MEDICAL MUTUAL®

Drug Policy

Policy:	**200913**	**Initial Effective Date: 11/24/2009**
Code(s):	**J0717**	**Annual Review Date: 11/15/2018**
SUBJECT:	**Cimzia® (certolizumab pegol for subcutaneous [SC] injection [lyophilized] and SC injection [solution] – UCB)**	**Last Revised Date: 11/15/2018**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Definition: 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).[1] 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).

Boxed Warnings
Cimzia has boxed warnings concerning risks of serious infection and the risk of malignancy.[1] Prior to initiating therapy with Cimzia, patients should be evaluated for active tuberculosis (TB) infection, and periodically during therapy patients should be assessed for latent TB infection. Patients should also be monitored for signs and symptoms of infection during and after treatment with Cimzia, and if a serious infection or sepsis develops, Cimzia should be discontinued. It is also recommended that patients treated with any TNF antagonist should be monitored for malignancies.

POLICY STATEMENT

This policy involves the use of Cimzia. Prior authorization is recommended for pharmacy and medical benefit coverage of Cimzia. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing (medical benefit requests only), Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Cimzia as well as the monitoring required for AEs and long-term efficacy, initial approval requires Cimzia be prescribed by or in consultation

with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

The site of care medical necessity criteria applies to initial therapy and reauthorizations under the medical benefit only.*

Recommended Authorization Criteria
Coverage of Cimzia is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Ankylosing Spondylitis (AS).**
   - **a)** Initial Therapy. Approve for 3 months if Cimzia is prescribed by or in consultation with a rheumatologist AND site of care medical necessity is met*.
   - **b)** Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response (e.g., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia. Site of care medical necessity must be met*

   Cimzia is indicated for AS.[1] In the pivotal trial, Cimzia was effective in patients with active AS despite therapy with a DMARD; approximately 20% of patients had previously tried a TNF blocker (note: primary failures were excluded).[1,9] In this study, Cimzia was equally effective in patients who had confirmed axial spondyloarthritis (axSpA) vs. non-radiographic (nr)-axSpA. According to the Assessment of SpondyloArthritis International Society/European League Against Rheumatism (ASAS/EULAR) 2010 recommendations for AS, all patients should have an adequate trial of at least two nonsteroidal anti-inflammatory drugs (NSAIDs) for pain and stiffness, unless contraindicated.[10-12] Recommendations for other therapies before receiving TNF blocker therapy vary according to the manifestations of the disease, level of current symptoms, clinical findings, etc. According to these recommendations, patients with pure axial manifestations do not have to try traditional DMARDs before anti-TNF agents; patients with symptomatic peripheral arthritis should have an insufficient response to at least one local corticosteroid injection, if appropriate; patients with persistent peripheral arthritis should normally have a trial of a DMARD, preferably sulfasalazine; and patients with enthesitis should try appropriate local therapy (e.g., corticosteroid injection in selected cases).

   Dosing in Ankylosing Spondylitis. The recommended dose of Cimzia for adult patients with ankylosing spondylitis is 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at weeks 2 and 4, followed by 200 mg every 2 weeks or 400 mg every 4 weeks.[1]

2. **Crohn's Disease in an Adult.** Approve if the patient meets the following criteria[1]:
   - **a)** Initial Therapy. Approve for 3 months if the patient meets the following criteria (i. ii, and iii)[1]:
     - **i.** The patient meets one of the following conditions (1 or 2):

1) The patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
2) The patient has tried one other agent for Crohn's disease (e.g., azathioprine, 6-mercaptopurine, methotrexate [MTX], Remicade® [infliximab], Humira® [adalimumab], Entyvio® [vedolizumab for IV infusion]) or Stelara [ustekinumab IV infusion, ustekinumab SC injection]; AND

ii. Cimzia is prescribed by or in consultation with a gastroenterologist; AND

iii. Site of care medical necessity is met*.

b) Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia. Site of care medical necessity must be met*.

Note: Patients with fistulizing Crohn's disease or Crohn's disease of the ileal pouch must meet the above criteria for Crohn's disease in adults.

Cimzia is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adults with moderately to severely active disease who have had an inadequate response to conventional therapy.[1]

Dosing in Crohn's Disease. The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous 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.[1]

3. Psoriatic Arthritis (PsA).

a) Initial Therapy. Approve for 3 months if Cimzia is prescribed by or in consultation with a rheumatologist or a dermatologist AND site of care medical necessity is met*.

b) Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvements in acute phase reactants [for example, CRP]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia. Site of care medical necessity must be met*.

Cimzia is indicated for PsA and can be used alone or in combination with DMARDs.[1] In the pivotal trial, Cimzia was effective in patients with active PsA despite therapy with a DMARD; approximately 20% of patients had previously tried a TNF blocker (note: primary failures were excluded).[1,7] There are few well-controlled, prospective studies with adequate duration that have evaluated the efficacy of the oral DMARDs.[13] According to the EULAR recommendations for treatment of PsA (2012), NSAIDs are recommended as first-line treatment.[14] Recommendations for other therapies before receiving a TNF blocker vary according to the manifestations of the disease, prognostic factors, and efficacy/toxicity of previous therapies. The TNF inhibitors indicated in PsA are equally effective for treatment of PsA, inhibition of radiographic progression, and improving physical function in patients with PsA. The traditional DMARDs have not been shown to prevent the progression of radiographic (structural) damage or to have significant impact on axial disease, dactylitis, or enthesitis in PsA.[14-15] This is in contrast with the newer biological DMARDs which have shown efficacy in well-controlled trials in reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with PsA.[1,7-8,14]

Dosing in Psoriatic Arthritis. The recommended dose of Cimzia for adult patients with psoriatic arthritis is 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at week 2 and 4, followed by 200 mg every other week. For maintenance dosing, Cimzia 400 mg every 4 weeks can be considered.[1]

4. Rheumatoid Arthritis (RA) in an Adult.

a) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):[16]

i. The patient meets one of the following conditions (1, 2, 3, or 4):

1) The patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine) (NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel, Humira, Remicade, Simponi {Aria or SC}, Actemra {IV or SC}, Kineret, Orencia {IV or SC}, and Rituxan]. These patients who have already tried a biologic for RA are not required to "step back" and try a conventional synthetic DMARD); AND

2) Patient is concurrently receiving MTX;[1] OR

3) Patient has a contraindication or intolerance to MTX and leflunomide, as determined by the prescribing physician; OR

4) Patient 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); extraarticular disease such as rheumatoid nodules, RA vasculitis, or Felty's syndrome; positive rheumatoid factor or anti-cyclic citrullinated peptide (CCP) antibodies; or bony erosions by radiograph;[16] AND

ii. Cimzia is prescribed by or in consultation with a rheumatologist; AND

iii. Site of care medical necessity is met*.

b) Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia. Site of care medical necessity must be met*.

Cimzia is indicated for moderate or severe active RA in adults and can be used alone or in combination with MTX or other non-biologic DMARDs.[1] Most patients will have received initial therapy with an oral DMARD(s) (e.g., hydroxychloroquine, leflunomide, sulfasalazine, MTX) or combination DMARD therapy (including double or triple therapy).[16] However, current recommendations from the American College of Rheumatology (ACR) [2012] note that patients with early RA (defined as disease duration < 6 months) with important markers of poor prognosis may be started early on a biologic agent, either alone or in combination with MTX. The criteria for patients with contraindications or intolerance to DMARDs are recommended based on the professional opinion of specialized physicians.

Dosing in Rheumatoid Arthritis. The recommended dose of Cimzia for adult patients with rheumatoid arthritis is 400 mg (given as two subcutaneous injections of 200 mg) initially and at Weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, Cimzia 400 mg every 4 weeks can be considered.

5. **Moderate to Severe Plaque Psoriasis.**
   - **A.** Initial Therapy. Approve for 3 months if the patient meets the following criteria:
     - **i.** The patient is 18 years of age or older; AND
     - **ii.** Cimzia is prescribed by or in consultation with a dermatologist; AND
     - **iii.** The patient has tried at least one traditional systemic agent for psoriasis (e.g. methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
       NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic agent (e.g. an adalimumab product, an etanercept product, an infliximab product, Cosentyx, Ilumya, Siliq, Stelara, Taltz, or Tremfya. These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis).
     - **iv.** Site of care medical necessity is met.*
   - **B.** Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia and site of care medical necessity is met.*

     Dosing in Plaque psoriasis: SubQ: 400 mg every other week. Note: For patients ≤90 kg, an initial dose of 400 mg at weeks 0, 2, and 4 followed by 200 mg every other week thereafter may be considered.

Other Uses with Supportive Evidence

6. **Spondyloarthritis (SpA), Subtypes Other than Ankylosing Spondylitis or Psoriatic Arthritits** (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter's disease]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications].
   - **A)** Initial Therapy. Approve for 3 months if the patient meets the following criteria (i or iiiii, and iv):
     - **i.** The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD (e.g., methotrexate [MTX], leflunomide, sulfasalazine) has been tried; OR
     - **ii.** The patient has axial spondyloarthritis; AND
     - **iii.** Cimzia is prescribed by or in consultation with a rheumatologist; AND
     - **iv.** Site of care medical necessity must be met*.

   - **B)** Patients Currently Receiving Cimzia. Approve for 1 year if the patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Cimzia. Site of care medical necessity must be met*.

Dosing in Ankylosing spondylitis: SubQ: Initial: 400 mg, repeat dose 2 and 4 weeks after initial dose; Maintenance: 200 mg every 2 weeks or 400 mg every 4 weeks

7. **Patient has been Established on Cimzia.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications) if the patient has been taking Cimzia for ≥ 90 days. Patients who have been taking Cimzia for < 90 days must meet the Criteria for an approved use in this *Cimzia Prior Authorization* policy. (In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.) Site of care medical necessity must be met*.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cimzia is recommended in circumstances that are listed in the Recommended Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). The following provides rationale for specific Exclusions. This is not an exhaustive list of Exclusions.

1. **Concurrent Use with a Biologic DMARD or Targeted Synthetic DMARD.** Cimzia should not be administered in combination with another biologic agent for an inflammatory condition (e.g., Actemra® [tocilizumab for IV infusion], Enbrel® [etanercept], Humira, Kineret® [anakinra for SC injection], Orencia® [abatacept for IV infusion, abatacept for SC injection], Remicade, Rituxan® [rituximab], Simponi® [golimumab for SC injection], or Tysabri® [natalizumab for IV infusion]). Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[17] Xeljanz® [tofacitinib] should not be used in combination with biologic DMARDs such as Remicade.[18] Targeted synthetic DMARDs (e.g., Xeljanz, Otezla® [apremilast]) do not have data supporting use in combination with biologic DMARDs. Due to similar safety concerns (i.e., increased risk of AEs) plus lack of evidence for additive efficacy, targeted synthetic DMARDs should not be used in combination with biologic DMARDs such as Cimzia. Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Cimzia.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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FOR MEDICAL BENEFIT COVERAGE REQUESTS:

***MMO Site of Care Medical Necessity Criteria:**

- Medications in this policy will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met†:

    1. Age less than 18* years; or
    2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
    3. History of a severe adverse event from previous administration of the prescribed medication; or
    4. Requested medication is being administered as follows:
        - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
        - administered with dialysis; or
    5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
    6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

No initial doses are allowed in a hospital based outpatient facility without other above criteria being met.
* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
†This criterion does not apply to Medicare or Medicare Advantage members.

MEDICAL MUTUAL®

Drug Policy

Prior approval is required for HCPCS Codes J0717

HCPCS Code(s):	
J0717	Injection, certolizumab pegol, 1 mg (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)