certolizumab pegol (Cimzia vials)

Commercial Medical Benefit Drug Policy

Place of Service

Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: Disease-modifying antirheumatic agent
HCPCS:
J0717: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)
How Supplied:

- 200 mg lyophilized powder for reconstitution, in a single-use glass vial, with 1 mL of sterile water for Injection. Per product labeling, Cimzia lyophilized powder for reconstitution should be administered by a healthcare professional.

Condition(s) listed in policy *(see coverage criteria for details)*

- Ankylosing Spondylitis (AS) or Non-Radiographic Axial Spondyloarthritis (nr-axSpA)
- Crohn's Disease
- Plaque Psoriasis
- Polyarticular Juvenile Idiopathic Arthritis
- Psoriatic Arthritis
- Rheumatoid Arthritis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Cimzia vials, administered by a health care professional, is managed under the Medical Benefit. There is no dosage form for Cimzia that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a health care professional using the vial kit. For doses more than 200 mg, please include medical rationale why the patient cannot use the self-administered Cimzia prefilled syringe in the home. The Cimzia prefilled syringe can be obtained

through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Ankylosing Spondylitis (AS) or Non-Radiographic Axial Spondyloarthritis (nr-axSpA)
Meets medical necessity if all the following are met:
Initial
1. ***Effective 2/1/2026 and after:*** Age is consistent with the FDA-approved indication
2. Prescribed by or in consultation with a rheumatologist
3. Meets ONE of the following:
   a. Inadequate response with a trial of any two-prescription strength NSAIDs
   b. Intolerable GI adverse events after a trial of a prescription strength NSAID in combination with a PPI
   c. Unable to take NSAIDs due to history of GI bleed
4. Meets ONE of the following (a or b):
   a. For ankylosing spondylitis (AS): Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Cosentyx, Enbrel, infliximab (Avsola or Inflectra), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents
   b. For non-radiographic axial spondyloarthritis (nr-axSpA): Inadequate response or intolerable side effect with two BSC-preferred agents (Cimzia [self-administered], Cosentyx and Rinvoq), or contraindication to all preferred agents
5. Not being used with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
400 mg given subcutaneously at Weeks 0, 2 and 4, followed by 200 mg every other week or 400 mg every four weeks

Coverage Period:
one year

ICD-10:
M45.0-M45.9, M48.8X1-M48.8X9

Crohn's Disease
Meets medical necessity if all the following are met:
Initial
1. ***Effective 2/1/2026 and after:*** Age consistent with the FDA-approved indication
2. ***Effective 2/1/2026 and after:*** Prescribed by or in consultation with a gastroenterologist

3. Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Simlandi 20 mg, infliximab (Avsola or Inflectra), Rinvoq, Skyrizi, Yesintek), or contraindication to all preferred agents
4. Not used with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
400 mg given subcutaneously at Weeks 0, 2 and 4, followed by 400 mg given every four weeks

Coverage Period:
one year

ICD-10:
K50.00-K50.119, K50.80-K50.819, K50.90-K50.919

Plaque Psoriasis
Meets medical necessity if all the following are met:

Initial
1. Age is consistent with FDA-approved indication
2. Prescribed by or in consultation with a dermatologist or rheumatologist
3. Meets ONE of the following:
    1. Baseline PASI score is 10 or more prior to starting immunomodulator therapy
    2. Baseline BSA (body surface area) affected is 3% or more prior to starting immunomodulator therapy
    3. Sensitive area is involved (i.e., groin, face, etc.)
    4. Disease is otherwise debilitating
4. Inadequate response, intolerable side effect, or contraindication to ONE of the following:
    1. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane)
    2. PUVA or UVB treatment
5. Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Cosentyx, Enbrel, infliximab (Avsola or Inflectra), Otezla, Skyrizi, Yesintek, and Tremfya), or contraindication to all preferred agents
6. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Not being used in combination with other targeted immunomodulator (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)
2. Meets ONE of the following:
    a. Improvement in PASI score from baseline
    b. Improvement in BSA from baseline
    c. Decrease in sensitive area disease severity

d. Decrease in debilitating disease severity

Covered Doses:
400 mg given subcutaneously every other week.
For some patients (with body weight less than or equal to 90 kg), a dose of 400 mg initially and at Weeks 2 and 4, followed by 200 mg every other week may be considered.

Coverage Period:
Initial: 24 weeks
Reauthorization: one year

ICD-10:
L40.0-L40.4

Polyarticular Juvenile Idiopathic Arthritis
Meets medical necessity if all the following are met:
Initial
1. ***Effective 2/1/2026 and after:*** Age is consistent with FDA-approved indication
2. Prescribed by or in consultation with a rheumatologist
3. Inadequate response, or intolerable side effect with one disease modifying anti-rheumatic drug (DMARD) or patient is unable to take methotrexate
4. Inadequate response, intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Simlandi 20 mg, Enbrel, infliximab (Avsola and Inflectra), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents
5. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
- 10 kg (22 lbs) to less than 20 kg (44 lbs): 100 mg at Weeks 0, 2 and 4, followed by 50 mg every other week
- 20 kg (44 lbs) to less than 40 kg (88 lbs): 200 mg at Weeks 0, 2 and 4, followed by 100 mg every other week
- Greater than or equal to 40 kg (88 lbs): 400 mg at Weeks 0, 2 and 4, followed by 200 mg every other week

Coverage Period:
one year

ICD-10:
M08.09

Psoriatic Arthritis
Meets medical necessity if all the following are met:
Initial

1. ***Effective 2/1/2026 and after:*** Age is consistent with FDA-approved indication
2. Prescribed by or in consultation with a rheumatologist
3. Inadequate response, intolerance, or contraindication to one or more disease modifying anti-rheumatic drugs (DMARDs) or has a medical reason why methotrexate, sulfasalazine, and leflunomide cannot be used
4. Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Cosentyx, Enbrel, infliximab (Avsola or Inflectra), Otezla, Rinvoq, Skyrizi, Yesintek, Tremfya, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents
5. Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
400 mg given subcutaneously at Weeks 0, 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered.

Coverage Period:
one year

ICD-10:
L40.50-L40.59

Rheumatoid Arthritis
Meets medical necessity if all the following are met:
Initial
1. ***Effective 2/1/2026 and after:*** Age is consistent with FDA-approved indication
2. Prescribed by or in consultation with a rheumatologist
3. Inadequate response, intolerable side effect, or contraindication to a DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, and sulfasalazine)
4. Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Enbrel, infliximab (Inflectra or Avsola), Rinvoq, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents
5. Not used in combination with another targeted immunomodulator (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Reauthorization
1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators (e.g., anti-TNFs, interleukin inhibitors, JAK inhibitors)

Covered Doses:
400 mg given subcutaneously at Weeks 0, 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered.

Coverage Period:

one year

ICD-10:
(X=0-9) M05.XXX, M06.0XX, M06.2XX, M06.3XX, M06.8XX, M06.9

References

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3. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018;113: 481-517.
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8. 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. Arthritis Rheumatol, 2019;71(10):1599-1613.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Crohn's disease: Added age, specialist, and reauthorization requirement
- Rheumatoid arthritis: Clarified prerequisite requirement to include DMARDs for rheumatoid arthritis, added age and reauthorization requirement
- Ankylosing spondylitis, Polyarticular juvenile idiopathic arthritis, Psoriatic arthritis: Added age and reauthorization requirement

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee