

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 2331-1
Program	Prior Authorization/Medical Necessity
Medication	Xphozah® (tenapanor)
P&T Approval Date	3/2024
Effective Date	6/1/2024

**1. Background:**

Xphozah® (tenapanor) is a sodium hydrogen exchanger 3 (NHE3) inhibitor 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.

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Xphozah** will be approved based upon **all** of the following criteria:

a. Diagnosis of chronic kidney disease (CKD)

-AND-

b. Patient is receiving dialysis

-AND-

c. Serum phosphorus is > 6.5 mg/dL

-AND-

d. Patient has had an inadequate response to a maximally tolerated dose of **two** of the following phosphate binders:

- (1) calcium acetate (generic PhosLo)
- (2) lanthanum carbonate (generic Fosenrol)
- (3) sevelamer carbonate (generic Renvela)
- (4) Velphoro (sucroferric oxyhydroxide)]

-AND-

e. Xphozah will be used as add-on therapy

-AND-

f. Prescribed by or in consultation with a nephrologist.

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Xphozah** will be approved based on **both** the following criterion:
  - a. Documentation of positive clinical response to Xphozah therapy [e.g., reduction of serum phosphorus towards the normal range (3.5 to 5.5 mg/dL)]

**-AND-**

- b. Prescribed by or in consultation with a nephrologist.

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. Reference:**

1. Xphozah® [package insert]. Waltham, MA: Ardelyx, Inc.; October 2023
2. National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis.* 2003;42(4 Suppl 3):S1-S201.
3. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). *Kidney Int Suppl.* 2009;(113):S1-S130. doi:10.1038/ki.2009.188
4. Ketteler M, Block GA, Evenepoel P, et al. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline Update: what's changed and why it matters [published correction appears in *Kidney Int.* 2017 Dec;92(6):1558]. *Kidney Int.* 2017;92(1):26-36. doi:10.1016/j.kint.2017.04.006

Program	Prior Authorization/Medical Necessity - Xphozah (tenapanor)
<b>Change Control</b>	
3/2024	New program.