

Entyvio® (vedolizumab) – New indication for subcutaneous use

- On April 19, 2024, <u>Takeda announced</u> the FDA approval of the subcutaneous (SC) formulation of <u>Entyvio (vedolizumab)</u>, for maintenance treatment in adults with moderately to severely active Crohn's disease (CD) after induction therapy with intravenous (IV) Entyvio.
- The SC formulation of Entyvio was approved for ulcerative colitis (UC) in September 2023.
- The IV formulation of Entyvio is also approved for both UC and CD.
- The approval of SC Entyvio for the new indication was based on a randomized, double-blind, placebo-controlled study in adult patients with moderately to severely active CD. All patients received open-label IV Entyvio at week 0 and week 2. In order to be randomized to treatment in the SC study, patients had to be in clinical response at week 6. A total of 409 patients were randomized at week 6 to SC Entyvio or placebo every 2 weeks. The primary endpoint was the proportion of patients with clinical remission at week 52.
 - Clinical remission was achieved in 48% of patients with Entyvio vs. 34% with placebo (treatment difference 14, 95% CI: 4, 24; p < 0.01).
- The recommended SC maintenance dose of Entyvio for the treatment of both CD and UC is 108 mg SC once every 2 weeks.
 - Patients may self-inject or caregivers may inject SC Entyvio using either the Entyvio prefilled syringe or Entyvio Pen after training in SC injection technique.



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