

Dupixent[®] (dupilumab) – Expanded indication

- On March 11, 2019, [Regeneron Pharmaceuticals](#) and [Sanofi](#) announced the FDA approval of [Dupixent \(dupilumab\)](#), for the treatment of patients aged 12 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 adults only.
- Dupixent is also indicated 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.
- The approval of Dupixent's expanded indication was based on a double-blind study in 251 adolescent patients with moderate-to-severe atopic dermatitis. Patients were randomized to Dupixent or placebo. The primary endpoint was the proportion of patients with an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) and at least a 2-point improvement from baseline to week 16.
 - Overall, 24% of patients receiving Dupixent met the primary endpoint of clear or almost clear skin with Dupixent vs. 2% with placebo.
- The recommended dose of Dupixent for patients 12 to 17 years of age with atopic dermatitis is an initial subcutaneous (SC) dose of 400 mg (two 200 mg injections) or 600 mg (three 200 mg injections) for patients less than 60 kg or 60 kg or more, respectively. Subsequent doses are 200 mg and 300 mg every other week, respectively.
 - Dupixent can be used with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.
 - Dupixent is intended for use under the guidance of a healthcare provider. A patient may self-inject Dupixent after training in SC injection technique.
- Refer to the Dupixent drug label for dosing recommendations for the treatment of moderate-to-severe asthma and for adult dosing in atopic dermatitis.