurrently with infliximab (Remicade), and the interval between vaccination and initiation of infliximab (Remicade) therapy must in accordance with current vaccination guidelines)
- Patient is going to have concurrent use with tumor necrosis factor antagonists or anakinra (Kineret)
- Patient has a diagnosis of Lymphoma and other malignancies
- Patient has a diagnosis of demyelinating disorders
- Patient currently receiving antineoplastic, immunosuppressant or immunomodulating agents
- Patient has diagnosis of congestive heart failure (CHF)

Pregnancy Risk Factor = B
Certolizumab pegol (Cimzia) has been assigned to pregnancy category B by the FDA. According to category B, Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women. Certolizumab pegol (Cimzia) should only be given during pregnancy when benefit outweighs risk.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from certolizumab pegol (Cimzia), a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

For Special Needs Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

For Medicare

NCD for certolizumab (Cimzia)

Medicare does not have a National Coverage Determination (NCD) for certolizumab pegol (Cimzia). In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, section 50 Drugs and Biologicals at:

http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf

Local Coverage Determinations (LCDs) for certolizumab pegol (Cimzia) do not exist at this time. (Accessed February 14, 2011)

Conditions of Coverage

Quantity Limitations	The monthly quantity will be approved initially for 400 mg (2 X 200mg) at weeks 0, 2 and 4 and then 400 mg (2 X 200mg) once a month thereafter based on appropriate clinical response.
J-Code	J0718
NDC	50474070062 50474071079 50474071081
Applicable ICD-9 Codes	555.0-555.9 Crohn's Disease 714.0-714.33 Rheumatoid Arthritis
Place Of Service	Office, Outpatient, Home *****Preferred place of service is in the home*.** **Note:** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost-effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.
Authorization Period	Approved initial authorizations are valid for 3 months. Continued treatment may be considered when the member has shown biological response to treatment. All authorizations are subject to continued eligibility.

D. REVIEW / REVISION HISTORY

6/15/2011

E. REFERENCES

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Maltz, BE., and Schwartz, DA., *Biologic therapy for crohn's disease: Selecting the right patient*. Medscape Gastroenterology 2008. http://medscape.org/ (February 8, 2011)

Hanauer, SB. and Sandborn, W. Practice Guidelines: *Management of crohn's disease in adults*. The American Journal of Gastroenterology 2001: 96:3

Agency for Healthcare Research and Quality (AHRQ). *Comparative effectiveness of pharmacologic therapies for the management of crohn's disease.* www.effectivehealthcare.ahrq.gov 2010, Sept. (February 8, 2011)

Winifred S. Hayes, Inc. *Infliximab for Rheumatoid Arthritis*. www.hayesinc.com Published: April 29, 2004 (February 8, 2011)

Saag, KG., et al. American College of Rheumatology 2008 *recommendations for the use of nonbiological and biological disease-modifying antirheumatic drugs in rheumatoid arthritis*. Arthritis & Rheumatology (Arthritis Care & Research), 59:6, 2008, June 15.

Wolters Kluwer. Facts & Comparisons. www.factsandcomparisons.com, 2011. (February 15, 2011)

U.S. Food and Drug Administration Information for Healthcare Professionals: Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Enbrel, Humira, Cimzia, and Simponi). http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124185.htm.

Accessed February 25, 2011.

American College of Gastroenterology Practice Guidelines: Management of Crohn's Disease in Adults. *Am J Gastroenterology*. January 2009:1-19.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

June 6, 2011

Chief Medical Officer **Date**

June 6, 2011

Senior Medical Director **Date**