MVP Health Care Medical Policy

Medicare Part B: Certolizumab

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**02/01/2025**
Approval Date:	**02/01/2026**
Effective Date:	**04/01/2026**
Related Policies:	**Abatacept, Golimumab, Infliximab, Risankizumab, Tocilizumab, Ustekinumab**

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies for drugs that may be covered under the Part D benefit.

Drug Requiring Prior Authorization under the medical benefit

J0717 Cimzia SQ (certolizumab pegol) powder for injection, physician administered, is non-preferred under the medical benefit

Overview/Summary of Evidence

Certolizumab pegol is a TNF-alpha blocker (TNF-blocker) conjugated to polyethylene glycol for subcutaneous use. It is FDA approved to treat Crohn's Disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondylarthritis. Members should be screened for immunologic and infectious disease prior to initiating therapy.

Indications/Criteria

A. **For all indications,** Certolizumab pegol powder for injection (physician administered) will only be considered for **medical** coverage when:

- Must be prescribed for an FDA approved indication **AND**

- Must be ordered by or with consult from a rheumatologist/immunologist unless otherwise specified below **AND**
- Member has coverage under Medicare Part B and meets the criteria below for a provider administered drug identified in this policy **AND**
- Member meets the diagnosis specific criteria below.

B. **Crohn's disease**

Certolizumab may be considered for coverage for Crohn's Disease when the above criteria is met **AND**:

- Diagnosis of moderate to severe active Crohn's disease confirmed by endoscopy (or capsule endoscopy when appropriate)
- Must be ordered by or with consult from a gastroenterologist/colorectal surgeon
- Documentation should include:
    - Assessment of growth, nutrition, extraintestinal complications, therapy-induced complications and functional ability.
    - Any clinical signs and symptoms outlined in Crohn's disease Activity Index (CDAI) such as frequent liquid stools >4/day, severity grade and frequency of abdominal pain, presence of an abdominal mass, general well-being, extra-intestinal symptoms (arthralgia, uveitis, erythema, stomatitis, absess, fever >37.5 in the last week), taking opiates or diphenoxylate/atropine for diarrhea, anemia, and weight loss >10%.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

C. **Rheumatoid arthritis**

Certolizumab may be considered for coverage for Rheumatoid Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe active adult RA as defined by persistent or recurrent symptoms with documented synovitis and morning stiffness of significant duration to inhibit activities of daily living.
- Chart notes are provided documenting a failure to respond to a three-month trial of methotrexate at a maximally tolerated dose.

- Failure is demonstrated by documentation of provider assessment without improvement in joint counts and/or physical symptoms and inflammatory markers while on therapy.
- If the member has a contraindication or significant intolerance to methotrexate
  - Chart notes documenting a failure to respond to at least one other nonbiologic DMARDs at a maximally tolerated dose for at least 3 months **AND** documentation confirming why methotrexate cannot be used is required. If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. **Psoriasis**

Certolizumab may be considered for coverage for psoriasis when the above criteria is met **AND**:

- The medication is ordered by or in consultation with a dermatologist
- A diagnosis of moderate to severe chronic plaque psoriasis and one of the following:
  - Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected **OR**
  - At least 10% of the body surface area (BSA) is affected **OR**
  - At least 3% of the body surface area (BSA) is affected AND the member meets any of the following criteria:
    - Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) **OR**
    - Member has had an inadequate response or intolerance to pharmacologic treatment with methotrexate, cyclosporine, or acitretin

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

E. **Psoriatic arthritis**
Certolizumab may be considered for coverage for Psoriatic Arthritis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe PsA as defined by three or more tender joints AND three or more swollen joints on two separate occasions at least one month apart

- Chart notes documenting failure of at least one NSAID at maximum tolerated dose unless the member has contraindications to NSAID therapy such as cardiovascular disease, peptic ulcer disease or renal disease **AND**

- Chart notes documenting failure to an adequate trial of at least one of the following nonbiologic disease modifying anti-rheumatic drugs (DMARDs): leflunomide, sulfasalazine, or methotrexate.

    - **Members with pure axial manifestations** do not have to have a trial of nonbiologic disease modifying anti-rheumatic drugs (DMARDs)

    - If a trial of methotrexate is not appropriate due to alcohol use, chart notes must be provided indicating that the patient has been counseled on the need to abstain from alcohol use while taking methotrexate and is unwilling to abstain from alcohol use.

- Members with a documented diagnosis of severe PsA do not require failure of NSAID or DMARD

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

F. **Ankylosing Spondylitis Non-radiographic axial spondylarthritis**

Certolizumab may be considered for coverage for Ankylosing Spondylitis when the above criteria is met **AND**:

- Member has a diagnosis of moderate to severe AS
- Chart notes documenting failure of at least one NSAID at maximum tolerated dose AND documented significant clinical symptoms such as fatigue, spinal pain, arthralgia, inflammation of joints and tendons, morning stiffness duration and therapy AND insufficient response to at least one local corticosteroid injection in patients with symptomatic peripheral arthritis

Initial approval for **6 months**.

Extension requests will be approved for 12 months if the member has a continued benefit to therapy
Extension requests where certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

G. **Juvenile idiopathic arthritis**
Requests for certolizumab treat Juvenile idiopathic arthritis will be reviewed on a case-by-case basis using the American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis.

Initial approval will be for 6 months

Extensions requests will be approved **up to 12 months** if the member has a continued benefit to therapy. Extension requests where the certolizumab did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

Exclusions

The use of certolizumab will not be covered for the following situations:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Combination therapy that is not supported by current clinical guidelines

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References

1. Clinical Pharmacology. Certolizumab. Revised 10/26/2021. Accessed 01/05/2023.
2. Cimzia (certolizumab pegol) for injection, for subcutaneous use. Prescribing information. Smyrna, GA. UCB, Inc. September 2025
3. Torres J, Bonovas S, Doherty G, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. J Crohns Colitis. 2020;14(1):4-22.
4. Lichtenstein G, Loftus E, Issacs K, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. 2018;113(4):481-517.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021;73(7):924-939.
6. 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(4):1029-1072.
7. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
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 Care Res (Hoboken). 2019;71(10):1285-1299.