Cimzia injection approved for new inflammatory arthritis indication

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(HealthDay)—Cimzia (certolizumab pegol) injection has been approved to treat adults with nonradiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, the U.S. Food and Drug Administration announced.

The injection is the first treatment approved for nr-axSpA. Approval was based on data from a randomized clinical trial of 317 adult patients with nr-axSpA and objective signs of inflammation as indicated by magnetic resonance imaging showing elevated C-reactive protein levels or sacroiliitis. Compared with those who received placebo, patients who received the Cimzia injection had a greater improvement in response on the Ankylosing Spondylitis Disease Activity Score.

A boxed warning in the prescribing information for Cimzia advises health care providers and patients about an increased risk for serious infections, including tuberculosis, bacterial sepsis, and invasive infections such as histoplasmosis. The FDA says that before patients start Cimzia, health care providers should perform testing for latent tuberculosis, and if patients test positive, they should start tuberculosis treatment. Health care providers should monitor all patients for active tuberculosis during treatment, regardless of the results of the initial test. Patients receiving Cimzia should also be aware of potential interactions with live vaccines and tumor necrosis factor blocker drug therapy and the interference with some coagulation assays.

Cimzia is administered by subcutaneous injection and is required to be dispensed with a patient Medication Guide. According to the manufacturer's prescribing information, Cimzia is available in two injection formulations: a lyophilized powder in a single-dose 200-mg/mL vial and a single-dose 200-mg/mL prefilled syringe. Both forms must be stored in the refrigerator until ready for administration. The recommended initial dose of Cimzia is 400 mg given as two subcutaneous injections of 200 mg; follow-up therapy is based on diagnosis. Acceptable injection sites include the abdomen or thigh; sites should be rotated and not be within 1 inch of a previous injection site.

Approval of Cimzia was granted to UCB.

More information: More Information