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## DRUG POLICY

# Cimzia (certolizumab pegol)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Cimzia drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Humira, Enbrel, Cosentyx, Xeljanz/Xeljanz XR, Otezla and Stelara are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product.. The criteria will require the use of two of the health plan's preferred products for before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, or the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indications

1. 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.
2. Treatment of adults with moderately to severely active rheumatoid arthritis.
3. Treatment of adult patients with active psoriatic arthritis.
4. Treatment of adults with active ankylosing spondylitis.
5. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
6. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

**POLICY**

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

**A) Ankylosing Spondylitis**

1. Criteria for initial approval for ankylosing spondylitis will only apply when at least ONE of the following criteria are met:
  - a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Enbrel and Cosentyx)
  - b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome
  - c) The member is currently pregnant or breastfeeding

**B) Psoriatic arthritis**

1. Criteria for initial approval for psoriatic arthritis will only apply when at least ONE of the following criteria are met:
  - a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Cosentyx, Enbrel, Humira, Otezla and Stelara)
  - b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome
  - c) The member is currently pregnant or breastfeeding

**C) Rheumatoid Arthritis**

1. Criteria for initial approval for rheumatoid arthritis will only apply when at least ONE of the following criteria are met:
  - a) Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Enbrel and Xeljanz/Xeljanz XR)
  - b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome
  - c) The member is currently pregnant or breastfeeding

**D) Crohn's Disease**

1. Criteria for initial approval for Crohn's disease will only apply when at least ONE of the following criteria are met:
  - a) Member has had an inadequate response to treatment or intolerable adverse event with BOTH of the preferred products (Humira and Stelara)
  - b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome
  - c) The member is currently pregnant or breastfeeding

**E) Plaque Psoriasis**

1. Criteria for initial approval on moderate to severe plaque psoriasis will only apply when at least ONE of the following criteria are met:

- a. Member has had an inadequate response to treatment or intolerable adverse event with at least TWO of the preferred products (Humira, Enbrel, Cosentyx, Otezla, and Stelara)
- b. Member is currently receiving treatment with requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome
- c. The member is currently pregnant or breastfeeding

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

#### Criteria for Initial Approval

##### **A) Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 12 months may be granted for members who have previously received a biologic or targeted synthetic DMARD (e.g., Rinvog, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when either of the following criteria is met:
  - a. Member has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week).
  - b. Member has an intolerance or contraindication to methotrexate (see Appendix A).

##### **B) Active psoriatic arthritis (PsA)**

1. Authorization of 12 months may be granted for treatment of active psoriatic arthritis (PsA).

##### **C) Active ankylosing spondylitis (AS) and axial spondyloarthritis**

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for active ankylosing spondylitis or axial spondyloarthritis.
2. Authorization of 12 months may be granted for treatment of active ankylosing spondylitis or axial spondyloarthritis when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
  - b. Member has an intolerance or contraindication to two or more NSAIDs.

##### **D) Moderately to severely active Crohn's disease (CD)**

1. Authorization of 12 months may be granted for members who have previously received a biologic indicated for the treatment of Crohn's disease.
2. Authorization of 12 months may be granted for the treatment of moderately to severely active CD in members who had an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix B).
3. Authorization of 12 months may be granted for the treatment of fistulizing CD.

##### **E) Moderate to severe plaque psoriasis (PsO)**

1. Authorization of 12 months may be granted for members who have previously received Otezla or a biologic indicated for the treatment of moderate to severe plaque psoriasis.
2. Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:
  - a. At least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - b. Member meets any of the following criteria:
    - i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or a pharmacologic treatment with methotrexate, cyclosporine or acitretin.

- ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (See Appendix C).
- iii. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy (i.e. at least 10% of the body surface area (BSA) or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected).

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who are using Cimzia for an indication outlined in the Criteria for Initial Approval and who achieve or maintain positive clinical response with Cimzia as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)\* within 6 months of initiating therapy for persons who are naïve to biologic DMARDs or targeted synthetic DMARDs (e.g., Xeljanz), and repeated yearly for members with risk factors\*\* for TB that are continuing therapy with biologics.

\* If the screening testing for TB is positive, there must be documentation of further testing to confirm there is no active disease. Do not administer certolizumab to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of certolizumab.

\*\* Risk factors for TB include: Persons with close contact to people with infectious TB disease; persons who have recently immigrated from areas of the world with high rates of TB (e.g., Africa, Asia, Eastern Europe, Latin America, Russia); children less than 5 years of age who have a positive TB test; groups with high rates of TB transmission (e.g., homeless persons, injection drug users, persons with HIV infection); persons who work or reside with people who are at an increased risk for active TB (e.g., hospitals, long-term care facilities, correctional facilities, homeless shelters).

For all indications: Member cannot use Cimzia concomitantly with any other biologic DMARD or targeted synthetic DMARD.

Cimzia is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**Quantity Limits Apply**

Trade Name	Generic Name	Quantity Limit
Cimzia®	Certolizumab pegol	Initiation of therapy: 3 maintenance kits (6 syringes/vials) (or 1 starter kit) per first 28days  Maintenance for Plaque Psoriasis: 2 kits ( 4 x 200mg vials/syringes) per 28 days

Trade Name	Generic Name	Quantity Limit
		Maintenance for all other indications: 1 kit (2 x 200mg vials/syringes) per 28 days

## APPENDIX

### Appendix A: Examples of Contraindications to Methotrexate

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or currently planning pregnancy
10. Renal impairment
11. Significant drug interaction

### Appendix B: Examples of Conventional Therapy Options for CD

1. Mild to moderate disease – induction of remission:
  - a). Oral budesonide
  - b). Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
  - a). Azathioprine, mercaptopurine
  - b). Alternatives: oral budesonide, methotrexate intramuscularly (IM) or subcutaneously (SC), sulfasalazine
3. Moderate to severe disease – induction of remission:
  - a). Prednisone, methylprednisolone intravenously (IV)
  - b). Alternatives: methotrexate IM or SC
4. Moderate to severe disease – maintenance of remission:
  - a). Azathioprine, mercaptopurine
  - b). Alternative: methotrexate IM or SC
5. Perianal and fistulizing disease – induction of remission:
  - a). Metronidazole ± ciprofloxacin, tacrolimus
6. Perianal and fistulizing disease – maintenance of remission:
  - a). Azathioprine, mercaptopurine
  - b). Alternative: methotrexate IM or SC

### Appendix C: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction with traditional systemic agent
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

## PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

## REFERENCES

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\*Some content reprinted from CVSHealth

## POLICY HISTORY

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