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Myriad treatments approved for allergic diseases in pediatric patients

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The Food and Drug Administration (FDA) has approved myriad new treatments for pediatric allergic diseases in recent years, marking important advances in care for children with these conditions.

"Many of these approvals have addressed important unmet needs for children, and some have provided innovative solutions that will hopefully make managing these conditions easier for families," said Kelly Stone, M.D., Ph.D., associate director of the Division of Pulmonology, Allergy, and Critical Care in the FDA's Center for Drug Evaluation and Research.

Allergic diseases are common in pediatric practice, and many children are diagnosed with more than one allergic disease. One in four U.S. children suffers from allergic diseases, including atopic dermatitis, food allergies and seasonal allergies, and more than 6% of children are diagnosed with asthma, according to the Centers for Disease Control and Prevention. In addition, an estimated 0.1% of children are diagnosed with eosinophilic esophagitis.

Following are recent notable approvals of pediatric indications for allergic disease treatments.

Anaphylaxis

Neffy (epinephrine nasal spray) was approved in August 2024 for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kilograms (kg) or greater. It is the first epinephrine product approved for the emergency treatment of allergic reactions, including anaphylaxis, that is not administered by injection.

"For children at risk for anaphylaxis who are afraid of injections, the availability of an epinephrine nasal spray might help reduce barriers to rapid treatment for a life-threatening emergency," Dr. Stone said.

Food allergy

Palforzia (Peanut [*Arachis hypogaea*] allergen powder-dnfp) for use in oral immunotherapy was the first drug approved to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Originally approved in January 2020 for patients 4-17 years, the indication for Palforzia was extended in July 2024 to include patients as young as 1 year with a confirmed diagnosis of peanut allergy.

Xolair (omalizumab) injection was approved in February 2024 for IgE-mediated food allergy in adult and pediatric patients ages 1 year and older for the reduction of allergic reactions (type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. Xolair is the first FDA-approved medication to reduce allergic reactions to more than one type of food in case of accidental exposure.

Xolair is an anti-IgE antibody given by subcutaneous injection every two to four weeks. It is not indicated as an emergency treatment.

"Although Xolair treatment will not eliminate food allergies or allow patients to consume food allergens freely, its repeated use will help reduce the health impact if accidental exposure occurs," Dr. Stone said.

Both Palforzia and Xolair are intended to reduce the risk of allergic reactions from accidental exposures, but patients should continue to avoid relevant food allergens.

Severe asthma

Tezspire (tezepelumab-ekko) injection was approved in December 2021 for the add-on maintenance treatment of adult and pediatric patients ages 12 years and older with severe asthma. Tezspire is the only biologic approved for the treatment of asthma that is not limited to an allergic or eosinophilic phenotype.

Tezspire is a human monoclonal antibody that inhibits thymic stromal lymphopoietin and is administered by subcutaneous injection every four weeks.

Eosinophilic esophagitis

Dupixent (dupilumab) injection was approved in August 2022 for the treatment of eosinophilic esophagitis in patients 12 years and older; the indication was expanded in January 2024 to include children 1-11 years who weigh at least 15 kg.

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 every two weeks. It was the first product approved for the treatment of eosinophilic esophagitis.

Eohilia (budesonide) oral suspension is the first oral therapy approved for treatment of eosinophilic esophagitis in patients 11 years and older. Approved in February 2024, Eohilia is a corticosteroid that is administered twice daily for 12 weeks.

The FDA has approved many other medications for pediatric allergic diseases in recent years, including products for treatment of atopic dermatitis, asthma, allergic rhinitis and chronic rhinosinusitis with nasal polyps.

“These approvals are evidence that the authorities given to us by Congress through laws like the Pediatric Research Equity Act are working to ensure the development of therapeutics for children,” Dr. Stone said.

While these approvals represent important advances, prevention of allergic diseases remains important, he added.

“As a medical community, we are trying to turn the tide on the rise in pediatric allergic diseases, with an emphasis on prevention. In the meantime, the FDA is committed to advancing therapeutics development for children who are diagnosed with these conditions,” Dr. Stone said.

The FDA’s Office of Pediatric Therapeutics and Office of New Drug’s Division of Pulmonology, Allergy, and Critical Care and Division of Pediatrics and Maternal Health contributed to this article.