Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Cimzia® (certolizumab pegol)**

Effective: January 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Cimzia (certolizumab pegol) is a tumor necrosis factor blocker indicated for:

Disease State	
Ankylosing Spondylitis	X
Crohn's Disease	X
Non-radiographic Axial Spondyloarthritis	X
Plaque Psoriasis	X
Polyarticular Juvenile Idiopathic Arthritis	X
Psoriatic Arthritis	X
Rheumatoid Arthritis	X

Clinical Guideline Coverage Criteria

The plan may authorization coverage of Cimzia for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to a prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
   b. Contraindication to non-steroidal anti-inflammatory drugs
   c. Previous treatment with a biologic agent indicated for the requested use
   d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a gastroenterologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, 5-aminosalycylates, 6-mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
    d. Previous treatment with a biologic agent indicated for the requested use
    e. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to a prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
    b. Contraindication to non-steroidal anti-inflammatory drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a dermatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response to one of the following topical therapies: a corticosteroid, a vitamin D analog, tazarotene, calcineurin inhibitor, anthralin, or coal tar
    b. Contraindication to all of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, and coal tar
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Patient is at least 2 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Patient Is at least 18 years of age

AND

3. Prescribed by or consultation with a rheumatologist or dermatologist

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent prior to enrollment

Limitations

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.

Codes

None

References

1. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; September 2024.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of HPHC Pharmacy PA Policy: Page 7 of 7 Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2021;73(7):924- 939.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. 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.

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;80:1029-72.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 12, 2023: No changes
- November 12, 2024: Added coverage criteria for the supplemental indication of polyarticular juvenile idiopathic arthritis (eff 1/1/25)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.