



**Commercial PA Criteria**  
**Effective: December 18, 2023**

**Prior Authorization:** Xphozah (tenapanor)

**Products Affected:** Xphozah (tenapanor) oral tablets

**Medication Description:** Tenapanor is a locally acting inhibitor that targets the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the epithelium of the small intestine and colon. Inhibition of NHE3 by tenapanor results in reduced sodium absorption and decreased phosphate absorption by reducing phosphate permeability through the paracellular pathway.

**Covered Uses:** XPHOZAH is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

**Exclusion Criteria:**

1. Patients less than 6 years of age due to the risk of serious dehydration
2. Patients with known or suspected mechanical gastrointestinal obstruction

**Required Medical Information:**

1. Diagnosis
2. Past therapies tried and failed

**Prescriber Restriction:** The medication is prescribed by or on consultation with a nephrologist.

**Age Restriction:** Patient is 18 years of age or older

**Coverage Duration:** 12 months

**Other Criteria:**

**Initial Approval Criteria**

**1. Hyperphosphatemia in Chronic Kidney Disease.**

- A. Patient has chronic kidney disease (CKD); **AND**
- B. Patient has been on maintenance dialysis for  $\geq 3$  months; **AND**
- C. Patient's serum phosphate level is  $\geq 5.5$  mg/dL and  $<10.0$  mg/dL; **AND**
- D. Patient meets one of the following (i or ii):
  - i. Patient meets both of the following (a and b):
    - a. Patient has tried at least two phosphate binders; **AND**

*Note: Examples of phosphate binders include: sevelamer, lanthanum, ferric citrate, and sucroferric oxyhydroxide, calcium carbonate, and calcium acetate.*

December 2023



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- b. Patient had an inadequate response and/or intolerance to at least two phosphate binders; **OR**
- ii. Patient meets one of the following (a or b):
  - a. Patient has a contraindication to at least two phosphate binders; **OR**  
*Note: Contraindication to phosphate binders includes bowel obstruction, iron overload, or hypercalcemia.*
  - b. Patient meets both of the following (1 and 2):
    - (1) Patient has inadequate response and/or intolerance to at least one phosphate binder; **AND**
    - (2) Patient has a contraindication to at least one phosphate binder.  
*Note: Contraindication to phosphate binders includes bowel obstruction, iron overload, or hypercalcemia.*

**Renewal Criteria**

- 1. Member has responded positively to the treatment as determined by the prescribing physician; **AND**
- 2. Member has not experienced unacceptable toxicity from the drug

**References:**

- 1. Product Information: XPHOZAH® oral tablets, tenapanor oral tablets. Ardelyx Inc (per FDA), Waltham, MA, 2023.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/18/2023