Cimzia® (certolizumab pegol)

Policy Number: 5.01.530  
Origination: 9/2008  
Last Review: 8/2019  
Next Review: 8/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Cimzia® (certolizumab pegol) when it is determined to be medically necessary because the criteria shown below are met

When Policy Topic is covered
Cimzia® (certolizumab pegol) requires prior authorization through the pharmacy services area.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of moderately to severely active **Crohn's Disease** in patients who have inadequate response to conventional therapy after at least a 12-week treatment course with Humira® (adalimumab) OR Stelara has not been effective.

- Certolizumab pegol dosing for Crohn's Disease is 400mg given as 2 subcutaneous injections (200mg each) at weeks 0, 2, and 4. If response occurs, follow with 400mg every 4 weeks.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of adults with moderately to severely active **rheumatoid arthritis (RA)** after at least a 12-week treatment course of each of 2 preferred agents (Actemra, Humira, Enbrel, Rinvoq, or Xeljanz/XR) has not been effective.

- Certolizumab pegol dosing for rheumatoid arthritis is 400mg given as 2 subcutaneous injections (200mg each) at weeks 0, 2, and 4 followed by 200mg every other week; for maintenance dosing, 400mg every 4 weeks can be considered.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of adult patients with active **ankylosing spondylitis**, after at least a 12-week treatment course of each of 2 preferred agents (Enbrel, Humira, or Cosentyx) has not been effective.

- Certolizumab pegol dosing for ankylosing spondylitis is 400mg given as 2 subcutaneous injections (200mg each) at weeks 0, 2 and 4. If response occurs, follow with 200mg every 2 weeks or 400mg every 4 weeks.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of adult patients with **psoriatic arthritis** after at least a 12-week treatment course of each of 2 preferred agents (Enbrel, Humira, Stelara, Xeljanz/XR or Cosentyx) has not been effective.

- Certolizumab pegol dosing for psoriatic arthritis is 400mg given as 2 subcutaneous injections (200mg each) at weeks 0, 2, and 4 followed by 200mg every other week; for maintenance dosing, 400mg every 4 weeks can be considered.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of adult patients with **plaque psoriasis** after at least a 12-week treatment course of each of 2 preferred agents (Cosentyx, Humira, Stelara, Skyrizi, Termfya or Otezla) has not been effective.
Certolizumab pegol dosing for plaque psoriasis is 400mg every other week. 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.

Cimzia® (certolizumab pegol) is considered medically necessary for treatment of adult patients with non-radiographic axial spondyloarthritis

Certolizumab pegol dosing for non-radiographic axial spondyloarthritis is an initial dose of 400 mg at weeks 0, 2, and 4 followed by 200 mg every other week thereafter.

When Policy Topic is not covered
Cimzia® (certolizumab pegol) is considered not medically necessary if the criteria above are not met.

Considerations
This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers

Description of Procedure or Service
Certolizumab pegol binds to and inhibits the activity of tumor necrosis factor (TNF) to reduce inflammation and improve symptoms in patients with Crohn’s disease and rheumatoid arthritis. Certolizumab is administered as a subcutaneous injection, either by the patient or a health care professional.

Rationale
Clinical Efficacy
In one 26-week double-blind study, 662 adults with moderate-to-severe Crohn’s disease were randomized to receive either certolizumab pegol 400 mg (given as two – 200 mg injections) or placebo SC at weeks 0, 2, and 4, then every 4 weeks. (1)

* After 6 weeks, 35% of patients receiving certolizumab pegol experienced a response to treatment (defined as a decrease of 100 points or more on the Crohn’s Disease Activity Index score – “CDAI”) as compared with 27% of patients receiving placebo. Therefore, one of 13 patients treated with certolizumab pegol would have a meaningful response at 6 weeks.

* Twenty-three percent of patients receiving certolizumab pegol experienced a response to treatment at BOTH week 6 and 26, compared to 16% of patient receiving placebo. Therefore, 15 patients would need to be treated with certolizumab pegol for up to 26 weeks for one patient to experience a sustained response to treatment.

In another 26 week double-blind, randomized controlled trial, all patients (n=668) were administered certolizumab pegol 400 mg at weeks 0, 2 and 4. At week 6, 64% (n=428) of these patients experienced a response to therapy. These patients were then randomized to continue certolizumab pegol 400 mg or placebo, every 4 weeks. (1)

* At week 26, 63% of the patients continued on certolizumab experienced a response to therapy compared with 36% of the patients who continued on placebo. Therefore, in patients that experienced a response to induction, 4 patients would need to be treated with certolizumab pegol for one patient to experience a response at 26 weeks.

There is inadequate evidence to distinguish between the effectiveness of the TNFα inhibitors (adalimumab, infliximab, and certolizumab) for the management of patients with moderate
to severe Crohn’s disease.

* There have been no direct comparative trials that have demonstrated a difference in clinical effect of safety of one agent over another.

* There is inadequate evidence to establish the efficacy of certolizumab in fistulizing Crohn’s disease.

In this class of medications, only infliximab has been adequately studied in the management of patients with ulcerative colitis.(2)

In two double-blind, placebo-controlled trials a total of 1,601 patient patients were randomized to receive certolizumab pegol 200 mg, 400 mg, or placebo every 2 weeks (following a loading dose of 400 mg at weeks 0, 2, and 4) along with methotrexate for 24 weeks. At the end of 24 weeks, 57% to 59% of patients who received certolizumab pegol plus methotrexate experienced at least a 20% improvement in the symptoms of their rheumatoid arthritis, compared to only 9 to 14% of patients receiving a methotrexate treatment alone. [1,4,5]

Safety
- Certolizumab pegol carries a black-box warning for tuberculosis (TB) (frequently disseminated or extrapulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections that have been observed in patients receiving certolizumab. (2,3)
- Serious adverse events observed with the use of certolizumab in the treatment of Crohn’s disease include serious infections, tuberculosis, hepatitis B virus reactivation, malignancies, hypersensitivity reactions, neurologic and hematologic reactions, use with anakinra, heart failure, autoimmunity, immunizations, and immunosuppression. (2,3)
- The most common issues observed with the use of certolizumab in the treatment of Crohn’s disease include (incidence ≥ 5% and higher than placebo): upper respiratory tract infection (20%), urinary tract infection (7%), and worsening joint pain (6%).(2,3)

References

Billing Coding/Physician Documentation Information

J0717 Injection, certolizumab pegol, 1 mg

Pharmacy Benefit

Additional Policy Key Words
5.01.530

Policy Implementation/Update Information
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<td>06/2015</td>
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