Generic Name:
Certolizumab pegol
Trade Name:
Cimzia
Company:
UCB
Notes:

FDA approved certolizumab pegol injection for treatment of adults with nonradiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation. This is the first time FDA has approved a treatment for nr-axSpA.

Nr-axSpA is a type of inflammatory arthritis that causes inflammation in the spine and other symptoms. There is no visible damage seen on x-rays, so it is referred to as nonradiographic.

The drug was originally approved in 2008 and is also indicated for adult patients with Crohn?s disease, moderate to severe rheumatoid arthritis, active ankylosing spondylitis, and moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Its efficacy for treatment of nr-axSpA was studied in a randomized clinical trial in 317 adult patients with nr-axSpA with objective signs of inflammation, indicated by elevated C-reactive protein (CRP) levels and/or sacroiliitis on MRI.

The trial measured the improvement response on the Ankylosing Spondylitis Disease Activity Score, a composite scoring system that assesses disease activity including patient-reported outcomes and CRP levels. Responses were greater for patients treated with certolizumab pegol compared with patients treated with placebo. The overall safety profile observed in the certolizumab pegol treatment group was consistent with the known safety profile of the drug.

The prescribing information includes a boxed warning about the increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis, an infection that affects the lungs), and other infections.

Certolizumab pegol should be discontinued if a patient develops a serious infection or sepsis. Health care providers are advised to perform testing for latent TB and, if positive, to start treatment for TB prior to starting certolizumab pegol. All patients should be monitored for active TB during treatment, even if the initial latent TB test is negative.

The boxed warning also advises that lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor blockers such as certolizumab pegol. The agent is not indicated for use in pediatric patients.

Certolizumab pegol must be dispensed with a patient Medication Guide that describes important information about the drug?s uses and risks.

Medication Monitor Categories:
Supplemental Approvals