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Policy Number: C10269-A

## Cimzia (certolizumab pegol)

### PRODUCTS AFFECTED

Cimzia (certolizumab pegol)

### COVERAGE POLICY

*Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive*

#### **DIAGNOSIS:**

Active psoriatic arthritis, Active ankylosing spondylitis, Crohn's Disease, Rheumatoid Arthritis, Non- Radiographic Axial Spondyloarthritis, Plaque Psoriasis

#### **REQUIRED MEDICAL INFORMATION:**

*This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review*

#### **FOR ALL INDICATIONS:**

1. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests  
OR  
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12

## Drug and Biologic Coverage Criteria

months) OR that member has been cleared by an infectious disease specialist to begin treatment AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment  
AND
3. Member is not on concurrent treatment or will be used in combination with other TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation  
AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections  
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT/DOSAGE FORM:  
Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. If yes, please submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s)

### A. MODERATE TO SEVERE RHEUMATOID ARTHRITIS:

1. Documentation of moderate to severe rheumatoid arthritis diagnosis  
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate of therapy at renewal  
AND
3. (a) Member is concurrently receiving methotrexate  
OR  
(b) Member tried, failed, or has an FDA labeled contraindication or intolerance to methotrexate, as determined by the prescribing physician AND member has tried one additional disease modifying antirheumatic drug (DMARD) (brand or generic; oral or injectable) for at least 3 months  
*(NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the Member has already had a 3-month trial at least one biologic. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD)*  
OR  
(c) has early RA (defined as disease duration of < 6 months) with at least one of the following features of poor prognosis: functional limitation (e.g., based on Health Assessment Questionnaire Disability Index [HAQ-DI] score); extra articular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome; positive rheumatoid factor or anti-cyclic citrullinated protein (anti-CCP) antibodies; or bony erosions by radiograph

### B. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis  
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy  
AND
3. (a) Documented treatment failure with or an FDA labeled contraindication to a minimum 3-month trial of ONE  
of the following Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine  
OR  
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]

## Drug and Biologic Coverage Criteria

OR

(c) Documentation member has severe psoriasis [PASI  $\geq 12$ , BSA of  $>5$ -10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]

### C. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA 3%-10%-moderate,  $>10$ %-severe) OR  $\leq 10$ % body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (ex. face, neck, hands, feet, genitals)  
AND
2. (a) Documentation of treatment failure with or a clinical contraindication to TWO of the following systemic therapies for  $\geq 3$  months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, sulfasalazine, or tacrolimus  
OR  
(b) Documentation of treatment failure to Phototherapy for  $\geq 3$  months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)  
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

### D. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:

1. Documentation of moderate to severe ankylosing spondylitis diagnosis  
AND
2. Prescriber attests to inadequate response or FDA labeled contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for  $\geq 3$  consecutive months at maximal recommended or tolerated anti-inflammatory doses  
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal  
AND
4. FOR THE MEMBER'S WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of trial ( $\geq 3$  consecutive months) or FDA labeled contraindication to methotrexate OR sulfasalazine

### E. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:

1. Prescriber attests to diagnosis of adult-onset active axial spondylarthritis  
AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease  
AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints.  
AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal  
AND
5. Prescriber attestation of member having an inadequate response or FDA labeled contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for  $\geq 3$  consecutive months at maximal recommended or tolerated anti-

## Drug and Biologic Coverage Criteria

inflammatory doses

### F. MODERATE TO SEVERE ACTIVE CROHN'S DISEASE:

1. Documentation of a diagnosis of currently ACTIVE moderate to severely active Crohn's Disease (Crohn's disease activity index-CDAI score of 221- 450)  
AND
  2. (a) Member has had a trial (>3 months) and inadequate response to ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses unless contraindicated or significant adverse reactions are experienced  
OR  
(b) Prescriber provides documented medical justification that supports the inability to use immunomodulators
    - i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
    - ii. High-risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction, or abscess
    - iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgery
- AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal

### CONTINUATION OF THERAPY:

#### FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)  
AND
2. Documentation of no intolerable adverse effects or drug toxicity  
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms.  
AND
4. (a) Prescriber attests member has had a negative TB screening or TB test result within the last 12 months for initial and continuation of therapy requests  
OR  
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months)  
OR that member has been cleared by an infectious disease specialist to begin treatment

### DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

### PRESCRIBER REQUIREMENTS:

MODERATE TO SEVERE RHEUMATOID ARTHRITIS: Prescribed by or in consultation with a board-certified rheumatologist

PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a board-certified rheumatologist or dermatologist

## Drug and Biologic Coverage Criteria

**CHRONIC PLAQUE PSORIASIS:** Prescribed by or in consultation with a board-certified dermatologist

**MODERATE TO SEVERE ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:** Prescribed by or in consultation with a board-certified rheumatologist

**CROHNS DISEASE:** Prescribed by or in consultation with a board-certified gastroenterologist, colorectal surgeon or specialist who is consulting with a board-certified gastroenterologist or colorectal surgeon

[If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

### **AGE RESTRICTIONS:**

18 years of age or older

### **QUANTITY:**

Plaque psoriasis: 400mg (two 200 mg syringes) every other week (4 syringes per 28 days). For some patients (with body weight  $\leq 90$  kg), CIMZIA 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at Weeks 2 and 4, followed by 200 mg every other week can be considered.

All other indications: Six 200mg syringes for the initial 4 weeks, then two syringes per 28 days thereafter

### **PLACE OF ADMINISTRATION:**

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

### **ROUTE OF ADMINISTRATION:**

Subcutaneous

### **DRUG CLASS:**

Tumor Necrosis Factor Alpha Blockers

### **FDA-APPROVED USES:**

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, Treatment of adults with moderately to severely active rheumatoid arthritis, Treatment of adult patients with active psoriatic arthritis, Treatment of adults with active ankylosing spondylitis, Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation, Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

### **COMPENDIAL APPROVED OFF-LABELED USES:**

None

## APPENDIX

### **APPENDIX:**

## Drug and Biologic Coverage Criteria

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or enthesal) with  $\geq 3$  points from any of the following five categories:

1. Evidence of current psoriasis,<sup>b,c</sup> a personal history of psoriasis, or a family history of psoriasis<sup>d</sup>
2. Typical psoriatic nail dystrophy<sup>e</sup> observed on current physical examination
3. A negative test result for rheumatoid factor
4. Either current dactylitis or a history of dactylitis recorded by a rheumatologist
5. Radiographic evidence of juxtaarticular new bone information<sup>g</sup> in the hand or foot

<sup>a</sup> Specificity of 99% and sensitivity of 91%. <sup>b</sup> Current psoriasis is assigned 2 points; all other features assigned 1 point. Psoriatic skin or scalp disease at the time of examination, as judged by a rheumatologist or dermatologist. <sup>c</sup> H

hyperkeratosis. <sup>f</sup> Swelling of an entire digit. <sup>g</sup> Ill-defined ossification near joint margins, excluding osteophyte formation.  
Source: From W Taylor et al: Arthritis Rheum, 54:2665,2006.

### Psoriatic Arthritis

An estimated 1% of the U.S. adult population harbors cutaneous evidence of psoriasis, characterized by well- demarcated erythematous scaly plaques, some of whom develop a related arthritis. In fact, there are several distinct subsets of psoriatic arthritis, including (a) an asymmetric oligoarthritis affecting lower extremity joints; (b) a symmetric polyarthritis affecting upper and lower extremity joints; (b) monoarticular involvement of a distal interphalangeal joint alone; (d) a destructive finger joint arthritis that produces “telescoping,” a shortening of the digit as a consequence of aggressive bone destruction and resorption (arthritis mutilans); and (e) axial skeleton involvement (spondylitis, sacroiliitis).

## BACKGROUND AND OTHER CONSIDERATIONS

### BACKGROUND:

Cimzia is a tumor necrosis factor (TNF) alpha blocker and is a recombinant humanized antibody Fab fragment (fragment antigen binding) that is a covalent conjugate to polyethylene glycol (PEG). Pegylation delays the elimination of PEG polymers and the antibody, thus increasing the terminal elimination half-life of the Fab fragment. Unlike Remicade® (infliximab for intravenous [IV] infusion) and Humira® (adalimumab for SC injection), Cimzia does not contain an Fc portion of the antibody. Cimzia neutralizes the biological activity of TNF $\alpha$  and inhibits binding of TNF $\alpha$  with its receptors.

TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. Increased levels of TNF have been implicated in the pathology of Crohn's disease, psoriatic arthritis, and rheumatoid arthritis (RA). Increased levels of TNF are found in the synovial fluid of patients with RA and TNF has an important role in both the pathologic inflammation and the joint destruction that are characteristic of this disease. Increased levels of TNF are found in the bowel wall in areas involved by Crohn's disease. After treatment with Cimzia, patients with Crohn's disease have decreased levels of C-reactive protein (CRP).

### CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cimzia (certolizumab pegol) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

### OTHER SPECIAL CONSIDERATIONS:

Boxed warning for serious infections and malignancy.

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

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## Drug and Biologic Coverage Criteria

HCPCS CODE	DESCRIPTION
N/A	N/A

### AVAILABLE DOSAGE FORMS:

Cimzia KIT 2 X 200MG

Cimzia Prefilled KIT 2 X 200MG/ML

Cimzia Starter Kit 6 X 200MG/ML

### REFERENCES

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc; September 2019.
2. Lichtenstein GR, Abreu MT, Cohen R, Tremaine W. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. *Gastroenterology* 2006 Mar;130(3):935-9.
3. van der Heijde D, Ramiro S, Landewe R, et al. 2016 Update of the international ASAS-EULAR management recommendations for axial spondyloarthritis. *Ann Rheum Dis*. 2017;0:1-14.
4. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Ann Rheum Dis*. 2017;0:1-18.
5. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
6. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum*. 2008;59(6):762-784.
7. Menter A, Korman NJ, Elmetts CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011;65(1):137- 174.
8. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies; 2015 update. *Ann Rheum Dis*. 2016;75(3):499-510.
9. Gladman DD, Antoni C, P Mease, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64(Suppl II):ii14–ii17.
10. Peluso R, Lervolino S, Vitiello M, et al. Extra-articular manifestations in psoriatic arthritis patients. [Published online ahead of print May 8, 2014]. *Clin Rheumatol*. 2014.
11. Braun J, van den Berg R, Baraliakos X, et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis*. 2011;70:896–904.
12. Landewe R, Braun J, Deodhar A, et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. *Ann Rheum Dis*. 2014;73(1):39-47.
13. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2015; 10.1002/art.39298. [Epub ahead of print].
14. Talley NJ, Abreu MT, Achkar J, et al. An evidence-based systematic review on medical therapies for inflammatory bowel disease. *Am J Gastroenterol*. 2011;106(Suppl 1):S2-S25