BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 07/09/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

CIMZIA® (certolizumab pegol)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Cimzia is a tumor necrosis factor (TNF) inhibitor. TNF inhibitors are naturally occurring proteins involved in the body's normal immune responses. Overproduction of TNF can cause inflammation and tissue damage. TNF inhibition may ease certain inflammatory disease symptoms and prevent disease progression.

Definitions:

Adult: Age 18 years and older

Preferred TNF Medications:
- Enbrel®
- Humira®
- Remicade®

CIMZIA® (certolizumab pegol)

Definitions: (cont.)

Significant Adverse Drug Event:
A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Criteria:

See Resources section for FDA-approved dosage.

- FDA-approved dosage of Cimzia is considered ***medically necessary*** for adults with moderately to severely active rheumatoid arthritis or moderately to severely active Crohn's disease, active psoriatic arthritis or ankylosing spondylitis with documentation of **ALL** of the following:

  1. Failed response to the preferred TNF medications Enbrel **AND** Humira **AND** Remicade (unless otherwise contraindicated) with documentation of **ANY** of the following: [1]

     - Individual's condition has not improved or has worsened
     - Individual experienced a significant adverse drug event to the preferred TNF medications
     - Individual is intolerant to the preferred TNF medications
     - Individual is non-adherent to the preferred TNF medications

  2. No evidence of active serious infections including clinically important localized infections or sepsis when initiating or continuing therapy
  3. Evidence of testing for latent tuberculosis before Cimzia use and during therapy and any treatment for latent infection has been initiated prior to Cimzia therapy
  4. Evidence of testing for hepatitis B infection before Cimzia use and ongoing monitoring in individuals who are known hepatitis B carriers for reactivation of this viral infection during Cimzia therapy
  5. No evidence of lupus-like syndrome while on Cimzia therapy
  6. Evidence of close monitoring in individuals who have a history of or develop heart failure while on Cimzia therapy
  7. Cimzia is not being used concurrently with anakinra (e.g., Kineret®), abatacept (e.g., Orencia®), rituximab (e.g., Rituxan®), natalizumab (e.g., Tysabri®), other biologic DMARDs, TNF antagonists, live vaccines or live attenuated vaccines
  8. Dosage is not greater that the FDA approved dosing for the labeled indication (refer to dosing table)

CIMZIA (certolizumab pegol) (cont.)

Criteria: (cont.)

- Cimzia for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These indications include, *but are not limited to:*

  - Inflammatory bowel diseases other than Crohn's disease
  - Ulcerative colitis

[1] Not applicable for current members on Cimzia prior to 07/09/14 or new members who are actively being treated with Cimzia prior to their effective date with BCBSAZ. (Excludes any changes in route of administration, such as changing intravenous delivery to subcutaneous delivery.)

Resources:

1. Biologics & Non-TNF Agents Potentially Winners in the New ACR Guidelines for Early & Experienced Rheumatoid Arthritis (RA) Patients. Specialty Pharma Journal. Received 06/11/2012.

CIMZIA (certolizumab pegol) (cont.)

Resources: (cont.)

Cimzia Package Insert:

- FDA-approved indication and dosage:

Indication	Recommended Dose
Adult moderately to severely active Crohn's Disease	Cimzia is administered by subcutaneous injection. 400 mg (given as two injections of 200 mg) initially and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.
Adult moderately to severely active rheumatoid arthritis	400 mg (given as two subcutaneous injections of 200 mg) initially and at Weeks 2 and 4, followed by 200 mg every other week or alternatively 400 mg every four weeks.
Adult psoriatic arthritis	400 mg (given as two subcutaneous injections of 200 mg) initially and at Weeks 2 and 4, followed by 200 mg every other week or alternatively 400 mg every four weeks.
Adult ankylosing spondylitis	400 mg (given as two subcutaneous injections of 200 mg) initially and at Weeks 2 and 4, followed by 200 mg every two weeks or alternatively 400 mg every four weeks.