

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 10, 2024

Xphozah® (tenapanor)

LENGTH OF AUTHORIZATION: Up to 1 year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of chronic kidney disease (CKD) and is on dialysis; **AND**
- Patient has a serum phosphate level ≥ 5.5 mg/dL despite treatment compliance with a phosphate binder. *(Official labs drawn within 30 days of PA submission must be provided).*
- Medication will be prescribed as add-on therapy in patients who had an inadequate response, contraindication, or intolerance (at any dose) to previous trials of at least 2 phosphate binders (e.g., Calcium acetate, Renvela, Velphoro). *(Clinical documentation demonstrating response to previous therapies must be provided).*
- The medication is prescribed by, or in consultation with a nephrologist.

CONTINUATION OF THERAPY

- Patient has met initial review criteria; **AND**
- Documentation of improved clinical response compared to baseline labs *(supporting documentation and official lab results required)*; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 10 mg, 20 mg, and 30 mg tablets