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First treatment for pediatric functional constipation approved by FDA

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The Food and Drug Administration (FDA) has approved the first treatment for functional constipation in children ages 6-17 years.

Functional constipation, a condition commonly seen by pediatricians, is characterized by infrequent bowel movements with hard stools that can be difficult or painful to pass. The newly approved treatment, Linzess (linaclotide) capsules, is a guanylate cyclase-C agonist that works by increasing intestinal fluid and accelerating intestinal transit. The recommended dosage for patients ages 6-17 years is 72 micrograms orally once daily.

The safety and efficacy of Linzess for the treatment of functional constipation in patients 6-17 years old were established in a 12-week double-blind, placebo-controlled, randomized, multicenter, clinical trial (https://bit.ly/3pPELqM), and supported by data from adequate and well-controlled trials in adults with chronic idiopathic constipation.

To be enrolled in the clinical trial, pediatric patients had to meet modified Rome III diagnostic criteria for functional constipation. They were required to have fewer than three spontaneous bowel movements (SBMs) per week (defined as a bowel movement that occurred in the absence of laxative, enema or suppository use on the calendar day of or before the bowel movement). Patients also were required to

meet at least one of the following criteria at least once per week for at least two months before the screening visit:

- history of stool withholding or excessive voluntary stool retention,
- history of painful or hard bowel movements,
- history of large diameter stools that may obstruct the toilet,
- presence of a large fecal mass in the rectum,
- at least one episode of fecal incontinence per week.

The primary efficacy endpoint was a change from baseline in SBM frequency rate.

Results showed patients who received Linzess experienced a greater improvement in the average number of SBMs per week than patients who received placebo. SBM frequency improved during week one and was maintained throughout the remainder of the 12-week treatment period.

The safety of Linzess in pediatric patients was similar to adults. The most common adverse reaction reported in pediatric trial participants was diarrhea. If severe diarrhea occurs, patients should stop taking Linzess and be rehydrated.

Linzess also contains a boxed warning that the medication should not be taken by patients younger than 2 years. In neonatal mice, linaclotide caused deaths due to dehydration. The medication also is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

The FDA's Office of Pediatric Therapeutics and Office of New Drug's Division of Pediatrics and Maternal Health and Division of Gastroenterology contributed to this article.

Resources

- Linzess prescribing information
- Information for parents from HealthyChildren.org on constipation