PREMERA HMO

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PHARMACY POLICY – 5.01.598

Pharmacologic Treatment to Reduce Serum Phosphorus

Effective Date:	July 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	June 11, 2024	None
Replaces:	N/A	

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POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Phosphate is an element in the body. Formed from the mineral phosphorus, phosphate is needed to form bones and teeth, help the nerves work, and allow muscles to contract. If a person eats a diet that is too high in phosphorus, the body is usually able to efficiently eliminate the excess amount. For people with severe kidney problems or on dialysis, however, the body can't easily eliminate excess phosphate. This policy describes when certain drugs used to reduce serum phosphorus may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
• **Fosrenol (lanthanum carbonate)** • **Renagel (sevelamer HCl)**	**Fosrenol (lanthanum carbonate), Renagel (sevelamer HCl), Renvela (sevelamer carbonate) and Velphoro (sucroferric oxyhydroxide) may be considered medically necessary for the**

Drug	Medical Necessity
• **Renvela (sevelamer carbonate)** • **Velphoro (sucroferric oxyhydroxide)**	**treatment of hyperphosphatemia when the following criteria are met:** • Individual has tried and failed or had an intolerance to sevelamer HCl or sevelamer carbonate.
Auryxia (ferric citrate)	**Auryxia (ferric citrate) may be considered medically necessary for the treatment of hyperphosphatemia when the following criteria are met:** • Individual has tried and failed or had an intolerance to sevelamer HCl or sevelamer carbonate. **Auryxia (ferric citrate) may be considered medically necessary for the treatment of iron deficiency anemia when the following criteria are met:** • Individual has tried and failed or had an intolerance to both oral iron and IV iron. **Note:** Examples of oral iron include ferrous fumarate, ferrous gluconate and ferrous sulfate. **Note:** Examples of IV iron include iron dextran (INFeD), iron sucrose (Venofer), and sodium ferric gluconate complex (Ferrlecit).
Xphozah (tenapanor)	**Xphozah (tenapanor) may be considered medically necessary to reduce serum phosphorus when all the following criteria are met:** • The individual has been diagnosed with chronic kidney disease (CKD) **AND** • The individual is currently receiving dialysis **AND** • Xphozah will be used as add-on therapy to reduce serum phosphorus **AND** • The individual has tried and had an inadequate response or intolerance to phosphate binder therapy (e.g., calcium acetate, sevelamer, or lanthanum)

Drug	Investigational
• Auryxia (ferric citrate) • Fosrenol (lanthanum carbonate) • Renagel (sevelamer HCl) • Renvela (sevelamer carbonate) • Velphoro (sucroferric oxyhydroxide) • Xphozah (tenapanor)	**All other uses of Auryxia (ferric citrate), Fosrenol (lanthanum carbonate), Renagel (sevelamer HCl), Renvela (sevelamer carbonate), Velphoro (sucroferric oxyhydroxide), and Xphozah (tenapanor) for conditions not outlined in this policy are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Auryxia (ferric citrate), Fosrenol (lanthanum carbonate), Renagel (sevelamer HCl), Renvela (sevelamer carbonate), Velphoro (sucroferric oxyhydroxide), and Xphozah (tenapanor) may be approved up to 12 months.**
Re-authorization criteria	**Future re-authorization of Auryxia (ferric citrate), Fosrenol (lanthanum carbonate), Renagel (sevelamer HCl), Renvela (sevelamer carbonate), Velphoro (sucroferric oxyhydroxide), and Xphozah (tenapanor) may be approved up to 1 year in duration when there is documentation of continued clinical response and that ongoing treatment is required.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis and medication history

Coding

N/A

Related Information

Benefit Application

The drugs in this policy are oral medications and managed through the pharmacy benefit.

Evidence Review

Background

Hyperphosphatemia is associated with atherosclerosis, vascular calcification, cardiovascular (CV) events, and increased mortality based on retrospective, cohort, and observational studies. Hyperphosphatemia occurs commonly with chronic kidney disease (CKD), increasing in frequency and severity as CKD worsens. Hyperphosphatemia occurs in 37% of individuals on dialysis. The attributable risk of disorders of mineral metabolism in individuals in dialysis is 17.5%, driven by increased risks associated with hyperphosphatemia.

Because of the relationship between hyperphosphatemia and mortality, hyperphosphatemia is commonly treated in individuals with CKD. However, randomized controlled trial data linking serum phosphate to individual outcomes is lacking in individuals with CKD; therefore, treatment of hyperphosphatemia is based on epidemiologic evidence and biological plausibility.

Summary of Evidence

Xphozah (tenapanor)

Xphozah was evaluated in three Phase 3 clinical trials (BLOCK [TEN-02-201], PHREEDOM [TEN-02-301], and AMPLIFY [TEN-02-202]), as monotherapy and in combination with phosphate binder therapy. Both monotherapy trials (BLOCK and PHREEDOM) enrolled individuals who, following a 3-week washout period, had an increase in serum phosphorus of ≥1.5 mg/dL (compared to pre-washout value) and a serum phosphorus level of ≥6.0 mg/dL and ≤10.0 mg/dL. All three trials met their primary and key secondary endpoints, demonstrating that Xphozah significantly reduced elevated serum phosphorus in individuals receiving maintenance hemodialysis. Approximately 47% of individuals experienced diarrhea across the three trials, with

most cases reported as mild to moderate in severity. This side effect is a direct result of Xphozah's mechanism of action.

Meaningful Differences in Efficacy in Clinical Trials

All phosphate binders decrease phosphate significantly more than placebo and are approved on this basis for the treatment of hyperphosphatemia in individuals with ESRD. A total of four large good-moderate quality meta-analyses and network meta-analysis evaluating the efficacy of phosphate binders have been completed in the last 3 years. Results were inconsistent between the meta-analyses. A single meta-analyses found iron-based binders decreased serum phosphorus more than all other binders (sevelamer, lanthanum, calcium-based binders) (OR 0.09, 95% CI 0.03-0.25). In contrast, another meta-analysis found lanthanum less effective than calcium-based binders (mean difference 0.18, 95% CI 0.10-0.25) but found no difference between sevelamer and all other binders (calcium-based, lanthanum, and iron-based). No other meta-analyses addressed this issue.

The goal of treatment with phosphate binders is to reduce mortality, cardiovascular (CV) outcomes, and bone fractures in individuals with hyperphosphatemia. Long-term, placebo-controlled RCT data designed to evaluate these endpoints are lacking. The four meta-analyses mentioned above evaluated the effect of phosphate binders on all-cause mortality as well as CV mortality. Three of four meta-analyses found significantly improved all-cause mortality with sevelamer compared to calcium-based binders (RR 0.53, CI 0.30-0.91 for CKD G5D; OR 0.39, 95% CI 0.21-0.74; RR 1.89, 95% CI 1.02-3.50). The absolute mortality increase with calcium-based binders ranged from 43-96 per 1,000 individuals. The fourth meta-analysis found the same significant difference when only higher quality studies were included (RR 0.51, 95% CI 0.21-0.83; NNT 16). The meta-analysis also found sevelamer decreased mortality in comparison with calcium carbonate (RR 0.44, 95% CI 0.25-0.76) but not in comparison with calcium acetate (RR 0.43, 95% CI 0.13-1.38). Because there is a lack of placebo-controlled study data evaluating mortality, it is not known if the difference in mortality between sevelamer and calcium-based binders represents an increase in mortality with calcium-based binders, a decrease in mortality with sevelamer, or both. Based the above data, the current Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for CKD-mineral and bone disorder (MBD) concluded there is a potential for benefit or an absence of harm with non-calcium-based phosphate binders compared to calcium-based agents and suggested restricting the dose of calcium-based phosphate binders.

Data was insufficient to assess changes in CV mortality in two meta-analyses. Additionally, two meta-analysis found no difference in CV mortality between groups assessed (calcium vs non-

calcium-based binders RR 2.54, 95% CI 0.67-9.62; sevelamer vs calcium-based binders (RR 0.29, 95% CI 0.05-1.82). A total of two meta-analyses assessed hospitalizations; results were not consistent between meta-analyses. Sevelamer significantly decreased hospitalizations compared to calcium-based binders (RR 0.50, 95% CI 0.31-0.81, NNT 4) while no difference between lanthanum and calcium-based binders (RR 0.80, 95% CI, 0.34-1.93). Another meta-analysis found no difference in hospitalizations between calcium- and non-calcium-based binders (RR 1.28, 95% CI 0.94-1.74). The meta-analyses either did not evaluate bone fracture data or found insufficient data for evaluation.

Differences in Safety Profiles

Adverse events vary between different classes of phosphate binders.

- As discussed above, calcium-based binders are associated with increased risks of hypercalcemia (16.3%) including vascular calcification.
- Sevelamer is associated with more constipation than any other class of phosphate binders. Common AEs (≥10%) include vomiting (22%), nausea (20%), diarrhea (19%), and dyspepsia (16%). Sevelamer HCl (Renagel) is associated with metabolic acidosis; however, this risk is not present with sevelamer carbonate (Renvela).
- Lanthanum is associated with more nausea than other phosphate binders and more GI events than calcium-based binders. Common AEs (≥10%) include nausea (11%).
- Iron-based binders as associated with an increased risk of diarrhea compared with calcium-based agents; common AEs (≥10%) include diarrhea (21%), discolored feces (19%), and nausea (11%). Monitoring for iron accumulation is recommended and fatal poisoning is possible in children.

Evidence of Real-World Comparative Effectiveness

Data from a Phase IV, 5-year, observational cohort study comparing lanthanum and other phosphate binders found no difference in all-cause mortality (adjusted HR 0.94, 95% CI 0.88-1.01) or bone fractures requiring hospitalization (adjusted HR 0.86, 95% CI 0.71-1.05) as well as no increased risk of GI disease, liver disease, malignancy, or major infection with lanthanum.

Practice Guidelines and Position Statements

The Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for mineral and bone disorder were last updated in 2017 (see Table 1). The guidelines do not support the idea that all phosphate binders are interchangeable. Due to concerns about adverse events seen with calcium-based phosphate binders, the committee suggests excess exposure to calcium through diet, medications, or dialysate maybe be harmful for all individuals with CKD. Of note, significant survival benefit was noted with sevelamer compared to calcium-based binders. Based on trial data, the committee concluded there is a potential for benefit or an absence of harm with calcium-free phosphate binders compared to calcium-based agents. Evidence gaps include uncertainty if effects differ between formulations of calcium-based binders and a lack of hard clinical outcomes and comparative effectiveness between binder classes. Lastly, the committee noted a lack of long-term patient centered outcomes in published Phase III trials with iron-containing phosphate binders.

Table 1. Selected KDIGO Guidelines for Lowering High Serum Phosphate and Maintaining Serum Calcium in Individuals with CKD G3a-G5D[15]

4.1.1	Base treatment of CKD-MBD on serial assessments of phosphate, calcium, and PTH levels, considered together.
4.1.2	Suggest lower elevated phosphate towards the normal range.
4.1.3	Suggest avoiding hypercalcemia.
4.1.5	Base treatment decisions on phosphate-lowering on progressively or persistently elevated serum phosphate.
4.1.6	Suggest restricting the dose of calcium-based phosphate binders.
4.1.7	Avoid long-term use of aluminum-containing phosphate binders.
4.1.8	Suggest limiting dietary phosphate intake.

Notes: G3a = GFR 45-59 ml/min/1.73m2, G5D = GFR <15 ml/min/1.73m2 and on dialysis

Abbreviations: CKD = chronic kidney disease, GFR = glomerular filtration rate, KDIGO = Kidney Disease: Improving Global Outcomes, MBD = mineral bone disease, PTH = parathyroid hormone

2020 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search for updated treatment guidelines. No new evidence found that would change this policy.

2021 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search on the management of hyperphosphatemia. No new evidence found that would change this policy.

2022 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search on the management of hyperphosphatemia. No new evidence was found that would change this policy.

2023 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search on the management of hyperphosphatemia. Removed Phoslyra (calcium acetate solution) due to product discontinuation.

2024 Update

Reviewed prescribing information for all drugs in policy and conducted a literature search on the management of hyperphosphatemia. Added coverage criteria for Xphozah (tenapanor).

References

1. Lanthanum carbonate chewable tablets prescribing information. Lupin Pharmaceuticals, Inc.; Balti-more, MD. Revised February 2019.
2. Fosrenol (lanthanum carbonate tablet, chewable and powder) prescribing information. Shire US Inc.; Lexington, MA. Revised May 2023.
3. Sevelamer carbonate film-coated tablet and oral suspension prescribing information. Winthrop U.S.; Bridgewater, NJ. Revised October 2018.
4. Renagel (sevelamer hydrochloride) tablets prescribing information. Genzyme Corporation; Cambridge, MA. Revised April 2020.
5. Renvela (sevelamer carbonate) film coated tablet and oral suspension prescribing information. Genzyme Corporation; Cambridge, MA. Revised April 2020.
6. Auryxia (ferric citrate) tablets prescribing information. Keryx Biopharmaceuticals, Inc.; Boston, MA. Revised March 2021.

7. Velphoro (sucroferric oxyhydroxide) chewable tablet prescribing information. Fresenius medical Care North America; Waltham, MA. Revised February 2020.
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14. Hutchison A, Shelton A, Thadhani R, et al. Long-term mortality and bone safety in patients with end-stage renal disease receiving lanthanum carbonate. Nephron. 2018;140:265-274.
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17. Berkoben M, Quarles L. Management of hyperphosphatemia in adults with chronic kidney disease. UpToDate. Accessed March 5, 2024.
18. Xphozah (tenapanor) prescribing information. Ardelyx, Inc; Waltham, MA. Revised October 2023.

History

Date	Comments
05/01/19	New policy, approved April 9, 2019. Add to Prescription Drug section. Auryxia® (ferric citrate), Phoslyra, Fosrenol, Renagel, Renvela, and Velphoro may be considered medically necessary when criteria are met, considered investigational when criteria not met.
10/01/20	Annual Review, approved September 1, 2020. References updated; no changes to policy statements.
11/01/21	Annual Review, approved October 21, 2021. No changes to policy statements.

Date	Comments
12/01/22	Annual Review, approved November 7, 2022. No changes to policy statements. Changed the wording from "patient" to "individual" throughout the policy for standardization.
12/01/23	Annual Review, approved November 20, 2023. Removed Phoslyra (calcium acetate solution) due to product discontinuation.
04/01/24	Annual Review, approved March 25, 2024. Minor correction to reflect removal of Phoslyra (calcium acetate solution).
07/01/24	Interim Review, approved June 11, 2024. Added coverage criteria for Xphozah (tenapanor). Policy title change from Phosphate Binders to Pharmacologic Treatment to Reduce Serum Phosphorus.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 844-722-4661 (TTY: 711).

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