

Policy: MBP 74.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Cimzia (certolizumab pegol)

I. Policy:

Cimzia (certolizumab pegol)

II. Purpose/Objective:

To provide a policy of coverage regarding Cimzia (certolizumab pegol)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Cimzia (certolizumab pegol) is a tumor necrosis factor alpha (TNF α) inhibitor PEGylated humanized Fab fragment of an anti-tumor necrosis factor – α monoclonal antibody. It binds with high affinity to both membrane-bound and soluble TNF α and demonstrated neutralizing of cytokines.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Cimzia (certolizumab pegol) will be considered medically necessary for the commercial, exchange and CHIP lines of business when all of the following criteria are met:

1. Crohn's disease:

- Physician documentation for a diagnosis of moderate to severe Crohn's disease **AND**
- Prescription written by a gastroenterologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Humira* (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of Crohn's disease at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Cimzia therapy.

2. Rheumatoid Arthritis

- Physician documentation for a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis); **AND**
- Prescription written by a rheumatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira*, Rinvoq*, OR Xeljanz* (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of rheumatoid arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid while on Cimzia therapy.

3. Psoriatic Arthritis

- Must be ordered by a rheumatologist or dermatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Physician documentation for a diagnosis of active psoriatic arthritis as evidenced by:
 - Documentation of either active psoriatic lesions or a history of psoriasis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Cimzia therapy.

4. Ankylosing Spondylitis

- Must be ordered by a rheumatologist; **AND**
- Insured individual is 18 years of age or older; **AND**
- Physician documentation of a diagnosis of ankylosing spondylitis; **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Cosentyx* (*requires prior authorization)

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ankylosing spondylitis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on Cimzia therapy.

5. Plaque Psoriasis

- Prescription written by a dermatologist **AND**
- Medical record documentation of age greater than 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure of, contraindication to, or intolerance of a minimum 3-month trial of Humira* **AND** Cosentyx*

QUANTITY LIMIT (FOR PLAQUE PSORIASIS ONLY): 2 kits per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Cimzia therapy.

6. Non-radiographic Axial Spondylarthritis

- Medical record documentation that Cimzia is written by a rheumatologist **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
 - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
 - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent.

Quantity Limit: One-week authorization for QL of 3 kits per 28 days; Remainder of the 6-month authorization duration: QL of 1 kit per 28 days

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of non-radiographic axial spondylarthritis on six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of non-radiographic axial spondylarthritis while on Cimzia therapy.

Cimzia (certolizumab pegol) will be considered medically necessary for Medicare line of business when all of the following criteria are met:

1. Crohn's disease:

- Physician documentation for a diagnosis of moderate to severe Crohn's disease **AND**
- Prescription written by a gastroenterologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of Crohn's disease at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Cimzia therapy.

2. Rheumatoid Arthritis

- Physician documentation for a diagnosis of moderate to severe rheumatoid arthritis (made in accordance with the American College of Rheumatology Criteria for the Classification of Diagnosis of Rheumatoid Arthritis); **AND**
- Prescription written by a rheumatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of rheumatoid arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid while on Cimzia therapy.

3. Psoriatic Arthritis

- Must be ordered by a rheumatologist or dermatologist **AND**
- Insured individual is 18 years of age or older **AND**
- Physician documentation for a diagnosis of active psoriatic arthritis as evidenced by:
 - Documentation of either active psoriatic lesions or a history of psoriasis **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of psoriatic arthritis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year.

Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Cimzia therapy.

4. Ankylosing Spondylitis

- Must be ordered by a rheumatologist; **AND**
- Insured individual is 18 years of age or older; **AND**
- Physician documentation of a diagnosis of ankylosing spondylitis; **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent

QUANTITY LIMIT:

New starts: One-week authorization for QL of 3 kits per 28 days, Remainder of the 6-month authorization duration QL of 1 kit per 28 days

Continued maintenance: QL of 1 kit per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ankylosing spondylitis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on Cimzia therapy.

5. Plaque Psoriasis

- Prescription written by a dermatologist **AND**
- Medical record documentation of age greater than 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent

QUANTITY LIMIT (FOR PLAQUE PSORIASIS ONLY): 2 kits per 28 days

Note: This product is billed per kit. Each kit contains two 200mg syringes.

AUTHORIZATION DURATION:

Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of plaque psoriasis at six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of plaque psoriasis while on Cimzia therapy.

6. Non-radiographic Axial Spondylarthritis

- Medical record documentation that Cimzia is written by a rheumatologist **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of at least one of the following:
 - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
 - Sacroiliitis on magnetic resonance imaging (MRI)

AND

- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cimzia is not being used concurrently with a TNF blocker or other biologic agent.

Quantity Limit: One-week authorization for QL of 3 kits per 28 days; Remainder of the 6-month authorization duration: QL of 1 kit per 28 days

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of non-radiographic axial spondylarthritis on six (6) months of Cimzia therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of non-radiographic axial spondylarthritis while on Cimzia therapy.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Cimzia [prescribing information]. Smyrna, GA: UCB Inc; December 2022.
2. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. American College of Rheumatology (ACR). Arthritis & Rheumatology; 2019 October; 71(10):1599-1613 [cited 2023 Dec 27]. Available from: <https://rheumatology.org/axial-spondyloarthritis-guideline>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/13/10

Revised: 11/11(indications clarified); 2/12 (PA timeframe added); 3/14 (added indications); 8/14; 11/18/14; 12/31/14 (formulary alternatives criteria for each indication updated), 09/15/15 (removed joint counts), 3/20/18 (form alt, QL, duplicate therapy), 4/24/18 (per DHS, grandfather), 9/18/18 (RA form alt), 11/20/18 (plaque psoriasis), 9/17/19 (Non-radiographic axial spondylarthritis), 1/21/20 (RA form alt), 1/17/23 (LOB carve out), 12/31/23 (references added), 1/9/24 (Medicaid business segment)

Reviewed: 11/18/14, 9/28/16, 7/31/17, 1/19/21, 1/17/22

MA UM Committee approval: 12/31/23