Cimzia® (certolizumab pegol) – New indication

- On March 28, 2019, the FDA announced the approval of UCB's Cimzia (certolizumab pegol), for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

- Cimzia is also approved for Crohn's disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.

- 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 non-radiographic.

- The approval of Cimzia's new indication was based on a double-blind study in 317 patients with active axial spondyloarthritis without definitive radiographic evidence of structural damage on sacroiliac joints. Patients were randomized to Cimzia or placebo. The primary endpoint was the proportion of patients achieving an Ankylosing Spondylitis Disease Activity Score-Major Improvement (ASDAS-MI) response at week 52.

    — At week 52, 47% of patients treated with Cimzia had an ASDAS-MI response vs. 7% of patients treated with placebo (Odds Ratio: 15.2; 95% CI: 7.3, 31.6).

- Cimzia carries a boxed warning for serious infections and malignancy.

- The recommended dose of Cimzia for adult patients with nr-axSpA is 400 mg (given as 2 subcutaneous injections of 200 mg each) initially and at weeks 2 and 4, followed by 200 mg every 2 weeks or 400 mg every 4 weeks.

    — Cimzia may be used as monotherapy or concomitantly with non-biological disease modifying anti-rheumatic drugs (DMARDs).
    — The use of Cimzia in combination with biological DMARDs or other tumor necrosis factor blocker therapy is not recommended.
    — Refer to the Cimzia drug label for dosing recommendations for its other indications.