Cimzia® (certolizumab pegol)
Effective: 10/1/15

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<td>Fax: 617-673-0988</td>
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OVERVIEW
FDA-APPROVED INDICATIONS
Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker indicated for:

Ankylosing Spondylitis
Treatment of adults with active ankylosing spondylitis (AS).

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.

Psoriatic Arthritis
Treatment of adult patients with active psoriatic arthritis (PsA).

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

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Cimzia (certolizumab pegol) for members when all the following criteria for a particular regimen are met and limitations do not apply:

For 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 does the patient have a contraindication to at least one NSAID AND
5. Failure or intolerance to adalimumab (Humira®) and etanercept (Enbrel®).

For 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, prednisolone, methylprednisolone)
   - 5-Aminosalicylates (e.g., sulfasalazine, Azulfidine®, Apriso™, Delzicol™, Pentasa®, Rowasa®, Dipentum®, Colazal®)
   - 6-mercaptopurine (6-MP, Purinethol®), azathioprine (Imuran®) or cyclosporine
   - Methotrexate (MTX) OR
4. Failure or intolerance to adalimumab (Humira®).

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

**For 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®).

**LIMITATIONS**

1. 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.
2. Coverage of Cimzia prefilled syringe is approved in 12 month intervals when the provider indicates improvement with therapy.
   - 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 the Pharmacy and Therapeutics Committee.
- December 2, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
- September 16, 2015: No changes.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.