

Tremfya[®] (guselkumab) – New indication

- On July 14, 2020, [Janssen announced](#) the FDA approval of [Tremfya \(guselkumab\)](#), for the treatment of adult patients with active psoriatic arthritis (PsA).
- Tremfya is also approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
- Tremfya is the first FDA approved interleukin (IL)-23 inhibitor for the treatment of active PsA.
- PsA is a chronic, progressive, immune-mediated disease characterized by joint inflammation, enthesitis, dactylitis, axial disease and the skin lesions associated with psoriasis. PsA affects about 1.5 million Americans.
- The approval of Tremfya for the new indication was based on two randomized, double-blind, placebo-controlled studies in 1,120 patients with active PsA. In the first study, approximately 31% of patients had been previously treated with up to 2 anti-tumor necrosis factor alpha agents whereas in the second study all patients were biologic naïve. The primary endpoint in both studies was the percentage of patients achieving an ACR20 response at week 24.
 - In the first study, 52% of patients receiving Tremfya 100 mg every 8 weeks after two starter doses achieved an ACR20 response vs. 22% treated with placebo (difference of 30, 95% CI: 19, 41).
 - In the second study, 64% of patients receiving Tremfya 100 mg every 8 weeks after two starter doses achieved an ACR20 response vs. 33% treated with placebo (difference of 31; 95% CI: 23, 40).
- The recommended subcutaneous (SC) dose of Tremfya for the treatment of PsA is 100 mg at week 0, week 4, and every 8 weeks thereafter. Tremfya may be administered alone or in combination with a conventional disease-modifying antirheumatic drug (eg, methotrexate).
 - Tremfya is intended for use under the guidance and supervision of a physician. Tremfya may be administered by a health care professional, or a patient may self-inject after proper training in SC injection technique.
 - Refer to the Tremfya drug label for dosing in plaque psoriasis.