

**IBSRELA
(tenapanor)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Ibsrela (tenapanor) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium. By inhibiting NHE3 on the apical surface of the enterocytes, Ibsrela reduces absorption of sodium from the small intestine and colon, resulting in an increase in water secretion into the intestinal lumen, which accelerates intestinal transit time and results in softer stool consistency (1).

Regulatory Status

FDA-approved indication: Ibsrela is a sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults (1).

Ibsrela has a boxed warning regarding the risk of serious dehydration in pediatric patients. Ibsrela is contraindicated in patients less than 6 years of age. Use should be avoided in patients 6 years to less than 12 years of age. The safety and effectiveness of Ibsrela have not been established in pediatric patients less than 18 years of age (1).

Ibsrela is also contraindicated in patients with known or suspected mechanical gastrointestinal obstruction (1).

The safety and effectiveness of Ibsrela in pediatric patients less than 18 years of age have not been established (1).

Summary

Ibsrela (tenapanor) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium. Ibsrela is indicated for use in patients with irritable bowel syndrome with constipation (IBS-C). The safety and effectiveness of Ibsrela in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of



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Ibsrela while maintaining optimal therapeutic outcomes.

References

1. Ibsrela [package insert]. Fremont, CA: Ardelyx, Inc.; April 2022.