Pharmacy Medical Necessity Guidelines:
Cimzia® (certolizumab pegol)

Effective: January 1, 2023

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<th>Guideline Type</th>
<th>☒ Prior Authorization</th>
<th>☐ Non-Formulary</th>
<th>☐ Step-Therapy</th>
<th>☐ Administrative</th>
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Applies to:

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

CareLinkSM – 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:

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<td>Ankylosing Spondylitis</td>
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<td>Crohn’s Disease</td>
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<td>Plaque Psoriasis</td>
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<td>Psoriatic Arthritis</td>
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<td>Rheumatoid Arthritis</td>
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Clinical Guideline Coverage Criteria

The plan may authorize 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
2. Patient is at least 18 years of age
3. Prescribed by or in consultation with a gastroenterologist
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
2. Patient is at least 18 years of age
3. Prescribed by or in consultation with a rheumatologist
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
2. Patient is at least 18 years of age
3. Prescribed by or in consultation with a dermatologist
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
Psoriatic Arthritis
1. Documented diagnosis of psoriatic arthritis
2. Patient is at least 18 years of age
3. Prescribed by or consultation with a rheumatologist or dermatologist

Rheumatoid Arthritis
1. Documented diagnosis of rheumatoid arthritis
2. Patient is at least 18 years of age
3. Prescribed by or in consultation with a rheumatologist
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 2019.

Approval And Revision History
September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

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.