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Dupixent (dupilumab) Injection
Clinical Update

Clinical Update: FDA has approved Dupixent (dupilumab) as First Biologic Medicine for Children Aged 6 to 11 Years with Moderate-to-Severe Atopic Dermatitis.

FDA approval date: May 26, 2020

Dupixent is a fully-human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins, and is not an immunosuppressant. Data from Dupixent clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis (CRSwNP). Dupixent is an injection under the skin (subcutaneous injection) at different injection sites. In the pediatric (6-11 years of age) population, Dupixent is given either every two weeks (200 mg) or four weeks (300 mg), based on weight, following an initial loading dose. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home by self-administration after training by a healthcare professional. In children younger than 12 years of age, Dupixent should be administered by a caregiver. Dupixent is also approved in the U.S. to treat patients aged 12 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled.

The U.S. Food and Drug Administration (FDA) has approved Dupixent (dupilumab) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent is the only biologic medicine approved for this population. The FDA evaluated the Dupixent application under Priority Review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions. The FDA approval is based on data that includes pivotal Phase 3 results on the efficacy and safety of Dupixent combined with topical corticosteroids (TCS) compared to TCS alone in children with severe atopic dermatitis. In the trial, children treated with Dupixent and TCS experienced significant improvements in overall disease severity, skin clearance and itch.

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