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FDA approves Dupixent for eosinophilic esophagitis; expands indication for atopic dermatitis

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The Food and Drug Administration (FDA) has expanded approval for Dupixent (dupilumab) to include a new indication for the treatment of eosinophilic esophagitis (EoE) in patients 12 years and older weighing at least 40 kilograms (kg). The agency also expanded use for the treatment of moderate-to-severe atopic dermatitis in patients 6 months to 6 years.

Dupixent is a recombinant human immunoglobulin-G4 monoclonal antibody that inhibits interleukin (IL)-4 and (IL)-13 signaling and is administered as a subcutaneous injection. It is the first product approved for the treatment of EoE and the first biologic approved for the treatment of moderate-to-severe atopic dermatitis in patients 6 months to 6 years. Dupixent previously was approved for the treatment of moderate-to-severe atopic dermatitis and as an add-on maintenance treatment of moderate-to-severe asthma in patients 6 years and older.

Dupixent also is approved as an add-on maintenance treatment in adults with inadequately controlled chronic rhinosinusitis with nasal polyposis.

The safety and effectiveness of Dupixent for the treatment of EoE in adolescents 12 to 17 years and weighing at least 40 kg was established in an adequate and well-controlled trial conducted in adult and adolescent patients, with additional pharmacokinetic data collected in adolescents. Of the 240 patients enrolled, 72 were adolescents. Efficacy was established based on evidence of histological remission and improvements in dysphagia at week 24. The safety profile was similar in adults and adolescents. The most common adverse reactions in patients treated with Dupixent were injection site reactions, upper respiratory tract infections, arthralgia and herpes viral infections.

The safety and effectiveness of Dupixent with concomitant topical corticosteroids (TCS) for the treatment of moderate-to-severe atopic dermatitis in patients 6 months to 6 years was established in an adequate and well-controlled 16-week trial in 161 patients (mean age 3.8 years). Efficacy was established based on improvement in overall atopic dermatitis severity using an investigator-based scale at week 16. The safety profile was similar to that seen in patients 6 years and older.

The most common adverse reactions occurring in patients treated with Dupixent plus topical corticosteroids were injection site reactions, conjunctivitis, blepharitis, oral herpes, eye pruritis and dry eye. In addition, hand, foot and mouth disease and skin papilloma were reported in patients 6 months to 6 years during an open-label extension study to assess long-term safety of Dupixent with or without TCS.

The FDA's Office of Pediatric Therapeutics (OPT), Division of Pediatrics and Maternal Health (DPMH), Division of Gastroenterology (DG) and Division of Dermatology and Dental (DDD) contributed to this article. OPT resides in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH resides in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine. DG and DDD reside within the Office of Immunology and Inflammation. DPMH, DG and DDD reside within the Office of New Drugs in the Center for Drug Evaluation and Research.

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Dupixent labeling