



# 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 trial and failure, or contraindication to phosphate binders (such as calcium acetate, sevelamer, lanthanum, etc)
- 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. Ibsrela (tenapanor) [prescribing information]. Waltham, MA: Ardelyx Inc; April 2022.
- 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). *Kidney* 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

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.