

## Dupixent® (dupilumab) – Expanded indication

- On May 26, 2020, [Regeneron](#) and [Sanofi](#) announced the FDA approval of [Dupixent \(dupilumab\)](#), for the treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
  - Dupixent was previously approved for this indication in patients 12 years and older.
- Dupixent is also approved as an add-on maintenance treatment:
  - In patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma
  - In adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.
- The approval of Dupixent for the expanded indication was based on a randomized, double-blind, placebo-controlled study in 367 patients 6 to 11 years of age with atopic dermatitis. Patients received Dupixent plus topical corticosteroids (TCS) or placebo plus TCS. The primary endpoint was the proportion of patients with an Investigator's Global Assessment (IGA) of 0 (clear) or 1 (almost clear) at week 16.
  - In patients with a baseline weight of less than 30 kg, 30% receiving Dupixent plus TCS achieved the primary endpoint vs. 13% with placebo plus TCS.
  - In patients with a baseline weight greater than or equal to 30 kg, 39% receiving Dupixent plus TCS achieved the primary endpoint vs. 10% with placebo plus TCS.
- The recommended subcutaneous (SC) dose of Dupixent for the treatment of pediatric patients with atopic dermatitis is weight-based.

| Body weight           | Initial dose                   | Subsequent doses        |
|-----------------------|--------------------------------|-------------------------|
| 15 to less than 30 kg | 600 mg (two 300 mg injections) | 300 mg every 4 weeks    |
| 30 to less than 60 kg | 400 mg (two 200 mg injections) | 200 mg every other week |
| 60 kg or more         | 600 mg (two 300 mg injections) | 300 mg every other week |

- Dupixent is intended for use under the guidance of a healthcare provider. A patient may self-inject Dupixent after training in SC injection technique using the pre-filled syringe. Dupixent pre-filled syringe should be given by a caregiver in children 6 to 11 years of age.
- Refer to the Dupixent drug label for dosing recommendations for its other indications.