Certolizumab pegol (Cimzia®) Vials	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: J0717 per 1 mg (administered by healthcare provider)

Conditions listed in policy (*see criteria for details*)

- Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)
- Crohn's disease
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis

AHFS therapeutic class: Disease-Modifying Antirheumatic Agent

Mechanism of action: Certolizumab pegol, a recombinant humanized pegylated antibody, is a TNF [tumor necrosis factor] blocker

(1) Special Instructions and Pertinent Information

Cimzia vials are managed under the Medical Benefit. Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Cimzia® (certolizumab pegol) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

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

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. ONE of the following:
    a. Inadequate response with a trial of any two-prescription strength NSAIDs, OR
    b. Intolerable GI adverse events after a trial of a prescription strength NSAID in combination with a PPI, OR
    c. Unable to take NSAIDs due to history of GI bleed

AND

3. Not being used with other targeted immunomodulators, **AND**
4. For ankylosing spondylitis (AS) only: Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses
Initial: 400 mg SC (given as two 200 mg injections) at weeks 0, 2 and 4.

Maintenance: 400 mg SC every four weeks.

Coverage Period
Cover yearly, based upon continued response

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

Crohn's disease

1. Not used with another targeted immunomodulator, AND
2. Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses
Initial: 400 mg SC (given as two 200mg injections) at weeks 0, 2 and 4.
Maintenance: 400 mg SC every four weeks.

Coverage Period
Yearly based on continued response to therapy

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

Plaque psoriasis

1. Age ≥ 18 years of age, **AND**
2. Prescribed by or in consultation with a dermatologist or rheumatologist, **AND**
3. One of the following:
    a. Baseline PASI score is 10 or more prior to starting immunomodulator therapy, OR
    b. Baseline BSA (body surface area) affected is 3% or more prior to starting immunomodulator therapy, OR
    c. Sensitive area is involved (i.e., groin, face, etc.), OR
    d. Disease is otherwise debilitating

AND

4. Inadequate response, intolerable side effect, or contraindication to one of the following:
    a. Methotrexate, cyclosporine (Neoral), acitretin (Soriatane), OR
    b. PUVA or UVB treatment

AND

5. Not being used in combination with another targeted immunomodulator, **AND**
6. Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses
400 mg (given as 2 subcutaneous injections of 200 mg each) every other week

For some patients (with body weight ≤ 90 kg), a dose of 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at Weeks 2 and 4, followed by 200 mg every other week may be considered.

Coverage Period
Initial: 24 weeks
Reauthorization: Yearly if meets the following:

1. Not being used in combination with other targeted immunomodulator, AND
2. One of the following:
    i. Improvement in PASI score from baseline, OR
    ii. Improvement in BSA from baseline, OR
    iii. Decrease in sensitive area disease severity, OR
    iv. Decrease in debilitating disease severity

ICD-10:
L40.0-L40.4

Psoriatic arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. 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, **AND**
3. Not being used in combination with other targeted immunomodulators, **AND**
4. Inadequate response or intolerable side effect with preferred infliximab (Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses
Up to 400 mg SC at Weeks 0, 2, and 4 followed by either:
Cimzia 200 mg every other week OR Cimzia 400 mg every 4 weeks.

Coverage Period
Cover yearly, based upon continued response.

ICD-10:
L40.50-L40.59

Rheumatoid arthritis

1. Prescribed by or in consultation with a rheumatologist, **AND**
2. Inadequate response, intolerable side effect, or contraindication to methotrexate, **AND**
3. Not used in combination with another targeted immunomodulator, **AND**
4. Inadequate response or intolerable side effect with preferred infliximab (i.e., Avsola, Inflectra or Renflexis), or contraindication to all infliximab products

Covered Doses
Initial: 400 mg SC at weeks 0, 2, and 4
Maintenance: Dose does not exceed a total of 400 mg SC over a 4-week period (can be given 200 mg SC every other week or 400 mg SC monthly)

Coverage Period
Initial: 1 year
Reauthorization: Yearly based on continued clinical response

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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Cimzia® (certolizumab pegol) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

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.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Cimzia® (certolizumab pegol) [Prescribing Information]. Smyrna, GA: UCB, Inc.; 12/2022.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Fraenkel, L., Bathon, J.M., England, B.R., et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res, 2021;73:924-939.
- 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.
- Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
- Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Rheum 2013;65:2499-512.
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384-413.

- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum 2019;71:5-32.
- 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.

(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee