

Cimzia[®] (certolizumab pegol) – New indication

- On May 29, 2018, [UCB announced](#) the FDA approval of [Cimzia \(certolizumab pegol\)](#), for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Cimzia is also approved for the following:
 - 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.
 - Treatment of adults with moderately to severely active rheumatoid arthritis.
 - Treatment of adult patients with active psoriatic arthritis.
 - Treatment of adults with active ankylosing spondylitis.
- Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin. Psoriasis signs and symptoms can vary but may include red patches of skin covered with silvery scales; dry, cracked skin that may bleed; and thickened, pitted or ridged nails. For those who are more severely affected, psoriasis can have a major impact on quality of life.
 - Psoriasis affects nearly 3% of the population, or approximately 125 million people worldwide.
- The efficacy of Cimzia for moderate-to-severe plaque psoriasis in adult patients was evaluated in 3 placebo-controlled clinical studies. Studies 1 and 2 enrolled 461 patients to placebo, Cimzia 200 mg or 400 mg every other week and assessed the co-primary endpoints of the proportion of patients who achieved a Psoriasis Area and Severity Index (PASI) 75 and Physician's Global Assessment (PGA) of "clear" or "almost clear" with at least a 2-point improvement at week 16. Study 3 enrolled 559 patients to receive placebo, Cimzia 200 mg or 400 mg every other week, or a biologic comparator, and assessed the primary endpoint of proportion of patients who achieved a PASI 75 at week 12.
 - In study 1, 7% of placebo, 65% of Cimzia 200 mg and 75% of Cimzia 400 mg patients achieved a PASI 75. A total of 4% of placebo, 45% of Cimzia 200 mg and 55% of Cimzia 400 mg patients achieved a PGA of clear or almost clear.
 - In study 2, 13% of placebo, 81% of Cimzia 200 mg and 82% of Cimzia 400 mg patients achieved a PASI 75. A total of 3% of placebo, 61% of Cimzia 200 mg and 65% of Cimzia 400 mg patients achieved a PGA of clear or almost clear.
 - In study 3, 4% of placebo, 69% of Cimzia 200 mg and 75% of Cimzia 400 mg patients achieved a PASI 75.
- Cimzia carries a boxed warning for serious infections and malignancy.
- The recommended dosage of Cimzia for plaque psoriasis is 400 mg (given as 2 subcutaneous [SC] injections of 200 mg each) every other week.

- For some patients (with body weight \leq 90 kg), Cimzia 400 mg (given as 2 SC injections of 200 mg each) initially and at weeks 2 and 4, followed by 200 mg every other week can be considered.
- Consult the Cimzia drug label for dosing recommendations for all other indications.



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