I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

Certolizumab Pegol (Cimzia®) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the prior authorization process for Certolizumab Pegol (Cimzia)

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. **PROCEDURE**

Certolizumab pegol (Cimzia) is a PEGylated anti-tumor necrosis factor (TNF) indicated for reducing the signs and symptoms of Crohn’s disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

**Criteria**

**Initial Authorization Criteria**

- Members must have a negative Tuberculin PPD (purified protein derivative) test
- Members must have a confirming diagnosis by a gastroenterologist
- Members must have diagnosis of moderate to severe active Crohn’s disease
- Members must have:
  - Tried conventional therapy including aminosalicylates (i.e., sulfasalazine, mesalamine), corticosteroids or immunomodulators (i.e., azathioprine, 6-mercaptopurine)
- Member must currently not be using a TNF-blocking agent, such as Humira®, Enbrel®, or Remicade® or other biologic agent, such as Kineret®
- Dosage:
  - **Crohn’s Disease induction**: 400 mg subcutaneous at weeks 0, 2, and 4.
  - **Crohn’s Disease maintenance**: 400 mg subcutaneous every 4 weeks.
- Aminosalicylates, corticosteroids, and/or immunomodulatory agents may be continued during treatment with Cimzia
- The medication will be approved based upon the above criteria for an initial period of one year.

**Reauthorization Criteria**

All prior authorization renewals will be reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the provider that the member’s disease has improved/stable based upon the prescriber’s assessment while on therapy.

**Limitations**

If the established criteria are not met, the prior authorization request will be referred to the UPMC Health Plan Medical Director.

VI. **BIBLIOGRAPHY**

2. AMCP Dossier for Cimzia. UCB, Inc. Smyrna, GA; 2008.