

## Corporate Medical Policy

### Cimzia (Certolizumab Pegol)

<b>File Name:</b>	cimzia_certolizumab_pegol
<b>Origination:</b>	2/2018
<b>Last CAP Review:</b>	2/2019
<b>Next CAP Review:</b>	2/2020
<b>Last Review:</b>	6/2019

#### Description of Procedure or Service

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Tumor necrosis factor (TNF) is a cytokine produced by macrophages and T cells. Its name is based on the original observations 25 years ago that TNF killed tumor cells in vitro. Further research has revealed that TNF has a broad spectrum of biologic activities; in particular, it is a key mediator of inflammation and is produced in response to infection and immunologic injury.

Certolizumab pegol (Cimzia<sup>®</sup>) is a tumor necrosis factor (TNF) blocker indicated for reducing 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, and for treatment of adults with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, and moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. In addition, certolizumab pegol is indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

#### Policy

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**BCBSNC will provide coverage for certolizumab pegol (Cimzia) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy. This medical policy applies to products managed through the member's medical benefit and administered by a provider. Please refer to the member's pharmacy benefit for products with self-injector delivery mechanisms.

#### When Cimzia is covered

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Cimzia (certolizumab pegol) for subcutaneous injection may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient is not using Cimzia in combination with another biologic agent; **AND**

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- a. The patient is diagnosed with moderately to severely active rheumatoid arthritis; **AND**
  - i. The patient has tried and failed or has a clinical contraindication/intolerance to methotrexate (MTX) therapy; **OR**
- b. The patient is diagnosed with active psoriatic arthritis; **AND**
  - i. The patient has tried and failed or has a clinical contraindication/intolerance to conventional therapy (e.g., MTX, leflunomide, sulfasalazine); **OR**
- c. The patient is diagnosed with moderately to severely active Crohn's disease; **AND**
  - i. The patient has tried and failed or has a clinical contraindication/intolerance to conventional therapy (e.g., corticosteroids, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate); **OR**
- d. The patient is diagnosed with active ankylosing spondylitis; **OR**
- e. The patient is diagnosed with moderate-to-severe plaque psoriasis; **AND**
  - i. The patient is being managed by a dermatologist; **AND**
  - ii. The patient has Body Surface Area (BSA) involvement of at least 5% or the patient has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment; **AND**
  - iii. The patient has tried and failed conventional therapy (e.g., MTX, acitretin, cyclosporine, methoxsalen); **OR**
  - iv. The patient has tried and failed phototherapy; **OR**
  - v. The patient has a clinical contraindication/intolerance to BOTH conventional therapy and phototherapy; **OR**
- f. The patient is diagnosed with active non-radiographic axial spondyloarthritis; **AND**
  - i. The diagnosis was adult onset and the patient has had persistent disease for at least 12 months; **AND**
  - ii. There are the following objective signs of inflammation:
    - a) The patient has elevated CRP (C-reactive protein) levels above the upper limit of normal; **and**
    - b) The patient has had magnetic resonance imaging (MRI) performed that indicates the presence of sacroiliitis; **AND**
  - iii. The patient does not have radiographic evidence of structural damage on the sacroiliac joints; **AND**
  - iv. The patient has tried and failed or has a clinical contraindication/intolerance to conventional therapy (e.g., NSAIDs, DMARDs, corticosteroids) with trial and failure of at least two NSAIDs; **AND**

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- v. Continued approval is contingent upon a documented improvement in inflammatory disease through improvements in CRP levels and/or sacroiliitis; **AND**
- vi. Authorization is for 365 days.

### When Cimzia is not covered

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Certolizumab pegol (Cimzia) is considered **investigational** and therefore not covered when the criteria listed above are not met.

### Policy Guidelines

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The prescribing information for Cimzia does not list any contraindications; however, there are several warnings and precautions.

- Serious infections – do not start Cimzia during an active infection. If an infection develops, monitor carefully, and stop Cimzia if infection becomes serious
- Invasive fungal infections – for patients who develop a systemic illness on Cimzia, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic
- Cases of lymphoma and other malignancies have been observed among patients receiving TNF blockers
- Heart failure, worsening or new onset may occur
- Anaphylaxis or serious allergic reactions may occur
- Hepatitis B virus (HBV) reactivation – test for HBV infection before starting Cimzia. Monitor HBV carriers during and several months after therapy. If reactivation occurs, stop Cimzia and begin anti-viral therapy
- Demyelinating disease, exacerbation or new onset, may occur
- Cytopenias, pancytopenia – advise patients to seek immediate medical attention if symptoms develop, and consider stopping Cimzia
- Lupus-like syndrome – stop Cimzia if syndrome develops

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes:*

*J0717 – Injection, certolizumab pegol, 1 mg (code may be used when drug administered under the direct supervision of a physician, not for use when drug is self-administered)*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Scientific Background and Reference Sources

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# Cimzia (Certolizumab Pegol)

U.S. Food and Drug Administration. Cimzia (certolizumab pegol) injection, for subcutaneous use, prescribing information. Available at:

[https://www.cimzia.com/sites/default/files/docs/Prescribing\\_Information.pdf](https://www.cimzia.com/sites/default/files/docs/Prescribing_Information.pdf)

Cimzia Official Site: <http://www.cimziahcp.com/>

UCB, Inc. Cimzia (certolizumab pegol) injection for subcutaneous use. Highlights of prescribing information. June 2018. Available at:

[https://www.cimzia.com/sites/default/files/docs/CIMZIA\\_full\\_prescribing\\_information.pdf](https://www.cimzia.com/sites/default/files/docs/CIMZIA_full_prescribing_information.pdf).

Accessed January 2019.

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UCB, Inc. Cimzia (certolizumab pegol) injection for subcutaneous use. Highlights of prescribing information. March 2019. Available at:

[https://www.cimzia.com/sites/default/files/docs/CIMZIA\\_full\\_prescribing\\_information.pdf](https://www.cimzia.com/sites/default/files/docs/CIMZIA_full_prescribing_information.pdf).

Accessed May 2019.

Medical Director review 6/2019

## Policy Implementation/Update Information

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| 4/1/18  | New policy developed. Cimzia (certolizumab pegol) for subcutaneous injection may be considered medically necessary for adult patients to reduce signs and symptoms of Crohn's disease and to maintain clinical response in adults with moderately to severely active disease who have had inadequate response to conventional therapy; for treatment of adults with moderately to severely active rheumatoid arthritis, active psoriatic arthritis or active ankylosing spondylitis. <b>Notification given 4/1/18 for policy effective date 7/1/18.</b> (an) |
| 6/29/18 | Added code description for J0717. Updated "Benefits Application" section for clarity. (krc)  |
| 3/12/19 | Updated Description section and Policy Statement with indication of Cimzia (certolizumab pegol) for moderate-to-severe plaque psoriasis. Minor typographical edits made throughout policy for clarity. References added. Specialty Matched Consultant Advisory Panel review 2/20/2019. (krc)   |
| 6/11/19 | Updated Description section and Policy Statement with indication of Cimzia (certolizumab pegol) for active <u>non-radiographic axial spondyloarthritis</u> with objective signs of inflammation. References added. Medical Director review 6/2019. (krc)   |

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.