Preferred Step Therapy
Phosphate Binders

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Product Identifier(s)

59993

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National Formulary Medical Necessity

Drugs Affected

- Fosrenol® (lanthanum carbonate chewable tablets and oral powder, generics for the chewable tablets only)
- Phoslyra™ (calcium acetate oral solution)
- Renagel® (sevelamer hydrochloride tablets)
- Renvela® (sevelamer carbonate tablets and powder for oral suspension, generics)
- Velphoro® (sucroferric oxyhydroxide chewable tablet)

A preferred step therapy program has been developed to encourage the use of a Step 1 product prior to the use of a Step 2 product. If the preferred step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the preferred step therapy criteria below. Note: Auryxia and several calcium-based phosphate binders are not targeted in this policy. All approvals are provided for 1 year in duration

Step 1: generic lanthanum carbonate chewable tablets, Phoslyra oral solution, generic sevelamer carbonate powder for oral suspension, generic sevelamer carbonate tablets, generic sevelamer hydrochloride tablets, Velphoro chewable tablets

Step 2: Fosrenol chewable tablets, Fosrenol oral powder, Renagel tablets, Renvela powder for oral suspension, Renvela tablets

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 product, authorization for a Step 2 product may be given.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Fosrenol and Phoslyra are indicated to reduce serum phosphorus in individuals with end stage renal disease (ESRD).[1,2] Renagel, Renvela, and Velphoro are indicated for the control of serum phosphorus in individuals with chronic kidney disease (CKD) on dialysis.[3-5]

Fosrenol, sevelamer hydrochloride, and sevelamer carbonate are non-calcium based phosphate binders; Phoslyra contains calcium acetate as the binding agent.[1-4] Velphoro is an iron-based product.[5] Age indications and available dosage forms vary across the class.[1-5] In general, the phosphate binders appear to have similar efficacy in reducing serum phosphorous levels, although there are more data available with agents that have been on the market longer (e.g., sevelamer).[1-6] Adverse event (AE) profiles also differ with each agent; gastrointestinal AEs are most common with this class.

The phosphate binders are used for the management of hyperphosphatemia, an important and inevitable consequence of the advanced stages of CKD.[1-6] The rationale for controlling serum phosphorus in these individuals is based on epidemiological evidence suggesting that hyperphosphatemia is an important risk factor for both secondary hyperparathyroidism and cardiovascular disease.[6] Treatment of hyperphosphatemia includes taking phosphate binders, limiting dietary phosphate intake, and/or increasing the frequency/duration of dialysis.[6,7]

Guidelines
The Kidney Disease: Improving Global Outcomes (KDIGO) guidelines for CKD-mineral and bone disorder (MBD) [2017] recommend lowering elevated phosphate levels toward the normal range in individuals with CKD Stage 3 through 5D (glomerular filtration rate [GFR] < 59 mL/min/1.73m^2 and individuals receiving dialysis).[8] Overall, treatment decisions should be made after simultaneously evaluating phosphate, calcium, and parathyroid hormone (PTH) levels, due to the complexity of the interaction between these laboratory parameters. In individuals with CKD Stage 3 through 5D receiving phosphate-lowering treatment, it is recommended to restrict the dose of calcium-based phosphate binders. However, the guidelines do not recommend against the use of calcium-based binders as they may be necessary in some individuals. No preference for a specific non-calcium containing phosphate binder is provided. The availability of iron-containing phosphate binders was considered in the 2017 guideline update, but no specific recommendations were made due to the lack of long-term, patient-centered outcome data in published Phase III trials of these agents.

References

1. Fosrenol® chewable tablets and oral powder [prescribing information]. Lexington, MA: Takeda Pharmaceutical Company; May 2020.
2. Phoslyra oral solution [prescribing information]. Waltham, MA: Fresenius Medical Care; October 2015.
3. Renagel® tablets [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2016.
4. Renvela® tablets and oral suspension [prescribing information]. Cambridge, MA: Genzyme Corporation; April 2020.
5. Velphoro® chewable tablets [prescribing information]. Waltham, MA: Fresenius Medical Care; June 2018.

6. Kidney Disease: Improving Global Outcomes (KDIGO) CKF_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 International.* 2009;76(Suppl 113):S1-S130.
7. Uhlig K, Berns JS, Kestenbaum B, et al. KDOQI US commentary on the 2009 KDIGO clinical practice guideline for the diagnosis, evaluation, and treatment of CKD-mineral and bone disorder (CKD-MBD). *Am J Kidney Dis.* 2010;55:773-799.
8. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention and treatment of chronic kidney disease-mineral and bone disorder (CKD-MBD). *Kidney Int.* 2017;76(7):S1-S59.

Revision History

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/16/2020