

| 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