Original Effective Date: 10/1/2012
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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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

Drug and Biologic Coverage Criteria

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   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
   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 not 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 serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. 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 [DOCUMENTATION REQUIRED]
   AND
3. (a) Member is currently receiving maximally tolerated dose of methotrexate and is not at goal disease activity
   OR
   (b) Member has an FDA labeled contraindication or serious side effects 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 of at least one biologic. These members who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD.*)

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 [DOCUMENTATION REQUIRED]
   AND
3. (a) Documented treatment failure, serious side effects or clinical 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]
OR
(c) Documentation member has severe psoriasis [PASI ≥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%) OR < 3% 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, serious side effects, or clinical contraindication to TWO of the following systemic therapies for ≥3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥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 [DOCUMENTATION REQUIRED]

D. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of moderate to severe ankylosing spondylitis diagnosis
AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effect or clinical contraindication to a trial
(≥3 consecutive months) of methotrexate OR sulfasalazine AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:
1. Prescriber attests to diagnosis of adult-onset 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 [DOCUMENTATION REQUIRED]
AND

5. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti-inflammatory doses

F. MODERATE TO SEVERE ACTIVE CROHN'S DISEASE:

1. Documentation of a diagnosis of Crohn's Disease
AND
2. Member has one or more high risk feature:
   i. Diagnosis at a younger age (<30 years old)
   ii. History of active or recent tobacco use
   iii. Elevated C-reactive protein and/or fecal calprotectin levels
   iv. Deep ulcers on colonoscopy
   v. Long segments of small and/or large bowel involvement
   vi. Perianal disease
   vii. Extra-intestinal manifestations
   viii. History of bowel resections
AND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (> 3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses
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
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

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
AND
2. Prescriber attests to or clinical reviewer has found no evidence of 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 [DOCUMENTATION REQUIRED]
AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB

screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests

*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.

**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis

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:
RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 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

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

CROHN'S DISEASE: Prescribed by or in consultation with a board-certified gastroenterologist or colorectal surgeon
[If prescribed in consultation, consultation notes must be submitted with 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 ≤ 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: 400mg initially, and at weeks 2 and 4, followed by 200mg every other week OR 400mg every 4 weeks

Maximum Quantity Limits – Six 200mg syringes for the initial 4 weeks, then two syringes per 28 days

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:
Indicated for:

- 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:

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or entheseal) with ≥3 points from any of the following five categories:
1. Evidence of current psoriasis,[b,c] a personal history of psoriasis, or a family history of psoriasis[d]
2. Typical psoriatic nail dystrophy[e] observed on current physical examination
3. A negative test result for rheumatoid factor
4. Either current dactylitis[f] or a history of dactylitis recorded by a rheumatologist
5. Radiographic evidence of juxtaarticular new bone formation[g] in the hand or foot

[a] Specificity of 99% and sensitivity of 91%. [b] Current psoriasis is assigned 2 points; all other features are assigned 1 point. [c] Psoriatic skin or scalp disease present at the time of examination, as judged by a rheumatologist or dermatologist. [d] History of hyperkeratosis. [e] Swelling of an entire digit. [g] 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; (c) 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 TNFα and inhibits binding of TNFα 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. Contraindications to Cimzia (certolizumab pegol) include: Serious hypersensitivity reaction to certolizumab pegol or to any of the excipients, use with live (including attenuated) vaccines.

OTHER SPECIAL CONSIDERATIONS:

Cimzia has a Black Boxed warning for serious infections and malignancy. Increased risk of serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which Cimzia is a member. Cimzia is not indicated for use in pediatric patients.

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

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:

Cimzia KIT 2 X 200MG
Cimzia Prefilled Syringe KIT 2 X 200MG/ML
Cimzia Starter Kit 6 X 200MG/ML

REFERENCES

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Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity Other Special Considerations References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file