## Tremfya® (guselkumab) – New indication

- On March 20, 2025, Johnson and Johnson announced the FDA approval of Tremfya (guselkumab), for the treatment of adult patients with **moderately to severely active Crohn's disease (CD)**.

- Tremfya is also approved for the treatment of adult patients with:

  - Moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
  - Active psoriatic arthritis
  - Moderately to severely active ulcerative colitis.

- Tremfya is the first IL-23 inhibitor offering both subcutaneous (SC) and intravenous (IV) induction options for the treatment of CD.

- The approval of Tremfya for the new indication was based on three randomized, placebo-controlled, double-blind studies that enrolled adult patients with moderately to severely active CD who had a history of inadequate response, loss of response, or intolerance to oral corticosteroids, immunomodulators, and/or biologic therapy.

- In the CD1 and CD2 studies, 361 patients and 360 patients were randomized to receive IV Tremfya at weeks 0, 4, and 8 or placebo.

  - The combined clinical remission and endoscopic response at week 12 in CD1 was 20% in the Tremfya group vs. 3% in the placebo group (treatment difference 17%; 95% CI: 11, 23; $p < 0.001$).
  - The combined clinical remission and endoscopic response at week 12 in CD2 was 21% in the Tremfya group vs. 3% in the placebo group (treatment difference 18%; 95% CI: 12, 24; $p < 0.001$).

- In the CD3 study, 340 patients were randomized to receive SC Tremfya at weeks 0, 4, and 8 followed by SC Tremfya every 8 weeks (with the first dose given at week 16); SC Tremfya at weeks 0, 4, and 8 followed by SC Tremfya every 4 weeks (with the first dose given at week 12); or placebo. The coprimary endpoints were clinical remission at week 12 and endoscopic response at week 12 vs. placebo. The Tremfya dosing is identical through week 12, so patients in both Tremfya groups are combined for the analysis at week 12.

  - The **clinical remission** at week 12 was **56% in the Tremfya groups vs. 22% in the placebo group** (treatment difference: 34%; 95% CI: 24, 44; $p < 0.001$).
  - The **endoscopic response** at week 12 was **34% in the Tremfya groups vs. 15% in the placebo group** (treatment difference: 19%; 95% CI: 10, 28; $p < 0.001$).

- The most common adverse reactions (≥ 3%) with Tremfya use in CD were respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

- The recommended dose of Tremfya for the **induction** treatment of CD is:

  - 200 mg administered by IV infusion over at least one hour at week 0, week 4, and week 8 or
  - 400 mg administered by SC injection (given as two consecutive injections of 200 mg each) at week 0, week 4, and week 8.

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- The recommended dose of Tremfya for the **maintenance** treatment of CD is:
    - 100 mg administered by SC injection at week 16, and every 8 weeks thereafter, or
    - 200 mg administered by SC injection at week 12, and every 4 weeks thereafter.
    - The lowest effective recommended dosage should be used to maintain therapeutic response.

- Tremfya is intended for use under the guidance and supervision of a healthcare professional. Tremfya may be administered by a healthcare professional, or a patient/caregiver after proper training on correct SC injection technique.

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

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