Effective Date: 3/23/2017

Cimzia® (certolizumab pegol)

FDA approval: 2008
HCPCS: J0717
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when the below criteria are met:
   a. Crohn’s disease: acute treatment of an exacerbation of Crohn’s disease when at least one of the following criteria i, ii, or iii AND iv below are met:
      i. Treatment with an adequate course of systemic corticosteroid (e.g., 40 mg to 60 mg prednisone per day for 7 to 14 days) has been ineffective or is contraindicated
         OR
      ii. The patient has been unable to taper off an adequate course of systemic corticosteroids without experiencing worsening of disease
         OR
      iii. The patient is experiencing breakthrough disease (e.g., active disease flares) while stabilized for at least 2 months on immunomodulatory medication (such as azathioprine, mercaptopurine, cyclosporine, or methotrexate)
         AND
      iv. Treatment with Humira® and Remicade® is not effective after an adequate induction period, except if not tolerated due to documented clinical side effects
         OR
   
   b. Rheumatoid arthritis: treatment of moderately or severely active rheumatoid arthritis when the following criteria are met:
      i. Treatment with one DMARD (must be methotrexate unless contraindicated or not tolerated based on clinical documentation) is ineffective after at least a 3 month trial. Examples of DMARDs include: methotrexate, sulfasalazine, azathioprine, hydroxychloroquin/chloroquin, cyclosporine, gold, and penicillamine.
         AND
      ii. Treatment with 2 or more of: Enbrel®, Humira®, and Remicade® is not effective after at least a 12 week treatment course, except if not tolerated due to documented clinical side effects.
         OR
c. Psoriatic arthritis: treatment of adult patients with active psoriatic arthritis when the following criteria are met:
   
   i. Treatment with one nonbiologic DMARD is not tolerated or is ineffective after at least 12 weeks treatment at a target therapeutic dose.

   **AND**

   ii. Treatment with 2 or more of: Enbrel®, Humira®, and Remicade® is not effective after at least a 12 week treatment course, except if not tolerated due to documented clinical side effects.

   **OR**

   d. Ankylosing spondylitis: treatment of adult patients with active ankylosing spondylitis when the following criterion is met:

   i. Treatment with 2 or more of: Enbrel®, Humira®, and Remicade® is not effective after at least a 12 week treatment course, except if not tolerated due to documented clinical side effects.

B. Quantity Limitations, Authorization Period and Renewal Criteria

   a. Quantity Limit:

      i. Initial: 1200 (6 syringes) for first 4 weeks

      ii. Continued 400 mg (2 syringes) every 4 weeks

   b. Initial Authorization Period: 1 year

   c. Renewal Criteria:

      i. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

C. Cimzia is considered investigational when used for all other conditions, including but not limited to:

   a. Juvenile idiopathic arthritis

   b. Psoriasis

   c. Ulcerative colitis

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia

Therapeutic considerations:

A. FDA approved indication / Diagnosis

   a. Crohn’s disease

      i. 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

   b. Rheumatoid arthritis

      i. Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis

   c. Psoriatic arthritis

      i. Indicated for the treatment of adult patients with active psoriatic arthritis

   d. Ankylosing Spondylitis

      i. Indicated for the treatment of adult patients with active ankylosing spondylitis

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
B. Background Information

a. **Cimzia** is a tumor necrosis factor (TNF) blocker that is indicated for Crohn’s disease, rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.

b. **Crohn’s Disease**

Crohn’s disease (CD) is a chronic inflammatory disorder that is characterized by focal, asymmetric, transmural, and granulomatous inflammation which primarily affects the gastrointestinal tract. However, CD is a multisystem disorder with the potential to produce systemic and extraintestinal complications. The onset of disease occurs most often in teenagers and young adults, although any age group may be affected. Since CD is neither medically nor surgically curable, treatment options target symptomatic control to improve quality of life and reduce complications. Therapeutic recommendations are individualized and depend on disease location, severity, and complications present. Treatment options for CD include: glucocorticoids (conventional steroids and budesonide), immunosuppressants (azathioprine, mercaptopurine, methotrexate), 5-aminosalicylates (5-ASA), and biologic agents (infliximab (Remicade®), adalimumab (Humira®), natalizumab (Tysabri®) and certolizumab (Cimzia)). Initial response to therapy should be evaluated within several weeks and treatment should be continued for the active disease until remission is seen or treatment failure occurs.

c. **Rheumatoid Arthritis**

Rheumatoid arthritis (RA) is an autoimmune disease that most commonly affects the wrists, fingers, knees, feet, and ankle joints symmetrically. The long-term inflammation of these joints can spread to affect surrounding tissues and organs. RA affects an estimated 1.3 million U.S. adults. Studies have shown that RA yields an increased mortality rate compared to the general population. Treatment options for RA include: glucocorticoids (most often used for short-term management of flares), disease-modifying anti-rheumatic drugs (DMARDs): hydroxychloroquine, leflunomide, methotrexate, minocycline, and sulfasalazine; and biologic agents (non-TNF: abatacept (Orencia®), rituximab (Rituxan®), tocilizumab (Actemra®); anti-TNF: adalimumab (Humira), entanercept (Enbrel®), infliximab (Remicade), certolizumab pegol (Cimzia), and golimumab (Simponi®)). The therapeutic approach for the management of RA and drug selection is based on stage (early or established), disease activity (low or high), and prognosis of the disease.

d. **Psoriatic Arthritis**

Psoriatic Arthritis (PsA) is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur. Treatment options include NSAIDS, DMARDs, and anti-TNF biologic agents. If PsA does not respond to the initial treatment (NSAIDs, DMARDs (sulfasalazine, methotrexate, cyclosporine, and leflunomide)) as monotherapy, combination therapy may be used. Hydroxychloroquine should be avoided due to exacerbation of psoriasis. Anti-TNF agents may be utilized when initial treatment has been ineffective. Anti-TNF agents approved for PsA include: adalimumab (Humira), entanercept (Enbrel), infliximab (Remicade), certolizumab pegol (Cimzia) and golimumab (Simponi).

e. **Ankylosing Spondylitis**

Ankylosing Spondylitis (AS) belongs to a group of chronic rheumatic diseases affecting the bones and joints connecting the spine and pelvis known as spondyloarthritis. AS has been found to have a genetic predisposition and most frequently begins between the age of 20 and 40. The disease initially presents as low back pain and stiffness occurring most often in times of decreased activity such as at night or in the morning and tends to get

*Please refer to most recent prescribing information. [www.cimzia.com]*
better with activity. The prevalence of AS is estimated at 0.6-2.4 million adults over the age of 15. Treatment recommendations consist of physiotherapy to help improve posture and pharmacological agents to help alleviate pain, manage the disease, and prevent progression. Treatment options include NSAIDs, corticosteroids, DMARDs, and anti-TNF biologic agents. Anti-inflammatory agents such as NSAIDs may be used to reduce swelling; however, they do not affect disease progression. DMARDs (sulfasalazine, and methotrexate) have not been proven effective for the treatment of axial disease. Anti-TNF agents (entanercept (Enbrel), Adalimumab (Humira), infliximab (Remicade), certolizumab pegol (Cimzia) or golimumab (Simponi) target the pathophysiologic mechanism of AS and have been shown to be beneficial and effective.

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<th>Cross References</th>
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<tr>
<td>Medication Use Guidelines: Cimzia® (certolizumab pegol) February 9, 2017</td>
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C. Efficacy  
*Please refer to most recent prescribing information.

D. Medication Safety Considerations

Black Box Warning: Yes, warning for serious infections and malignancy

*Please refer to most recent prescribing information.

E. Dosing and administration

a. Dosing:
   i. Crohn’s disease
      1. Initial: 400 mg initially and at week 2 and 4
      2. Maintenance: 400 mg every 4 weeks
   ii. Rheumatoid arthritis
       1. Initial: 400mg initially and at week 2 and 4, followed by 200 mg every other week
       2. Maintenance: 400 mg every 4 weeks
   iii. Psoriatic arthritis
        1. Initial: 400 mg initially and at week 2 and 4, followed by 200 mg every other week
        2. Maintenance: 400 mg every 4 weeks
   iv. Ankylosing spondylitis
        1. Initial: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week
        2. Maintenance: 400 mg every 4 weeks

*Please refer to most recent prescribing information.

F. How supplied

a. Lyophilized power for reconstitution
   i. Type I glass vials (Qty: 2 per package) with rubber stopper and overseals each containing 200 mg of lyophilized Cimzia for reconstitution

b. Prefilled syringe
   i. Single use prefilled glass syringes (Qty: 2 per package) each containing 200 mg of Cimzia

c. Prefilled syringe starter kit
   i. 3 sets of 2 prefilled syringes each containing 200 mg of Cimzia to provide sufficient drug supply for the initial 3 induction doses at the start of treatment

*Please refer to most recent prescribing information.
References:


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<th>Date</th>
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<td>Effective Date: 4/22/2010</td>
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<td>1.1</td>
<td>Effective Date: 2/16/2013</td>
<td>Criteria Update</td>
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<td>1.2</td>
<td>Effective Date: 2/12/2015</td>
<td>Criteria Update: Updated requirement with specific number of tried and failed biologics from at least one and at least two for Crohn’s Disease and other diagnoses respectively to non-specified number of agents tried.</td>
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<td>Effective Date: 01/01/2016</td>
<td>Document updated with specified drugs required</td>
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<td>Effective Date: 2/9/2017</td>
<td>Annual review and template update</td>
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<td>1.5</td>
<td>Effective Date: 3/23/2017</td>
<td>Update to remove pharmacy benefit references</td>
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm