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# 5.50.011

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| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2026 |
| **Subsection:** | Gastrointestinal Agents | **Original Policy Date:** | November 15, 2013 |
| **Subject:** | Cimzia | **Page:** | 1 of 15 |

***Last Review Date:*** December 12, 2025

# Cimzia

## Description

## Cimzia (certolizumab pegol)

**Background**
Cimzia (certolizumab pegol) is a tumor necrosis factor-alpha (TNF-α) blocker. Tumor necrosis factor is an endogenous protein that regulates a number of physiologic processes, including the inflammation response associated with some autoimmune inflammatory diseases (1).

**Regulatory Status**
FDA-approved indications: Cimzia is a tumor necrosis factor (TNF) blocker indicated for: (1)

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 adult patients 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

Cimzia carries boxed warnings regarding serious infections and malignancies. Because Cimzia suppresses the immune system, patients are at a greater risk for getting serious infections leading to hospitalization or death, including tuberculosis (TB), invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers.

Patients should be screened for latent tuberculosis infection. Patients at risk for hepatitis B virus (HBV) infection should be evaluated for evidence of prior HBV infection. Hepatitis B virus carriers should be monitored for reactivation during and several months after therapy. Cimzia should not be used in combination with other biologic agents. Cimzia should not be initiated in patients with an active infection. Cimzia should be discontinued if a patient develops a serious infection during treatment (1).

Pancytopenia, aplastic anemia, lupus-like syndrome, anaphylaxis reactions, and congestive heart failure (new onset or worsening) may develop during Cimzia therapy and therapy should be discontinued (1).

The use of Cimzia in combination with other biological DMARDs is not recommended. Serious infections may occur with concurrent use of anakinra (an interleukin-1 antagonist) and another TNF blocker, etanercept. There is a higher risk of serious infections in the combination use of TNF blockers with abatacept and rituximab. Because of the nature of the adverse events seen with this combination therapy, similar toxicities may also result from the use of Cimzia in this combination. Therefore, the use of Cimzia in combination with other biological DMARDs is not recommended (1).

The safety and effectiveness of Cimzia in pediatric patients less than 2 years of age for polyarticular juvenile idiopathic arthritis have not been established. The safety and effectiveness of Cimzia in pediatric patients less than 18 years of age for all other indications have not been established (1).

**Related policies**
Enbrel, Humira, Infliximab, Simponi, Zymfentra

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Cimzia may be considered **medically necessary** if the conditions indicated below are met.

Cimzia may be considered **investigational** for all other indications.

## Prior-Approval Requirements

***Cimzia Lyophilized Powder submitted under the medical benefit is not subject to biologic step edits.***

### Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Moderate to severe Crohn's disease (CD)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 1)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Moderate to severely active rheumatoid arthritis (RA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 3)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active polyarticular juvenile idiopathic arthritis (pJIA)

a. 2 years of age or older
b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 3)
c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
    i. Age 2-17, weight 10kg to < 20kg: 50 mg every other week
    ii. Age 2-17, weight 20kg to < 40kg: 100 mg every other week
    iii. Age 2-17, weight ≥40kg: 200 mg every other week
    iv. Age 18 and older: 200 mg every other week
d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Active psoriatic arthritis (PsA)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 3)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Active ankylosing spondylitis (AS)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

6. Moderate to severe plaque psoriasis (PsO)

a. 18 years of age or older
b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 3) or phototherapy
    i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate response, intolerance, or contraindication to the other treatment option
c. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every other week
d. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**AND ALL** of the following for **ALL** indications:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
3. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
5. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

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**Diagnosis**

Patient must have the following:

1. Active non-radiographic axial spondyloarthritis (nr-axSpA)
    a. 18 years of age or older
    b. Patient has objective signs of inflammation

c. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
d. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks

**AND ALL** of the following:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
3. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
5. **NOT** given concurrently with live vaccines

## Prior – Approval *Renewal* Requirements

***Cimzia Lyophilized Powder submitted under the medical benefit is not subject to biologic step edits*.**

**Diagnoses**

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Crohn's disease (CD)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Rheumatoid arthritis (RA)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks

c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Polyarticular juvenile idiopathic arthritis (pJIA)
   a. 2 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Age 2-17, weight 10kg to < 20kg: 50 mg every other week
      ii. Age 2-17, weight 20kg to < 40kg: 100 mg every other week
      iii. Age 2-17, weight ≥40kg: 200 mg every other week
      iv. Age 18 and older: 200 mg every other week
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Psoriatic arthritis (PsA)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Ankylosing spondylitis (AS)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

6. Plaque psoriasis (PsO)
   a. 18 years of age or older

b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every other week
c. Patient **MUST** have tried the preferred product(s) (see Appendix 4) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

**AND ALL** of the following for **ALL** indications:

1. Condition has improved or stabilized with Cimzia
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
4. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

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**Diagnosis**

Patient must have the following:

1. Non-radiographic axial spondyloarthritis (nr-axSpA)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 400 mg every 4 weeks

**AND ALL** of the following:

1. Condition has improved or stabilized with Cimzia
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 3)
4. **NOT** given concurrently with live vaccines

## Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity**

| Diagnosis | Starter Pack | Strength | Quantity |
|---|---|---|---|
| Ankylosing Spondylitis | **Yes** | 200 mg | 1 starter pack and 6 units per 84 days |
| Crohn's Disease | | | |
| Psoriatic Arthritis | | | |
| Rheumatoid Arthritis | | | |
| Non-radiographic Axial Spondyloarthritis | | | |
| Plaque Psoriasis | **Yes** | 200 mg | 1 starter pack and 12 units per 84 days |
| Polyarticular Juvenile Idiopathic Arthritis | **Yes** | 200 mg | 1 starter pack and 6 units per 84 days |

**Duration** 12 months

## Prior – Approval *Renewal* Limits

**Quantity**

| Diagnosis | Strength | Quantity |
|---|---|---|
| Ankylosing Spondylitis | 200 mg | 6 units per 84 days |
| Crohn's Disease | | |
| Psoriatic Arthritis | | |
| Rheumatoid Arthritis | | |
| Non-radiographic Axial Spondyloarthritis | | |
| Plaque Psoriasis | 200 mg | 12 units per 84 days |
| Polyarticular Juvenile Idiopathic Arthritis | 200 mg | 6 units per 84 days |

**Duration** 18 months

## Rationale

**Summary**
Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker indicated for rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), psoriatic arthritis (PsA), plaque psoriasis (PsO), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and Crohn's disease (CD). Cimzia may be used as monotherapy or concurrently with non-biological disease modifying anti-rheumatic drugs (DMARDs). Cimzia should not be used in combination with other biological DMARDs or other tumor necrosis factor (TNF) blockers. Cimzia carries boxed warnings regarding increased risk of serious infections and malignancies. The safety and effectiveness of Cimzia in pediatric patients less than 2 years of age for polyarticular juvenile idiopathic arthritis have not been established. The safety and effectiveness of Cimzia in pediatric patients less than 18 years of age for all other indications have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cimzia while maintaining optimal therapeutic outcomes.

**References**

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.

## Policy History

| Date | Action |
|---|---|
| October 2013 | Addition to PA |
| December 2013 | Annual editorial review by the PMPC |
| September 2014 | Annual editorial review and renewal limit to 18 months |
| December 2015 | Annual editorial review and removed moderated to severely active from renewal diagnoses |
| September 2016 | Annual review and reference update<br>Addition of not given concurrently with live vaccines per SME<br>Policy number change 5.18.05 to 5.50.11 |
| December 2016 | Annual editorial review |
| March 2017 | Annual review |
| December 2017 | Annual editorial review and reference update<br>Addition of prescriber will be dosing the patient within the FDA labeled dose of 400 mg every 4 weeks |

| | |
|---|---|
| March 2018 | Annual editorial review and reference update<br>Addition of List of DMARDs appendix |
| June 2018 | Addition of the diagnosis of plaque psoriasis<br>Addition of additional requirements to initiation criteria<br>For diagnoses of RA: Inadequate response, intolerance, or contraindication to a 3-month trial of at least ONE conventional DMARD<br>For diagnoses of CD: inadequate treatment response, intolerance, or contraindication to at least one conventional systemic therapy<br>For diagnosis of AS: inadequate response, intolerance, or contraindication to at least 2 NSAIDs<br>For diagnosis of PsA: inadequate response, intolerance or contraindication to a 3-month trial of at least ONE conventional DMARD<br>Addition of List of Conventional Therapies, and Examples of Contraindications to Methotrexate appendices |
| September 2018 | Annual editorial review and reference update |
| March 2019 | Annual review |
| April 2019 | Addition of indication: non-radiographic axial spondyloarthritis |
| June 2019 | Annual review |
| September 2019 | Annual review and reference update |
| December 2019 | Annual review. Addition of requirement to trial preferred product |
| March 2020 | Annual review and reference update |
| September 2020 | Annual review |
| December 2020 | Added Appendix 4 with a list of preferred medications based on diagnosis and plan. Added PA quantity limits |
| January 2021 | Updated t/f options for CD to include trial of Humira first per FEP |
| March 2021 | Annual editorial review. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Updated Appendix 3. |
| June 2021 | Annual editorial review |
| January 2022 | Added Rinvoq as a preferred PsA product to chart (Appendix 4) |
| March 2022 | Annual review. Added Skyrizi as a preferred PsA product to chart (Appendix 4) |
| May 2022 | Added Rinvoq as a preferred AS product to chart (Appendix 4) |
| June 2022 | Annual review |
| July 2022 | Added Skyrizi as a preferred CD product to chart (Appendix 4). Also, added that Cimzia Lyophilized Powder submitted under the medical benefit is not subject to biologic step edits |
| September 2022 | Annual review |
| December 2022 | Annual review |
| March 2023 | Annual review and reference update |
| June 2023 | Annual review |
| March 2024 | Annual editorial review. Revised FDA dosing language |
| June 2024 | Annual review |

| | |
|---|---|
| September 2024 | Annual review |
| October 2024 | Per PI update, added indication of pJIA |
| December 2024 | Annual review |
| March 2025 | Annual review |
| December 2025 | Annual review. Revised Appendix 4. Added documentation requirement |

Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.**

## Appendix 1 - List of Conventional Therapies

| Conventional Therapy Options for CD |
|---|
| 1. Mild to moderate disease – induction of remission:<br>a. Oral budesonide, oral mesalamine<br>b. Alternatives: metronidazole, ciprofloxacin |
| 2. Mild to moderate disease – maintenance of remission:<br>a. Azathioprine, mercaptopurine<br>b. Alternatives: oral budesonide, methotrexate intramuscularly (IM) |
| 3. Moderate to severe disease – induction of remission:<br>a. Prednisone, methylprednisolone intravenously (IV)<br>b. Alternatives: methotrexate IM |
| 4. Moderate to severe disease – maintenance of remission:<br>a. Azathioprine, mercaptopurine<br>b. Alternative: methotrexate IM |
| 5. Perianal and fistulizing disease – induction of remission<br>c. Metronidazole ± ciprofloxacin |
| 6. Perianal and fistulizing disease – maintenance of remission<br>d. Azathioprine, mercaptopurine<br>e. Alternative: methotrexate IM |

## Appendix 2 – Examples of Contraindications to Methotrexate

| Contraindications to Methotrexate |
|---|
| 1. Alcoholism, 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 planning pregnancy (male or female) |
| 10. Renal impairment |
| 11. Significant drug interaction |

## Appendix 3 - List of DMARDs

**Conventional disease-modifying antirheumatic drugs (DMARDs)**

| Generic Name | Brand Name |
|---|---|
| azathioprine | Azasan, Imuran |
| cyclophosphamide | Cytoxan |
| cyclosporine | Neoral, Gengraf, Sandimmune |
| hydroxychloroquine | Plaquenil |
| leflunomide | Arava |
| methotrexate | Rheumatrex, Trexall |
| mycophenolate | Cellcept |
| sulfasalazine | Azulfidine, Sulfazine |

**Biological disease-modifying antirheumatic drugs (DMARDs)**

| Generic Name | Brand Name |
|---|---|
| abatacept | Orencia |
| adalimumab | Humira |
| anakinra | Kineret |
| bimekizumab-bkzx | Bimzelx |
| brodalumab | Siliq |
| certolizumab | Cimzia |
| etanercept | Enbrel |
| golimumab | Simponi/Simponi Aria |
| guselkumab | Tremfya |
| infliximab | Remicade |
| infliximab-dyyb | Zymfentra |
| ixekizumab | Taltz |
| risankizumab-rzaa | Skyrizi |
| rituximab | Rituxan |
| sarilumab | Kevzara |
| secukinumab | Cosentyx |
| spesolimab-sbzo | Spevigo |
| tildrakizumab-asmn | Ilumya |
| tocilizumab | Actemra |
| ustekinumab | Stelara |
| vedolizumab | Entyvio |

**Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)**

| Generic Name | Brand Name |
|---|---|
| apremilast | Otezla |
| baricitinib | Olumiant |
| deucravacitinib | Sotyktu |
| tofacitinib | Xeljanz/XR |
| upadactinib | Rinvoq |

## Appendix 4 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists