Generic Name:
Dupilumab
Trade Name:
Dupixent
Company:
Regeneron, Sanofi Genzyme
Notes:

Dupilumab gained FDA approval as add-on maintenance therapy for patients with moderate to severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.

Dupilumab inhibits the overactive signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13), two key proteins that contribute to the type 2 inflammation that may underlie moderate to severe asthma. This effect is associated with the reduction of inflammatory biomarkers, including fractional exhaled nitric oxide, immunoglobulin E, and eotaxin-3.

For people with asthma, dupilumab comes in two doses (200 mg and 300 mg) given every other week at different injection sites after an initial loading dose.

Approval for the indication was based on a pivotal trial program that evaluated 2,888 adult and adolescent patients with moderate to severe asthma in three randomized, placebo-controlled, multicenter trials for 6 months to 1 year (24 to 52 weeks).

The agent comes in a pre-filled syringe and is intended for subcutaneous injection under the guidance of a health care provider. It can be given in a clinic or, for convenience, at home by self-administration after training by a health professional.

Dupilumab was previously approved for treatment of adults with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable.

Medication Monitor Categories:
Supplemental Approvals