BlueCross BlueShield Federal Employee Program

CIMZIA
(certolizumab pegol)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Cimzia (certolizumab pegol) is a tumor necrosis factor-alpha (TNF-α) blocker. Tumor necrosis factor is an endogenous protein that regulates a number of physiologic processes, including the inflammation response associated with some autoimmune inflammatory diseases (1).

Regulatory Status

FDA-approved indications: Cimzia is a tumor necrosis factor (TNF) blocker indicated for: (1)

1. 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
2. Treatment of adults with moderately to severely active rheumatoid arthritis
3. Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older
4. Treatment of adult patients with active psoriatic arthritis
5. Treatment of adult patients with active ankylosing spondylitis
6. Treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation
7. Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Cimzia carries boxed warnings regarding serious infections and malignancies. Because Cimzia suppresses the immune system, patients are at a greater risk for getting serious infections leading to hospitalization or death, including tuberculosis (TB), invasive fungal infections, and infections due to other opportunistic pathogens. Lymphoma and other malignancies have been reported in children and adolescent patients treated with TNF blockers.

Patients should be screened for latent tuberculosis infection. Patients at risk for hepatitis B virus (HBV) infection should be evaluated for evidence of prior HBV infection. Hepatitis B virus carriers should be monitored for reactivation during and several months after therapy. Cimzia should not be used in combination with other biologic agents. Cimzia should not be initiated in patients with an active infection. Cimzia should be discontinued if a patient develops a serious infection during treatment (1).

Pancytopenia, aplastic anemia, lupus-like syndrome, anaphylaxis reactions, and congestive heart failure (new onset or worsening) may develop during Cimzia therapy and therapy should be discontinued (1).

The use of Cimzia in combination with other biological DMARDs is not recommended. Serious infections may occur with concurrent use of anakinra (an interleukin-1 antagonist) and another TNF blocker, etanercept. There is a higher risk of serious infections in the combination use of TNF blockers with abatacept and rituximab. Because of the nature of the adverse events seen with this combination therapy, similar toxicities may also result from the use of Cimzia in this combination. Therefore, the use of Cimzia in combination with other biological DMARDs is not recommended (1).

The safety and effectiveness of Cimzia in pediatric patients less than 2 years of age for polyarticular juvenile idiopathic arthritis have not been established. The safety and effectiveness of Cimzia in pediatric patients less than 18 years of age for all other indications have not been established (1).

Summary

Cimzia (certolizumab pegol) is a tumor necrosis factor (TNF) blocker indicated for rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), psoriatic arthritis (PsA), plaque psoriasis (PsO), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), and Crohn's disease (CD). Cimzia may be used as monotherapy or concurrently with non-biological disease modifying anti-rheumatic drugs (DMARDs). Cimzia should not be used in combination with other biological DMARDs or other tumor necrosis factor (TNF) blockers. Cimzia carries boxed warnings regarding increased risk of serious infections and malignancies. The safety and effectiveness of Cimzia in pediatric patients less than 2 years of age for polyarticular juvenile idiopathic arthritis have not been established. The safety and effectiveness of Cimzia in pediatric patients less than 18 years of age for all other indications have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cimzia while maintaining optimal therapeutic outcomes.

References

1. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.