UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2331-2
Program	Prior Authorization/Medical Necessity
Medication	Xphozah® (tenapanor)
P&T Approval Date	1/2025
Effective Date	4/1/2025

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[a]:

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. <u>Reauthorization</u>

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.

[a] 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)
Change Control	
3/2024	New program.
1/2025	Annual review with no updates.