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, Adalimumab-aacf, Enbrel, Entyvio, Cosentyx, Otezla, Otulfi (ustekinumab-aauz), Rinvoq, Simponi, Skyrizi, Tremfya, Velsipity, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment with Cimzia prefilled syringes 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 before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication. Additionally for this program, Avsola, Inflectra, Entyvio, Ilumya, Stelara, Skyrizi, and Simponi Aria are the preferred products and will apply to members requesting treatment with Cimzia Lyophilized Powder for reconstitution and administration by a healthcare professional for an indication that is FDA-approved for the preferred product. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

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 active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
4. Treatment of adult patients with active psoriatic arthritis.
5. Treatment of adults with active ankylosing spondylitis.
6. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.
7. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A) Rheumatoid arthritis (RA)
1. For initial requests:
   a) Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   b) Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B) Polyarticular juvenile idiopathic arthritis (pJIA):
1. Initial requests: Chart notes, medical records, claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes, medical record documentation supporting positive clinical response.

C) Ankylosing spondylitis (AS) active non-radiographic axial spondyloarthritis (nr-axSpA), and psoriatic arthritis (PsA):
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

D) Crohn's disease (CD)
1. Continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy or remission.

E) Plaque psoriasis (PsO)
1. Initial requests:
   a) Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   b) Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

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

Preferred Drug Plan Design for Cimzia prefilled syringes

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 (Cosentyx, Enbrel, Adalimumab-aacf, Rinvoq, Simponi, 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

B) Axial Spondyloarthritis

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 both of the preferred products (Cosentyx and Rinvoq)
   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) Polyarticular juvenile idiopathic arthritis

1. Criteria for initial approval on polyarticular juvenile idiopathic 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 (adalimumab-aacf, Enbrel, and Xeljanz/Xeljanz Oral solution)
   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) 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, Adalimumab-aacf , Otezla, Otulfi (ustekinumab-aauz), Rinvoq, Simponi, Skyrizi, Tremfya, 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

E) 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 (Adalimumab-aacf, Enbrel, Rinvoq, Simponi, 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

F) 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 at least two of the preferred products (Adalimumab-aacf, Entyvio, Otulfi (ustekinumab-aauz), Rinvoq, Skyrizi, and Tremfya)
   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

G) 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 (Adalimumab-aacf, Enbrel, Cosentyx, Otezla, Otulfi (ustekinumab-aauz), Skyrizi, , and Tremfya)
   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

<u>Preferred Drug Plan Design for Cimzia Lyophilized Powder for reconstitution and administration by a healthcare professional</u>

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 each of the following:
      a. Avsola
      b. Inflectra
      c. Simponi Aria
   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) <u>Polyarticular juvenile idiopathic arthritis</u>

1. Criteria for initial approval on polyarticular juvenile idiopathic arthritis will only apply when at least ONE of the following criteria are met:
   a) Member has a documented inadequate response or intolerable adverse event to Simponi Aria
   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) 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 each of the following:
      a. Avsola
      b. Inflectra
      c. Simponi Aria
      d. Skyrizi
   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) 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 each of the following:
      a. Avsola
      b. Inflectra
      c. Simponi Aria
   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) 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 to each of the following:
      a. Avsola
      b. Entyvio
      c. Inflectra
      d. Skyrizi
   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

F) 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 each of the following:
      a. Avsola
      b. Ilumya
      c. Inflectra
      d. Skyrizi

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).

Prescriber Specialties (only applies to initial requests)
This medication must be prescribed by or in consultation with one of the following:

A. Rheumatoid arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, or polyarticular juvenile idiopathic arthritis: rheumatologist
B. Psoriatic arthritis: rheumatologist or dermatologist
C. Crohn's disease: gastroenterologist
D. Plaque psoriasis: dermatologist

Criteria for Initial Approval

A) Moderately to severely active rheumatoid arthritis (RA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for moderately to severely active rheumatoid arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of moderately to severely active RA when all of the following criteria are met:
   a. Member meets either of the following criteria:
      i. Member has been tested for either of the following biomarkers and the test was positive:
         - Rheumatoid Factor (RF)
         - Anti-cyclic citrullinated peptide (anti-CCP)
      ii. Member has been tested for ALL of the following biomarkers:
         - RF
         - Anti-CCP
         - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
   b. Member meets either of the following criteria:
      i. Member 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).
      ii. Member has an intolerance or contraindication to methotrexate (see Appendix A).

B) Polyarticular juvenile idiopathic arthritis (pJIA)

1. Authorization of 12 months may be granted for members 2 years of age and older who have previously received a biologic or targeted synthetic drug (e.g., Xeljanz) indicated for active articular juvenile idiopathic arthritis.
2. Authorization of 12 months may be granted for members 2 years of age and older the treatment of active articular juvenile idiopathic arthritis when any of the following criteria are met:
   a. The member had an inadequate response to methotrexate or another conventional synthetic drug (e.g., leflunomide, sulfasalazine, hydroxychloroquine) administered at an adequate dose and duration.
   b. The member has had an inadequate response to a trial of scheduled non-steroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular glucocorticoids (e.g., triamcinolone hexacetonide) and one of the following risk factors for poor outcome:
      i. Involvement of ankle, wrist, hip, sacroiliac joint, and/or temporomandibular joint (TMJ)

ii. Presence of erosive disease or enthesitis
iii. Delay in diagnosis
iv. Elevated levels of inflammation markers
v. Symmetric disease

c. The member has risk factors for disease severity and potentially a more refractory disease course (See Appendix C) and the member also meets one of the following:
i. High-risk joints are involved (e.g., cervical spine, wrist, or hip).
ii. High disease activity
iii. Are judged to be at high risk for disabling joint disease.

C) Active psoriatic arthritis (PsA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis (PsA).
2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
   a. Member has mild to moderate disease and meets one of the following criteria:
      i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
      ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix A), or another conventional synthetic drug (e.g., sulfasalazine).
      iii. Member has enthesitis or predominantly axial disease.
   b. Member has severe disease.

D) Active ankylosing spondylitis (AS) and active non-radiographic axial spondyloarthritis (nr-axSpA)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active ankylosing spondylitis or active non-radiographic axial spondyloarthritis.

2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active 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.

E) Moderately to severely active Crohn's disease (CD)

1. Authorization of 12 months may be granted formembers for the treatment of moderately to severely active Crohn's disease.

F) Moderate to severe plaque psoriasis (PsO)

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

2. Authorization of 12 months may be granted adult members for treatment of moderate to severe plaque psoriasis in adult members when any of the following criteria is met:
   a. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
   b. At least 10% of the body surface area (BSA) is affected.
   c. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:

i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (See Appendix B).

Continuation of Therapy

A) Rheumatoid arthritis (RA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who 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.

B) Polyarticular juvenile idiopathic arthritis (pJIA)

Authorization of 12 months months may be granted for all members (including new members) who are using the requested medication for active articular juvenile idiopathic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability

C) Psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for psoriatic arthritis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

D) Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for ankylosing spondylitis or non-radiographic axial spondyloarthritis and who achieve or maintain a positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Functional status
2. Total spinal pain
3. Inflammation (e.g. morning stiffness)
4. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)

E) Crohn’s disease (CD)

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain remission.

2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
   i. Abdominal pain or tenderness
   ii. Diarrhea
   iii. Body weight
   iv. Abdominal mass
   v. Hematocrit
   vi. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
   vii. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

F) Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Other

For all indications: Member has had a documented negative TB test (which can include a tuberculosis skin test [TST], an interferon-release assay [IGRA], or a chest x-ray)* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

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

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

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

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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

APPENDIX

Appendix A: Examples of Contraindications to Methotrexate or Leflunomide

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 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
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)

Appendix C: Risk Factors for articular juvenile idiopathic arthritis

1. Positive rheumatoid factor
2. Positive anti-cyclic citrullinated peptide antibodies
3. Pre-existing joint damage

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.

- 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)

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