Pharmacy Policy

Cimzia (certolizumab pegol)

Policy Number: 9.116
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Cimzia (certolizumab pegol)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All medically accepted indications not otherwise excluded
Exclusion Criteria	Use of Cimzia with other biologics
Required Medical Information	1. Ankylosing Spondylitis (AS); ***AND*** a. An inadequate response, intolerance, or contraindication to at least one formulary NSAID; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel,Humira or Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira, or Cosentyx 2. Active Crohn's Disease (CD); ***AND*** a. An inadequate response, contraindication or intolerance to all of the following:

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	i. an aminosalicylate (e.g. mesalamine) ; and ii. methotrexate; and iii. a corticosteroid; and iv. an immunomodulator (e.g., azathioprine, 6-mercaptopurine, or methotrexate); ***AND*** b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira. 3. Moderate to severe Plaque Psoriasis (Ps); ***AND*** a. One of the following: i. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira or Cosentyx ; ***OR*** ii. An inadequate response, or adverse reaction to two conventional therapies in any one of the following combinations (please note: these combinations DO NOT have to be used concurrently): 1. one topical agent plus one systemic agent; ***OR*** 2. one topical agent plus one phototherapy; ***OR*** 3. one systemic agent plus one phototherapy; ***OR*** 4. two systemic agents; ***OR*** b. A contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents) 4. Psoriatic Arthritis (PsA); ***AND*** a. An inadequate response or intolerance to at least one non-biologic DMARD for at least three months; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira or Cosentyx 5. Rheumatoid Arthritis (RA); ***AND*** a. An inadequate response or intolerance to at least one formulary non-biologic DMARD, or is currently on methotrexate; ***AND*** b. An inadequate response, intolerance, or contraindication to Enbrel or Humira or a clinical rationale for the use Cimzia instead of Enbrel or Humira; ***OR*** 6. Non-Radiographic axial spondyloarthritis (nr-axSpA) a. Provider attestation that there is active inflammation of the sacroiliac joints b. An inadequate response, intolerance, or contraindication to at least 2 NSAIDs.
Age Restrictions	18 years of age and older
Prescriber Restriction	CD: Prescribed by or in consultation with a gastroenterologist AS, RA: Prescribed by or in consultation with a rheumatologist PsA: Prescribed by or in consultation with a dermatologist or rheumatologist Ps: Prescribed by or in consultation with a dermatologist nr-axSpA: Prescribed by or in consultation with a rheumatologist
Coverage	12 months

Duration	
Other criteria	Reauthorization: 1. Patient's clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J0717	Cimzia® (certolizumab pegol)

Clinical Background Information and References

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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.179 Cimzia Policy retired, new policy created. Updated to reflect NH PDL Preferred drugs, changed requirement for PsA from two to three months to reflect EULAR guidelines, removed MRI requirement for nr-axSpA, added prescriber restriction for nr-axSpA, updated Crohn's Disease T/F requirements to match Humira	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.