Pharmacy Medical Necessity Guidelines: Cimzia® (certolizumab pegol)

Effective: July 16, 2018

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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

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

- **Ankylosing Spondylitis**
  - Treatment of adults with active ankylosing spondylitis

- **Crohn's Disease**
  - 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

- **Plaque Psoriasis**
  - Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

- **Psoriatic Arthritis**
  - Treatment of adult patients with active psoriatic arthritis

- **Rheumatoid Arthritis**
  - Treatment of adults with moderately to severely active rheumatoid arthritis

**COVERAGE GUIDELINES**

The plan may authorize coverage of Cimzia (certolizumab pegol) for members when all of the following criteria for a particular regimen are met and limitations do not apply:

**Ankylosing Spondylitis**

1. The Member has a documented diagnosis of active ankylosing spondylitis **AND**
2. The prescription is written by a rheumatologist **AND**
3. The Member is 18 years of age or older **AND**
4. The Member has tried and failed treatment with, or the patient has a contraindication to at least one NSAID **AND**
5. Failure or intolerance to adalimumab (Humira®) and etanercept (Enbrel®) **OR**
6. Documentation of the following:
   - a. The Member is new to the plan and has been stable on Cimzia prior to enrollment
   - b. Documentation the Member has been previously hospitalized for ankylosing spondylitis
Crohn’s Disease
1. The Member has a documented diagnosis of Crohn’s disease by a gastroenterologist
   AND
2. The Member is 18 years of age or older
   AND
3. The Member has demonstrated an inadequate response to an appropriate trial with two or more of the following agents:
   • Corticosteroids (e.g., prednisone)
   • 5-Aminosalicylates (e.g., sulfasalazine)
   • 6-mercaptopurine and/or azathioprine
   • Methotrexate
   AND
4. Failure or intolerance to adalimumab (Humira®)
   OR
5. Documentation of the following:
   a. The Member is new to the plan and has been stable on Cimzia prior to enrollment
   b. Documentation the Member has been previously hospitalized for Crohn’s disease

Psoriatic Arthritis
1. The Member has a documented diagnosis of psoriatic arthritis
   AND
2. The prescription is written by a rheumatologist
   AND
3. The Member is 18 years of age or older
   AND
4. The Member has a documented inadequate response or inability to take methotrexate OR sulfasalazine at maximal doses for three months.
   AND
5. Failure or intolerance to adalimumab (Humira®) and etanercept (Enbrel)
   OR
6. Documentation of the following:
   a. The Member is new to the plan and has been stable on Cimzia prior to enrollment
   b. Documentation the Member has been previously hospitalized for psoriatic arthritis

Note: Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient’s tolerance.

Plaque Psoriasis
1. The Member has a documented diagnosis of plaque psoriasis
   AND
2. The prescribing physician is a dermatologist
   AND
3. The Member is 18 years of age or older
   AND
4. The Member has tried and failed treatment with, or the Member has a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine, or methotrexate
   AND
5. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with adalimumab (Humira®) and etanercept (Enbrel)
   OR
6. Documentation of the following:
   • The Member is new to the plan and has been stable on Cimzia prior to enrollment
   • Documentation the Member has been previously hospitalized for plaque psoriasis

Rheumatoid Arthritis
1. The Member has a documented diagnosis of rheumatoid arthritis by a rheumatologist
   AND
2. The Member is 18 years of age or older
   AND
3. The Member tried and failed treatment with, or has a contraindication to at least one DMARD (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, methotrexate, penicillamine, sulfasalazine, cyclosporine or leflunomide AND

4. Failure or intolerance to adalimumab (Humira®) and etanercept (Enbrel®) OR

5. Documentation of the following:
   a. The Member is new to the plan and has been stable on Cimzia prior to enrollment
   b. Documentation the Member has been previously hospitalized for rheumatoid arthritis

Note: Maximal doses of methotrexate are defined as 15mg to 25mg per week depending on the patient’s tolerance.

LIMITATIONS
1. Samples, free goods or similar offerings of Cimzia (certolizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
2. Members new to the plan and stable on Cimzia (certolizumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, sulfasalazine).
3. Initial approval of Cimzia (certolizumab pegol) will be limited to 12 months. Subsequent authorizations may be approved in 12 month intervals when the provider indicates improvement with therapy.
4. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
5. Documentation of a Member being a social drinker does not qualify a medically acceptable contraindication to methotrexate therapy.
6. Coverage of Cimzia prefilled syringe is limited to 28-day supplies as follows:
   - Cimzia 200 mg syringe – 6 syringes per 28 days (initial 4 weeks) then 2 syringes per 28 days thereafter.

CODES
Medical billing codes may not be used for this medication. This medication must be obtained via the Member’s pharmacy benefit.

REFERENCES


**APPROVAL HISTORY**

June 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- December 2, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- September 16, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- September 13, 2016: Added exception language for Members new to the plan and stable on Cimzia prior to enrollment.
- November 18, 2016: Administrative update; clarified for the diagnosis of Crohn’s disease that member must have tried and failed a nonbiologic DMARD and adalimumab (Humira).
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: Administrative update to add the following Limitation: Samples, free goods or similar offerings of Cimzia (certolizumab) do not qualify for an established clinical response and will not be considered for prior authorization.
- December 12, 2017: Effective January 1, 2018 updated the criteria allowing members new to the plan stable on Cimzia (certolizumab) to also require documentation of previous hospitalization for the requested indication due to new state requirements. Added the following limitation: Members new to the plan and stable on Cimzia (certolizumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., hydroxychloroquine, methotrexate, NSAID).
- July 10, 2018: Added coverage criteria for the supplemental indication for the treatment of plaque psoriasis. Added the following coverage limitations: For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy, and documentation of a
Member being a social drinker does not qualify a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.