SmartHealth Ascension

Certolizumab pegol

(Cimzia®) J0717 (1mg)

Covered with prior authorization

Certolizumab pegol (Cimzia®) may be authorized when the following criteria are met:

Crohn's Disease (CD)

- Individual is 18 years of age or older with moderate to severe CD; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as systemic corticosteroids or immunosuppressants).

Rheumatoid Arthritis (RA)

- Individual is 18 years of age or older with moderate to severe RA; **AND**
- Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose; **OR**
- If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine).

Ankylosing spondylitis (AS)

- Individual is 18 years of age or older with moderate to severe AS; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)].

Non-radiographic axial spondyloarthritis (nr-axSpA)

- Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)].

Psoriatic arthritis (PsA)

- Individual is 18 years of age or older with moderate to severe PsA; **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, or leflunomide)].

Plaque psoriasis (PsO)

- Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque PsO with either of the following:

    - Plaque PsO involving greater than three percent (3%) body surface area (BSA); **OR**
    - Plaque PsO involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
- Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate).

Exclusion criteria:
Requests may not be approved for the following:

- In combination with other TNF antagonists, apremilast, JAK inhibitors, ozanimod, or other biologic drugs (such as, abatacept, anakinra, IL-17 inhibitors, IL-23 inhibitors, ustekinumab, tocilizumab, rituximab, or vedolizumab).
- Tuberculosis, other active serious infections, or a history of recurrent infections.
- If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors).
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Excluded from medical benefit if self-administered.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria
Certolizumab pegol (Cimzia) is considered medically necessary for continued use when the individual has had a positive response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Certolizumab pegol (Cimzia®) is a tumor necrosis factor (TNF) blocker indicated for:

- 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
- 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 phototherapy

References:

1. Cimzia [Prescribing Information]. Smyrna,GA: UCB, Inc,; 2019.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. Fraenkel L, Bathon JM, England BR et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021;73(7):924-939.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022.
5. 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.
6. 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(1): 5-32.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.