Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

CIMZIA (certolizumab pegol)

GPI CODING:

525050201064**

DESCRIPTION:

CIMZIA® (certolizumab pegol) is a pegylated formulation of a tumor necrosis factor (TNF) blocker. It binds to human tumor necrosis factor alpha (TNFα) and inhibits its role as a mediator of inflammation. TNFα is a pro-inflammatory cytokine with a central role in inflammatory processes. Certolizumab pegol selectively neutralizes membrane-associated and soluble human TNFα in a dose-dependent manner, but does not neutralize lymphotoxin α (TNFβ). Biological activities ascribed to TNFα include the upregulation of cellular adhesion molecules and chemokines, upregulation of major histocompatibility complex (MHC) class I and class II molecules, and direct leukocyte activation. TNFα stimulates the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide. Elevated levels of TNFα have been implicated in the pathology of Crohn's disease and rheumatoid arthritis.

APPROVAL DURATION:

Approval is for lifetime

Certolizumab pegol will be subject to a quantity limit of 2 vials (200 mg) or prefilled syringes (200 mg/ml) every 28 days. For initial therapy, additional vials/syringes will be allowed for patients with rheumatoid arthritis (up to 6 vials/syringes in the first 4 weeks of therapy).

CRITERIA FOR CIMZIA

I. Patient does not have an active serious infection (including tuberculosis [TB]) **AND**
II. Patient has been tested for TB infection **AND**
III. Latent TB infection if present has been or is being treated

AND

<u>Crohn's Disease</u>

I. Patient has a diagnosis of moderate to severe Crohn's disease **AND**
II. Patient is ≥ 18 years of age **AND**
III. Patient has had inadequate responses to, is intolerant to, or is contraindicated to conventional therapy with two or more drugs in the following classes:
    a. Corticosteroids (i.e., prednisone, methylprednisolone)
    b. Non-biologic DMARDs (i.e., azathioprine, methotrexate, mercaptopurine; see Table 1) **AND**
IV. Patient has failed to achieve symptom control after an adequate therapy with, is intolerant to, or is contraindicated to adalimumab [HUMIRA®].

OR

<u>Rheumatoid Arthritis</u>

I. Patient has a diagnosis of moderate to severe rheumatoid arthritis **AND**
II. Patient is ≥ 18 years of age **AND**

III. Patient has had inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs; see Table 1) for at least 3 consecutive months **AND**

IV. Patient has failed to achieve symptom control after an adequate therapy with, is intolerant to, or is contraindicated to both adalimumab [HUMIRA®] AND etanercept [ENBREL®]

Table 1: Non-biologic Disease-Modifying Anti-rheumatic Drugs (DMARDs)		
Drug	**Treatment Period**	**Usual Maintenance Dose**
Hydroxychloroquine	2 to 6 months	200 mg twice daily
Sulfasalazine	1 to 3 months	1000 mg 2 to 3 times daily
Methotrexate	1 to 2 months	7.5-20 mg weekly
Leflunomide	4 to 12 weeks	10-20 mg daily
Injectable gold salts	3 to 6 months	25-50 mg IM every 2-4 weeks
Oral gold	4 to 6 months	3 mg once or twice daily
Azathioprine	2 to 3 months	50-150 mg daily
D-penicillamine	3 to 6 months	250-750 mg daily
Cyclosporine	2 to 4 months	2.5-4 mg/kg/day
Minocycline	1 to 3 months	100 mg twice daily