

Dupixent[®] (dupilumab) – New indication

- On June 20, 2025, [Sanofi](#) and [Regeneron](#) announced the FDA approval of [Dupixent \(dupilumab\)](#), for the **treatment of adult patients with bullous pemphigoid (BP)**.
- Dupixent is also approved for the treatment of atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic obstructive pulmonary disease, and chronic spontaneous urticaria.
- BP is a chronic and relapsing rare skin disease affecting approximately 27,000 adults in the U.S. whose disease is uncontrolled by systemic corticosteroids.
- The approval of Dupixent for the new indication was based on ADEPT, a randomized, double-blind, placebo-controlled study in 106 adult patients with BP. Patients were randomized to receive either Dupixent or placebo for 52 weeks. The primary endpoint was the proportion of subjects achieving sustained remission at week 36. Sustained remission was defined as the achievement of complete remission and off oral corticosteroids no later than week 16, absence of disease relapse from the time of completion of the corticosteroid taper to week 36, and absence of rescue therapy during the 36-week double-blind treatment period.
 - The proportion of patients achieving sustained remission was 18.3% and 6.1% in the Dupixent and placebo arms, respectively (difference 12.2, 95% CI: -0.8, 26.1).
- The most common adverse reactions ($\geq 2\%$) with Dupixent use in BP were arthralgia, conjunctivitis, blurred vision, herpes viral infections, and keratitis.
- The recommended dosage of Dupixent for adult patients is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week.
 - Dupixent should be used in combination with a tapering course of oral corticosteroids. Once disease control has occurred, corticosteroids should be gradually tapered after which Dupixent should be continued as monotherapy. In case of relapse, corticosteroids may be added if medically advisable.
- Refer to the Dupixent drug label for dosing for all its other indications.