Cimzia® (certolizumab pegol) – New indication

- On September 13, 2024, the FDA approved UCB's Cimzia (certolizumab pegol), for the treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
- Cimzia is also approved for Crohn's disease, rheumatoid arthritis (RA), psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and plaque psoriasis.
- The approval of Cimzia for the new indication was based on pharmacokinetic exposure and extrapolation of the established efficacy of Cimzia in RA patients. The efficacy of Cimzia was also assessed in an open-label study in 193 patients 2 to 17 years of age with JIA with active polyarthritis with an inadequate response or intolerance to at least 1 disease modifying anti-rheumatic drug (DMARD) (nonbiologic or biologic). The efficacy was generally consistent with responses in patients with RA.
- Cimzia carries a boxed warning for serious infections and malignancy.
- The recommended subcutaneous dose of Cimzia for the treatment of patients 2 years of age and older with pJIA is based on weight.

Weight range	Loading dose	Maintenance dose (Beginning at week 6)
10 kg (22 lbs) to less than 20 kg (44 lbs)	100 mg at week 0, 2 and 4	50 mg every 2 weeks
20 kg (44 lbs) to less than 40 kg (88 lbs)	200 mg at week 0, 2 and 4	100 mg every 2 weeks
Greater than or equal to 40 kg (88 lbs)	400 mg at week 0, 2 and 4	200 mg every 2 weeks

  - There is no dosage form for Cimzia that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a health care professional using the vial kit.

- Refer to the Cimzia drug label for dosing for all its other indications.