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# Certolizumab pegol

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## Disclaimer

*Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.*

### Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Legislative Mandates

**EXCEPTION: For HCSC members residing in the state of Ohio**, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

## Coverage

Certolizumab pegol (Cimzia®) **may be considered medically necessary** for the following U.S. Food and Drug Administration (FDA) labeled indications:

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adults 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 (RA);
- Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older;
- Treatment of adults 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.

All other non-FDA approved uses of Cimzia **are considered experimental, investigational and/or unproven.**

**NOTE 1:** Cimzia® (certolizumab pegol) may be self-administered. Refer to the applicable pharmacy benefit plan when self-administered.

## Policy Guidelines

None.

## Description

Certolizumab pegol is a tumor necrosis factor (TNF) inhibitor, which acts by binding and selectively neutralizing TNF-alfa. It does not neutralize TNF-beta. The inhibition of TNF-alfa, which is strongly expressed in the bowel wall and feces of patients with Crohn's disease, results in interference in the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor and nitric oxide. (1)

**Crohn's Disease**

Crohn's disease is a chronic inflammatory condition of the gastrointestinal (GI) tract. It belongs to a group of conditions known as inflammatory bowel diseases (IBD). While the disease can occur at any age, it is most often diagnosed in adolescents and adults between the ages of 20 and 30. While more common in Caucasians, Crohn's can affect people from all ethnic backgrounds. Rates are increasing among Hispanics and Asians. Crohn's may affect any part of the GI tract, but most commonly the end of the small bowel (ileum) and the beginning of the colon are affected. It can also affect the entire thickness of the bowel wall; and the inflammation may leave normal areas in between patches of diseased intestine. (2)

**Rheumatoid Arthritis**

Rheumatoid arthritis (RA) is an autoimmune and inflammatory disease in which the immune system attacks healthy cells by mistake, causing inflammation or painful swelling in affected parts of the body. RA mainly attacks the joints in the hands, wrists and knees, and usually attacks many joints at the same time. The lining of the joint becomes inflamed, causing damage to joint tissue, which in turn causes long-lasting or chronic pain, unsteadiness and deformity of the affected joints. RA can also affect other tissues in the body and cause problems in organs such as the lungs, heart and eyes. (3)

**Polyarticular Juvenile Idiopathic Arthritis**

Polyarticular juvenile idiopathic arthritis (formerly called polyarticular-onset juvenile rheumatoid arthritis [JRA]) is a subset of juvenile idiopathic arthritis (JIA) that is defined by the presence of more than four affected joints during the first six months of illness. The disease occurs more frequently in females and clinical presentation varies depending on age of onset. Complications are most commonly musculoskeletal in nature and include bony erosions and joint destruction, osteopenia and osteoporosis. The temporomandibular joint may be affected, and mobility may be impaired. Uveitis may be seen, and rarely, internal organ involvement may occur. (4)

**Psoriatic Arthritis**

Psoriatic arthritis is a condition involving joint inflammation (arthritis) that usually occurs in conjunction with psoriasis, a skin disorder characterized by patches of red, irritated skin that are often covered by flaky white scales. Psoriasis may cause changes to fingernails and toenails, causing pitting, ridges, crumbling of the nail or separation of the nail from the nail bed. Psoriatic arthritis causes stiff, painful joints with redness, heat and swelling in the surrounding tissues. Swelling and redness may result in a sausage-like appearance of the fingers or toes when the hands or feet are affected. Psoriasis appears before joint problems develop in most people. It typically begins during adolescence or as a young adult, with psoriatic arthritis occurring between the ages of 30 and 50. Both conditions may occur at any age; and in a small number of cases, psoriatic arthritis develops without any noticeable skin changes. (5)

**Ankylosing Spondylitis**

Ankylosing spondylitis is a form of arthritis that causes inflammation in the joints and ligaments of the spine, which may eventually lead to fusion of the vertebrae (bones in the spine). Symptoms may range from mild to severe and include pain and stiffness. Other joints such as

the shoulders, ribs, knees and feet may also be affected. Some people with ankylosing spondylitis develop eye disease (uveitis), skin disease (psoriasis), or gut disease (inflammatory bowel disease). Factors that increase the risk for developing ankylosing spondylitis include family history, age or other conditions such as Crohn's disease, ulcerative colitis or psoriasis. (6)

**Non-radiographic Axial Spondyloarthritis**
Axial spondyloarthritis (axSpA) is a disabling inflammatory arthritis of the spine, usually presenting as chronic back pain, typically before the age of 45. There are 2 subtypes of axSpA – ankylosing spondylitis, also known as radiographic axSpA, and non-radiographic axSpa (nr-axSpA). While patients with AS show radiographic abnormalities consistent with sacroiliitis, such findings are not evident on plain radiography in nr-axSpA. Instead, the diagnosis is supported by evidence of active inflammation of the sacroiliac joint (SI) on magnetic resonance imaging (MRI), or a combination of other findings. (7)

**Plaque Psoriasis**
Plaque psoriasis is the most common form of psoriasis, which is a chronic disease caused by an overactive immune system and is associated with inflammation throughout the body. Of people with psoriasis, 80-90 percent will have plaque psoriasis. It typically appears as raised, red patches covered with a silvery white buildup of dead skin cells or scale on Caucasian skin. On skin of color, it is more of a purple or grayish color or darker brown, as well as being darker and thicker. These plaques most often occur on the scalp, knees, elbows, and torso. Plaques are often itchy and usually arise symmetrically on the body. (8)

**Regulatory Status**
The U.S. Food and Drug Administration (FDA) approved Cimzia in 2008 for moderate to severe Crohn's Disease. In 2009, approval was granted for moderate to severe RA. Approval was granted in 2013 for ankylosing spondylitis and active psoriatic arthritis. In 2018, the FDA approved Cimzia for moderate to severe plaque psoriasis. In 2019, approval was granted for non-radiography axial spondylarthritis, and in 2024 approval was granted for polyarticular juvenile idiopathic arthritis. (9)

## Rationale

This policy is based on the U.S. Food and Drug Administration (FDA) labeled indications for certolizumab pegol (Cimzia®).

**Crohn's Disease (CD)**
Two double-blind, randomized, placebo-controlled studies assessed the efficacy and safety of Cimzia in patients aged 18 years and older with moderately to severely active Crohn's disease, as defined by a Crohn's Disease Activity Index (CDAI) of 220 to 450 points, inclusive. It was administered subcutaneously at a dose of 400 mg in both studies; and stable concomitant medications for Crohn's were permitted. (1)

Study CD1 enrolled 662 patients with active Crohn's disease. Cimzia or a placebo was administered at Weeks 0, 2, and 4, and then every four weeks to Week 24. Assessments were completed at Weeks 6 and 26. Clinical response was defined as at least a 100-point reduction in CDAI score compared to baseline, and clinical remission was defined as an absolute CDAI score of 150 points or lower. At Week 6, the proportion of clinical responders was statistically significantly greater for Cimzia-treated patients compared to controls. The difference in clinical remission rates was not statistically significant at Week 6. The difference in the proportion of patients who were in clinical response in Weeks 6 and 26 was also statistically significant, demonstrating maintenance of clinical response. The results for the CD1 study are provided in Table 1.

**Table 1. Study CD1 Clinical Response and Remission, Overall Study Population**

| | **% Response or Remission (95% CI)** | |
|---|---|---|
| **Timepoint** | **Placebo (N = 328)** | **Cimzia 400 mg (N = 331)** |
| **Week 6** | | |
| Clinical Response[b] | 27% (22%, 32%) | 35% (30%, 40%)[a] |
| Clinical Remission[b] | 17% (13%, 22%) | 22%, (17%, 26%) |
| **Week 26** | | |
| Clinical Response | 27% (22%, 31%) | 37% (32%, 42%)[a] |
| Clinical Remission | 18% (14%, 22%) | 29% (25%, 34%)[a] |
| **Both Weeks 6 and 26** | | |
| Clinical Response | 16% (12%, 20%) | 23% (18%, 28%)[a] |
| Clinical Remission | 10% (7%, 13%) | 14%, (11%, 18%) |

CI: confidence interval.

[a] p-value <0.05 logistic regression test

[b] Clinical response is defined as decrease in CDAI of at least 100 points, and clinical remission is defined as CDAI ≤150 points.

Study CD2 was a randomized treatment-withdrawal study in patients with active Crohn's disease. All patients who entered the study were dosed initially with Cimzia 400 mg at Weeks 0, 2, and 4 and then assessed for clinical response at Week 6 (as defined by at least a 100-point reduction in CDAI score). At Week 6, a group of 428 clinical responders was randomized to receive either Cimzia 400 mg or placebo, every four weeks starting at Week 8, as maintenance therapy through Week 24. Non-responders at Week 6 were withdrawn from the study. Final evaluation was based on the CDAI score at Week 26. Patients who withdrew or who received rescue therapy were considered not to be in clinical response. Three randomized responders received no study injections and were excluded from the intent-to-treat (ITT) analysis. The results for clinical response and remission are shown in Table 2. At Week 26, a statistically significantly greater proportion of Week 6 responders were in clinical response and in clinical remission in the Cimzia-treated group compared to the group treated with placebo.

**Table 2. Study CD2 Clinical Response and Clinical Remission**

| | **% Response or Remission (95% CI)** | |
|---|---|---|
| | **Cimzia 400mg x3 + Placebo** | **Cimzia 400mg** |

| | N = 210 | N = 215 |
|---|---|---|
| **Week 26** | | |
| Clinical response[b] | 36% (30%, 43%) | 63% (56%, 69%)[a] |
| Clinical remission[b] | 29% (22%, 35%) | 48% (41%, 55%)[a] |

CI: confidence interval.

[a] p-value <0.05

[b] Clinical response is defined as decrease in CDAI of at least 100 points, and clinical remission is defined as CDAI ≤150 points.

Baseline use of immunosuppressants or corticosteroids had no impact on the clinical response to Cimzia.

**Rheumatoid Arthritis (RA)**

The efficacy and safety of Cimzia were assessed in four randomized, placebo-controlled, double-blind studies (RA-I, RA-II, RA-III, and RA-IV) in patients ≥ 18 years of age with moderately to severely active RA diagnosed according to the American College of Rheumatology (ACR) criteria. Patients had ≥ nine swollen and tender joints and had active RA for at least six months prior to baseline. Cimzia was administered subcutaneously in combination with methotrexate (MTX) at stable doses of at least 10 mg weekly in Studies RA-I, RA-II, and RA-III. Cimzia was administered as monotherapy in Study RA-IV.

Cimzia treated patients had higher ACR20, 50 and 70 response rates at 6 months compared to placebo-treated patients. The results in study RA-II (619 patients) were similar to the results in RA-I at Week 24. The results in study RA-III (247 patients) were similar to those seen in study RA-IV. Over the one-year Study RA-I, 13% of Cimzia treated patients achieved a major clinical response, defined as achieving an ACR70 response over a continuous 6-month period, compared to 1% of placebo-treated patients. (1)

In Study RA-I, inhibition of progression of structural damage was assessed radiographically and expressed as the change in modified Total Sharp Score (mTSS) and its components, the Erosion Score (ES) and Joint Space Narrowing (JSN) score, at Week 52, compared to baseline. Cimzia inhibited the progression of structural damage compared to placebo plus MTX after twelve months of treatment. In the placebo group, 52% of patients experienced no radiographic progression (mTSS ≤0.0) at Week 52 compared to 69% in the Cimzia 200 mg every other week treatment group. Study RA-II showed similar results at Week 24.

In studies RA-I, RA-II, RA-III, and RA-IV, Cimzia-treated patients achieved greater improvements from baseline than placebo-treated patients in physical function as assessed by the Health Assessment Questionnaire – Disability Index (HAQ-DI) at Week 24 (RA-II, RA-III and RA-IV) and at Week 52 (RA-I).

**Polyarticular Juvenile Idiopathic Arthritis (pJIA)**

The efficacy of Cimzia in pediatric patients with pJIA is based on pharmacokinetic exposure and extrapolation of the established efficacy of Cimzia in RA patients.

The efficacy of Cimzia was also assessed in a multi-center, open-label study NCT01550003 in 193 patients 2 to 17 years of age with JIA with active polyarthritis with an inadequate response or intolerance to at least 1 disease-modifying anti-rheumatic drug (DMARD [nonbiologic or biologic]). Of those, 105 received the recommended dose. The patients had the following subtypes of JIA: polyarthritis rheumatoid factor-positive (20.0%), polyarthritis rheumatoid factor-negative (44.8%), extended oligoarthritis (13.3%), juvenile psoriatic arthritis (4.8%), and enthesitis-related arthritis (19.0%). Patients could be on stable methotrexate, glucocorticoids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs). Efficacy was assessed as secondary endpoints through Week 24. The efficacy was generally consistent with responses in patients with RA. (1)

**Psoriatic Arthritis (PsA)**

The efficacy and safety of Cimzia were assessed in a multi-center, randomized, double-blind, placebo-controlled trial (PsA001) in 409 patients aged 18 years and older with active psoriatic arthritis despite DMARD therapy. Patients in this study had ≥ 3 swollen and tender joints and adult-onset PsA of at least 6 months' duration as defined by the Classification Criteria for Psoriatic Arthritis (CASPAR) criteria and increased acute phase reactants. Patients had failed one or more DMARDs. Previous treatment with one anti-TNF biologic therapy was allowed, and 20% of patients had prior anti-TNF biologic exposure. Patients receiving concomitant NSAIDs and conventional DMARDs were 73% and 70 % respectively. Patients received a loading dose of Cimzia 400 mg at Weeks 0, 2 and 4 (for both treatment arms) or placebo followed by either Cimzia 200 mg every other week or Cimzia 400 mg every 4 weeks or placebo every other week. Patients were evaluated for signs and symptoms and structural damage using the ACR20 response at Week 12 and modified Total Sharp Score (mTSS) at Week 24. ACR20 response rates at Weeks 12 and 24 were higher for each Cimzia dose group relative to placebo (95% confidence intervals [CI] for Cimzia 200 mg minus placebo at weeks 12 and 24 of (23%, 45%) and (30%, 51%), respectively and 95% CI for Cimzia 400 mg minus placebo at weeks 12 and 24 of (17%, 39%) and (22%, 44%), respectively. (1)

Patients with enthesitis (inflammation of the entheses, the sites where tendons or ligaments insert into the bone) at baseline were evaluated for mean improvement in Leeds Enthesitis Index (LEI). Cimzia-treated patients receiving either 200 mg every 2 weeks or 400 mg every 4 weeks showed a reduction in enthesitis of 1.8 and 1.7, respectively as compared with a reduction in placebo-treated patients of 0.9 at Week 12. Similar results were observed for this endpoint at Week 24. Treatment with Cimzia resulted in improvement in skin manifestations in patients with PsA.

In study PsA001, inhibition of progression of structural damage was assessed radiographically and expressed as the change in modified total Sharp score (mTSS) and its components, the Erosion Score (ES) and Joint Space Narrowing score (JSN) at Week 24, compared to baseline. The mTSS score was modified for psoriatic arthritis by addition of hand distal interphalangeal (DIP) joints. Patients treated with Cimzia 200 mg every other week demonstrated greater reduction in radiographic progression compared with placebo-treated patients at Week 24 as

measured by change from baseline in total modified mTSS Score (estimated mean score was 0.18 in the placebo group compared with -0.02 in the Cimzia 200 mg group; 95% CI for the difference was [-0.38, -0.04]). Patients treated with Cimzia 400 mg every four weeks did not demonstrate greater inhibition of radiographic progression compared with placebo-treated patients at Week 24. Cimzia-treated patients showed improvement in physical function as assessed by the HAQ-DI at Week 24 as compared to placebo (estimated mean change from baseline was 0.19 in the placebo group compared with 0.54 in the Cimzia 200 mg group; 95% CI for the difference was [-0.47, -0.22] and 0.46 in the Cimzia 400 mg group; 95% CI for the difference was [-0.39, -0.140]).

**Ankylosing Spondylitis (AS)**

The efficacy and safety of Cimzia were assessed in one multicenter, randomized, double-blind, placebo-controlled study (AS-1) in 325 patients ≥18 years of age with adult-onset active axial spondyloarthritis for at least 3 months. The majority of patients in the study had active AS. Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4, and spinal pain ≥4 on a 0 to 10 Numerical Rating Scale (NRS). Patients must have been intolerant to or had an inadequate response to at least one NSAID. Patients were treated with a loading dose of Cimzia 400 mg at Weeks 0, 2 and 4 (for both treatment arms) or placebo followed by either 200 mg of Cimzia every 2 weeks or 400 mg of Cimzia every 4 weeks or placebo. Concomitant NSAIDs were received by 91% of the AS patients. The primary efficacy variable was the proportion of patients achieving an ASAS20 response at Week 12. In study AS-1, at Week 12, a greater proportion of AS patients treated with Cimzia 200 mg every 2 weeks or 400 mg every 4 weeks achieved ASAS20 response compared to AS patients treated with placebo. Responses were similar in patients receiving Cimzia 200 mg every 2 weeks and Cimzia 400 mg every 4 weeks. Among patients receiving Cimzia, clinical responses were seen in some AS patients within one to two weeks after initiation of therapy. (1)

**Non-radiographic Axial Spondyloarthritis (nr-axSpA)**

The efficacy and safety of Cimzia were assessed in a multicenter, randomized, double-blind, placebo-controlled study (nr-axSpA-1) (NCT02552212) in 317 subjects ≥18 years of age with adult-onset active axial spondyloarthritis for at least 12 months. Patients must have had objective signs of inflammation indicated by C-reactive protein (CRP) levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease [positive CRP (> ULN) and/or positive MRI], but without definitive radiographic evidence of structural damage on sacroiliac joints. Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4, and spinal pain ≥4 on a 0 to 10 Numerical Rating Scale (NRS). Patients must have been intolerant to or had an inadequate response to at least two NSAIDs. Patients were treated with a loading dose of Cimzia 400 mg at Weeks 0, 2 and 4 or placebo followed by 200 mg of Cimzia every 2 weeks or placebo. Utilization and dose adjustment of concomitant medications (including NSAIDs, DMARDs, corticosteroids, opioids) were permitted at any time. Patients were allowed to transition to use of open-label Cimzia at any time at the discretion of the investigator. However, no patients transitioned before Week 12. The primary endpoint was the proportion of patients achieving an Ankylosing Spondylitis Disease Activity Score-Major Improvement (ASDAS-MI)

response at Week 52. The ASDAS is a composite weighted scoring system that assesses disease activity, including patient-reported outcomes and CRP levels. A response in ASDAS-Major Improvement (MI) is indicated by a change from baseline of ≥2.0 in the ASDAS and/or reaching the lowest possible ASDAS value. In study nr-axSpA-1, at Week 52, a greater proportion of nr-axSpA patients treated with Cimzia had ASDAS-MI response compared to patients treated with placebo. At both Weeks 12 and 52, ASAS40 responses were greater for patients treated with Cimzia compared to patients treated with placebo. At Week 12, patients with nr-axSpA treated with Cimzia 200 mg every 2 weeks and Cimzia 400 mg every 4 weeks had an ASAS20 response of 42% and 47%, respectively, compared to 20% of patients treated with placebo. The ASAS40 response in patients treated with Cimzia 200 mg every 2 weeks and 400 mg every 4 weeks was 30% and 37%, respectively, compared to 11% of patients treated with placebo at Week 12. Patients also achieved significantly greater improvement from baseline in the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL) score compared to patients treated with placebo at week 12. (1)

**Plaque Psoriasis**

Three multicenter, randomized, double-blind studies (Study PS-1 [NCT02326298], Study PS-2 [NCT02326272], and Study PS-3 [NCT02346240]) enrolled subjects 18 years of age or older with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Subjects had a Physician Global Assessment (PGA) of ≥ 3 ("moderate") on a 5-category scale of overall disease severity, a Psoriasis Area and Severity Index (PASI) score ≥ 12, and body surface area (BSA) involvement of ≥10%.

Study PS-1 (234 subjects) and PS-2 (227 subjects) randomized subjects to placebo, Cimzia 200 mg every other week (following a loading dose of Cimzia 400 mg at Weeks 0, 2, and 4), or Cimzia 400 mg every other week. Studies PS-1 and PS-2 assessed the co-primary endpoints of the proportion of patients who achieved a PASI 75 and PGA of "clear" or "almost clear" with at least a 2-point improvement at Week 16. Other evaluated outcomes were PASI 90 at Week 16 and maintenance of efficacy to Week 48. (1)

Study PS-3 randomized 559 subjects to receive placebo, Cimzia 200 mg every other week (following a loading dose of Cimzia 400 mg at Weeks 0, 2, and 4), Cimzia 400 mg every other week up to Week 16, or a biologic comparator (up to Week 12). Study PS-3 assessed the proportion of patients who achieved a PASI 75 at Week 12 as the primary endpoint. Other evaluated outcomes were PGA of "clear" or "almost clear" at Week 16, PASI 75 at Week 16, PASI 90 at Week 16, and maintenance of efficacy to Week 48.

Of the 850 subjects randomized to receive placebo or Cimzia in these placebo-controlled studies, 29% of patients were naïve to prior systemic therapy for the treatment of psoriasis, 47% had received prior phototherapy or chemo-phototherapy, and 30% had received prior biologic therapy for the treatment of psoriasis. Of the 850 subjects, 14% had received at least one TNF alpha agent and 16% had received an anti-interleukin (anti-IL) agent. Eighteen percent of subjects reported a history of psoriatic arthritis at baseline.

Across all studies and treatment groups, the mean PASI score at baseline was 20 and ranged from 12 to 69. The baseline PGA score ranged from moderate (70%) to severe (30%). Mean baseline BSA was 25% and ranged from 10% to 96%. Subjects were predominantly men (64%) and White (94%), with a mean age of 46 years.

In PS-1 and PS-2, among subjects who were PASI 75 responders at Week 16 and received Cimzia 400 mg every other week, the PASI 75 response rates at Week 48 were 94% and 81%, respectively. In subjects who were PASI 75 responders at Week 16 and received CIMZIA 200 mg every other week, the PASI 75 response rates at Week 48 were 81% and 74%, respectively.

In PS-1 and PS-2, among subjects who were PGA clear or almost clear responders at Week 16 and received Cimzia 400 mg every other week, the PGA response rates at Week 48 were 79% and 73%, respectively. In subjects who were PGA clear or almost clear responders at Week 16 and received Cimzia 200 mg every other week, the PGA response rates at Week 48 were 79% and 76%, respectively.

In PS-3 study, subjects who achieved a PASI 75 response at Week 16 were re-randomized to either continue treatment with Cimzia or be withdrawn from therapy (i.e., receive placebo). At Week 48, 98% of subjects who continued on Cimzia 400 mg every other week were PASI 75 responders as compared to 36% of subjects who were re-randomized to placebo. Among PASI 75 responders at Week 16 who received Cimzia 200 mg every other week and were re-randomized to either Cimzia 200 mg every other week or placebo, there was also a higher percentage of PASI 75 responders at Week 48 in the Cimzia group as compared to placebo (80% and 46%, respectively).

**Summary of Evidence**

Based on the clinical studies provided to the U.S. Food and Drug Administration (FDA) for approval, Cimzia may be considered medically necessary for the FDA labeled indications of 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 (RA); treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older; treatment of adult patients with active psoriatic arthritis (PsA); treatment of adults with active ankylosing spondylitis (AS); treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Cimzia is considered experimental, investigational and/or unproven for all other non-FDA approved indications.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|---|---|
| **CPT Codes** | None |
| **HCPCS Codes** | J0717 |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

## References


**U.S. Food and Drug Administration Label:**

1. U.S. Food and Drug Administration, Drugs @ FDA. Highlights of Prescribing Information: Cimzia. (Revised 9/2024). Available at <https://www.accessdata.fda.gov> (accessed May 5, 2025).

**Other:**

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8. National Psoriasis Foundation. Plaque Psoriasis (Updated March 26, 2025). Available at: <https://www.psoriasis.org> (accessed May 5, 2025).
9. Cimzia History. A History of helping adults across seven chronic inflammatory diseases (2025). Available at <https://www.cimzia.com> (accessed May 5, 2025).


## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

| Policy History/Revision | |
|---|---|
| **Date** | **Description of Change** |
| 08/15/2025 | Document updated with literature review. The following changes were made to Coverage: 1) Added "Treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older" to list of medically necessary indications; 2) Added "non-FDA approved" to EIU statement; and 3) Removed NOTE 2 and 3. Added reference 4; others updated. |
| 05/15/2024 | Document updated with literature review. Coverage unchanged. No new references added, others updated. |
| 05/01/2023 | Reviewed. The following editorial change was made to Coverage: Added NOTE 1: Cimzia® (certolizumab pegol) may be self-administered. Refer to the applicable pharmacy benefit plan when self-administered. |
| 12/01/2022 | Document updated with literature review. The following change was made to Coverage: Added Note 3 to Coverage: Certolizumab Pegol shall not be used concurrently with other biologics used to treat the indications above. Please refer to Table 1 in the Description Section for a list of biological disease-modifying antirheumatic drugs (DMARDs). Added table to Description with list of disease-modifying antirheumatic drugs (DMARDs). References revised; none added. |
| 09/15/2021 | Reviewed. No changes. |
| 10/01/2020 | New medical document originating from RX501.051 Biologic Response Modifiers (BRMs) for the Treatment of Rheumatoid Arthritis (RA) and Other Chronic Inflammatory Diseases. Certolizumab pegol (Cimzia®) may be considered medically necessary for the following U.S. Food and Drug Administration (FDA) labeled indications: 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 (RA); 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 |

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| | phototherapy. All other uses of Cimzia are considered experimental, investigational and/or unproven. |