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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, Polyarticular juvenile idiopathic arthritis

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.

A. FOR ALL INDICATIONS:

1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label

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AND

2. 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
3. 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).
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

B. 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 efficacy 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.

C. 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 \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]

D. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA $\geq 3\%$) 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 or serious side effects 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

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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, or number of sessions.

OR

(c) Documentation of contraindication to systemic therapy and phototherapy

NOTE: Contraindications to phototherapy 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]

E. 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]

F. NON-RADIOGRAPHIC AXIAL Spondyloarthritis:

1. Documented 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

G. 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

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- 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]

H. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS:

- 1. Documented diagnosis of polyarticular juvenile idiopathic arthritis in a pediatric member
AND
- 2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
- 3. Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (generally ≥12 weeks) of one or more of the following: Methotrexate, hydroxychloroquine, sulfasalazine, leflunomide

CONTINUATION OF THERAPY:

A. 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. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:

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

PRESCRIBER REQUIREMENTS:

RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS, NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS, POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: Prescribed by or in

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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:

POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS: 2 years of age and older

ALL OTHERS: 18 years of age and older

QUANTITY:

Plaque psoriasis: 400mg (two 200 mg injections) 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.

Polyarticular juvenile idiopathic arthritis:

10kg to less than 20kg: 100 mg initially and at weeks 2 and 4, followed by 50 mg every other week

20kg to less than 40kg: 200 mg initially and at weeks 2 and 4, followed by 100 mg every other week

Greater than or equal to 40kg: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week

Crohn's Disease: 400 mg initially and at Weeks 2 and 4. If response occurs, follow with 400 mg every four weeks

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 as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Cimzia (certolizumab pegol) to channel to the prescription drug benefit for member self-administration as appropriate. For information on site of care, see [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](http://molinamarketplace.com).

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

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- Treatment of adults with moderately to severely active rheumatoid arthritis
- Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
- 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:

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

State Specific Information

State Marketplace

Illinois (Source: [Illinois General Assembly](#))

"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

To meet the CASPAR criteria, a patient must have inflammatory articular disease (joint, spine, or enthesal) 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. ^f 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

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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 α and inhibits binding of TNF α 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 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, avoid 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.

CODING/BILLING INFORMATION

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
N/A	N/A

AVAILABLE DOSAGE FORMS:

Cimzia KIT 2 X 200MG single-dose vial

Cimzia (2 Syringe) PSKT 200MG/ML single-dose prefilled syringe

Cimzia Starter PSKT 200MG/ML single-dose prefilled syringe

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Quantity Place of Administration Appendix References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Other Special Considerations References	Q4 2024
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