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FDA approves first oral therapy for EoE

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The Food and Drug Administration (FDA) has approved the first oral therapy for adolescents and adults with eosinophilic esophagitis (EoE).

Eohilia (budesonide oral suspension) is a corticosteroid from Takeda that can be used for patients ages 11 years and older with EoE, a chronic allergic inflammatory condition in the esophagus that has limited treatment options.

Erin P. Syverson, M.D., FAAP, a member of the AAP Section on Gastroenterology, Hepatology and Nutrition, said she is excited about the FDA approval.

“I am hopeful this will make a big difference for our patients in increasing accessibility to a swallowed topical steroid that is commercially available and formulated specifically for delivery to the esophagus for EoE treatment,” said Dr. Syverson, associate director of the Eosinophilic Gastrointestinal Disease Program at Boston Children’s Hospital.

Clinicians already have been using oral viscus budesonide off-label. The treatment presented challenges because patients had to combine it with another mixing agent, which lacked standardized practices and could be cumbersome. Takeda described Eohilia as “flowing more freely when shaken and returning to a more viscous state when swallowed” and said it will provide a consistent dose.

Another common treatment for children with EoE has been fluticasone HFA, which also was used off-label. However, GSK discontinued its brand name version, Flovent, at the end of 2023. While it is manufacturing a

generic version, some insurers aren't covering it. The AAP has been working with payers and federal health officials on this issue.

Dr. Syverson said it "remains to be seen how readily this new medication (Eohilia) is going to be covered by insurance."

Another EoE treatment, Dupixent (dupilumab), recently received an expanded indication from the FDA to include children with EoE who are 1-11 years old and weigh at least 15 kilograms.

Eohilia is given in doses of 2 milligrams twice a day for 12 weeks. The label notes it has not been shown to be safe and effective for longer.

The FDA accepted Takeda's new drug application in December 2020. A year later, the FDA determined more study was needed. Takeda revised its application and resubmitted it in September 2023.

Takeda conducted two multicenter, randomized, placebo-controlled trials in patients 11 to 56 years and 11 to 42 years, respectively. The first found 53% of the treatment group achieved histologic remission compared to 1% receiving a placebo. The second found 38% of the treatment group achieved remission vs. 2% of the placebo group, according to Takeda.

The most common adverse reactions were respiratory tract infection, gastrointestinal mucosal candidiasis and headache.

"Despite lack of FDA approval up until now, there is strong data on the effectiveness and safety profile of swallowed topical steroids in treating EoE dating back to the early 2000s," Dr. Syverson said.

The treatment is contraindicated for patients with hypersensitivity to budesonide, and the full prescribing information includes warnings about immunosuppression and increased risk of infection. Dr. Syverson noted it is important to remind patients to refrain from eating or drinking for at least 30 minutes after taking Eohilia. After 30 minutes, patients should rinse their mouth and spit to reduce the risk of developing thrush.

Resource

Prescribing information for Eohilia

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