Dupixent® (dupilumab) – Expanded indication

- On January 25, 2024, Regeneron and Sanofi announced the FDA approval of Dupixent (dupilumab), for the treatment of adult and *pediatric patients aged 1 year and older, weighing at least 15 kg*, with eosinophilic esophagitis (EoE).
    - Dupixent was previously approved for this indication in adult and *pediatric patients aged 12 years and older, weighing at least 40 kg*.
- Dupixent is also approved for atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyposis, and prurigo nodularis.
- The approval of Dupixent for the expanded indication was based on a randomized, blinded study in 61 pediatric patients 1 to 11 years of age, weighing at least 15 kg, with EoE. Patients received Dupixent or placebo. The primary endpoint was the proportion of patients achieving histological remission defined as peak esophageal intraepithelial eosinophil count of ≤ 6 eos/hpf at week 16.
    - At week 16, histological remission was achieved in 65.6% and 3.4% of patients with Dupixent and placebo, respectively (difference 62.0, 95% CI: 44.00, 79.95).
- The recommended subcutaneous dosage of Dupixent for EoE is provided in the table below.

Body weight	Recommended dosage
15 to less than 30 kg	200 mg every other week
30 to less than 40 kg	300 mg every other week
40 kg or more	300 mg every week

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