MEDICAL MUTUAL®

Drug Policy

Policy:	Xphoza (Tenapanor)	Annual Review Date: 01/18/2024 Last Revised Date: 01/18/2024

OVERVIEW

Xphozah, a sodium hydrogen exchanger 3 (NHE3) inhibitor, 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.

POLICY STATEMENT

This policy involves the use of Xphozah. Prior authorization is recommended for pharmacy benefit coverage of Xphozah. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Xphozah as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Xphozah be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xphozah is recommended in those who meet the following criteria:

1. Hyperphosphatemia in Chronic Kidney Disease.
Criteria. *Patient must meet the following criteria*

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has chronic kidney disease (CKD); AND
- **C)** Patient has been on maintenance dialysis for ≥ 3 months; AND
- **D)** Patient's serum phosphate level is ≥ 5.5 mg/dL and <10.0 mg/dL; AND
- **E)** 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.

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.

F) The medication is prescribed by or on consultation with a nephrologist.

Initial Approval/ Extended Approval.
A) *Initial Approval: 12 months*
B) *Extended Approval: 12 months*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xphozah has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Xphozah® tablets [prescribing information]. Waltham, MA: Ardelyx; October 2023.
2. Ketteler M, Block G, Evenepoel P, et al. Diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder: synopsis of the kidney disease: improving global outcomes 2017 clinical practice guideline update. *Ann Intern Med*. 2018; 168 (6): 422-430.

3. Ketteler M, Block G, 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. *Kidney Int*. 2017; 92(1):26.