



## Pharmacy Drug Policy & Procedure

<b>Policy Name:</b>	<b>Tenapanor Products</b>	<b>Policy#:</b>	<b>3119P</b>
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### Purpose of the Policy

The purpose of this policy is to define coverage criteria for tenapanor products, Isbrela and Xphozah.

### Statement of the Policy

Health Alliance Medical Plans will approve the use of tenapanor products, Isbrela or Xphozah, under the pharmacy benefit if the following criteria are met.

### Criteria

#### 1. Coverage Criteria for Irritable Bowel Syndrome – Constipation (Ibsrela)

- 1.1 Diagnosis of irritable bowel syndrome with constipation (IBS-C)
- 1.2 Age 18 years or older
- 1.3 Documented trial and failure of, or contraindication to Amitiza AND Linzess

#### 2. Coverage Criteria for Hyperphosphatemia (Xphozah)

- 2.1 Diagnosis of chronic hyperphosphatemia in patients with chronic kidney disease on dialysis
- 2.2 Age 18 years or older
- 2.3 Prescribed by or in consultation with a nephrologist (kidney doctor)
- 2.4 Documented minimum 30-day supply trial and failure, or contraindication to phosphate binders (such as calcium acetate, sevelamer, lanthanum, etc)
- 2.5 Documented minimum 30-day supply trial and failure, or contraindication to Velphoro

#### 3. Exclusion Criteria

- 3.1 Patients with known or suspected mechanical gastrointestinal obstruction

#### 4. Managed Dose Limit

- 4.1 #60 tablets per 30 days

#### 5. Approval Period

- 5.1 Initial: 12 months
- 5.2 Subsequent Approvals: 12 months with documentation of positive response to therapy

### CPT Codes

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### HCPCS Codes

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### References

- 1. Isbrela (tenapanor) [prescribing information]. Waltham, MA: Ardelyx Inc; January 2025.

2. Xphozah (tenapanor) [prescribing information]. Waltham, MA: Ardelyx Inc; October 2023.
3. Block GA, Bleyer AJ, Silva AL, et al. Safety and efficacy of tenapanor for long-term serum phosphate control in maintenance dialysis: a 52-week randomized phase 3 trial (PHREEDOM). *Kidney360*. 2021;2(10):1600-1610.
4. Chang L, Sultan S, Lembo A, et al. American Gastroenterological Association Institute Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. *Gastroenterology* 2022;163: 118–136.
5. Ketteler M, Block GA, Evenepoel P, et al. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline. *Kidney Int*. 2017 Jul;92(1):26-36.

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#### DISCLAIMER

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