**RX.PA.092.CCH CIMZIA (CERTOLIZUMAB PEGOL)**

The purpose of this policy is to define the prior authorization process for Cimzia (certolizumab pegol) 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.
- Treatment of adults with moderately to severely active rheumatoid arthritis.
- Treatment of adult patients with active psoriatic arthritis.
- Treatment of adults with active ankylosing spondylitis.
- Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
- Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

**POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Cimzia (certolizumab pegol), is subject to the prior authorization process.

**PROCEDURE**

**Initial Authorization Criteria:**

*Must meet all the criteria listed under the respective diagnosis:*

**For all diagnoses:**

- Must have a negative tuberculosis skin test [such as Tuberculin PPD (purified protein derivative) test] or Interferon-Gamma Release Assay (IGRA) whole-blood test [such as QuantiFERON®-TB Gold In-Tube test (QFT-GIT) or T-SPOT®.*TB* test (T-Spot)]
- Must currently not be using a biologic drug or targeted synthetic drug in combination with the requested product
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling

## 1. Rheumatoid arthritis (RA)

- Must be 18 years of age or older
- Must have documentation of moderately-to-severely active RA
- Must be prescribed by, or in consultation with, a rheumatologist
- Must meet all criteria in either A. OR B.:
  - **A.** Has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis **OR**
  - **B**. Meets ALL of the following:
    - Has documentation of testing for ALL the following biomarkers:
      - Rheumatoid factor (RF)
      - Anti-cyclic citrullinated peptide (anti-CCP)
      - Anti-CCP C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
    - At least one of the following biomarker tests is positive:
      - RF
      - Anti-CCP
    - Has experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week) OR has an intolerance or contraindication to methotrexate (see Appendix)

## 2. Plaque Psoriasis

- Must be 18 years of age or older
- Must have documentation of moderate-to-severe plaque psoriasis
- Must be prescribed by, or in consultation with, a dermatologist
- Must meet ONE of the following:
  - Has previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis
  - Has crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected
  - Has at least 10% of body surface area (BSA) affected
  - Has at least 3% of body surface area (BSA) affected and the member meets either of the following criteria:
    - Has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin
    - Has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix)

**3. Psoriatic arthritis (PsA)**

- Must be 18 years of age or older
- Must have documentation of active psoriatic arthritis
- Must be prescribed by, or in consultation with, a dermatologist or rheumatologist
- Must meet **ONE** of the following:
    - Has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis
    - Has severe disease
    - Has mild-to-moderate disease and meets ONE of the following:
        - Has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) OR has an intolerance or contraindication to methotrexate or leflunomide (see Appendix), or another conventional synthetic drug (e.g., sulfasalazine).
        - Has enthesitis or predominantly axial disease

**4. Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)**

- Must be 18 years of age or older
- Must have documentation of active Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
- Must be prescribed by, or in consultation with, a rheumatologist
- Must meet ONE of the following:
    - Has previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis
    - Has had an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) OR has an intolerance or contraindications to NSAIDs

**5. Crohn's disease (CD)**

- Must be 18 years of age or older
- Must have documentation of moderately-to-severely active Crohn's disease
- Must be prescribed by, or in consultation with, a gastroenterologist

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation of the following:

- For **all diagnoses:** must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling
- For **rheumatoid arthritis:** must achieve or maintain a positive clinical response as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain or disability
- For **plaque psoriasis**: must achieve or maintain a positive clinical response as evidenced by ONE of the following:
    - Reduction in body surface area (BSA) affected from baseline
    - Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)
- For **psoriatic arthritis**: must achieve or maintain a positive clinical response as evidenced by improvement in any of the following from baseline:
    - Number of swollen joints
    - Number of tender joints
    - Dactylitis
    - Axial disease
    - Enthesitis
    - Skin and/or nail involvement
- For **ankylosing spondylitis (AS) and non-radiographic axial spondylarthritis (nr-axSpA)**: must achieve or maintain a positive clinical response as evidenced by improvement in any of the following from baseline:
    - Functional status
    - Total spine pain
    - Inflammation (e.g., morning stiffness)
- For **Crohn's disease:** must achieve or maintain a positive clinical response as evidenced by improvement in any of the following from baseline:
    - Abdominal pain or tenderness
    - Diarrhea
    - Body weight
    - Abdominal mass
    - Hematocrit
    - Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

## Limitations:

| Length of Authorization (if above criteria met) | |
|---|---|
| Initial Authorization | Up to 12 months |
| Reauthorization | Same as initial |

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

## Appendix:

**Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, Acitretin, or Leflunomide**

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

## Codes:

| CPT Codes / HCPCS Codes / ICD-10 Codes | | |
|---|---|---|
| Code | Brand | Description |
| J0717 | Cimzia | Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered) |

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## Revision History

| DESCRIPTION OF REVIEW / REVISION | DATE APPROVED |
|---|---|
| New Policy | 01/2024 |
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## Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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