



## Stelara® (ustekinumab) – New indication

- On October 21, 2019, [Janssen announced](#) the FDA approval of [Stelara \(ustekinumab\)](#), for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).
- Stelara is also approved for the treatment of psoriasis, psoriatic arthritis, and Crohn's Disease.
- UC is a serious, chronic and progressive immune-mediated inflammatory disease of the large intestine, affecting approximately 910,000 people in the U.S.
  - Stelara is the first FDA approved biologic therapy for UC that targets the interleukin (IL)-12 and IL-23 cytokines. The IL-12 and IL-23 cytokines have been shown to play an important role in inflammatory and immune responses.
- The approval of Stelara for the new indication was based on two randomized, double-blind, placebo-controlled clinical studies in adult patients with moderately to severely active UC. The 8-week intravenous induction study (UC-1; N = 961) was followed by the 44-week subcutaneous randomized withdrawal maintenance study (UC-2; N = 523) for a total of 52 weeks of therapy.
  - In UC-1, a significantly greater proportion of patients treated with Stelara (at the recommended dose of approximately 6 mg/kg dose) were in clinical remission at week 8 vs. placebo (19% vs. 7%, respectively). The treatment difference was 12% (97.5% CI: 7, 18).
  - In UC-2, clinical remission was achieved in 26% and 45% of patients treated with placebo or Stelara, respectively. The treatment difference was 19% (95% CI: 9, 28).
- The most common adverse reaction ( $\geq 3\%$ ) with Stelara use for UC induction therapy was nasopharyngitis. The most common adverse reactions ( $\geq 3\%$ ) with Stelara use for UC maintenance therapy were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.
- The recommended induction dose of Stelara for the treatment of UC is a single intravenous infusion using a weight-based dosage regimen. The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
  - Refer to the Stelara drug label for complete dosing details for UC and for dosing recommendations for all its other indications.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.