



PREFERRED STEP THERAPY POLICY

- POLICY:** Phosphate Binders Preferred Step Therapy Policy
- Fosrenol® (lanthanum carbonate chewable tablets and oral powder – Takeda, generic [chewable tablets only])
 - Phoslyra™ (calcium acetate oral solution – Fresenius)
 - Renagel® (sevelamer hydrochloride tablets – Genzyme, generic)
 - Renvela® (sevelamer carbonate tablets and powder for oral suspension – Genzyme, generic)
 - Velphoro® (sucroferric oxyhydroxide chewable tablet – Fresenius)

REVIEW DATE: 10/23/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Fosrenol and Phoslyra are indicated to **reduce serum phosphorus in patients with end stage renal disease (ESRD)**.^{1,2} Renagel, Renvela, and Velphoro are indicated for the **control of serum phosphorus in patients 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).⁶

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 patients with CKD Stage 3 (glomerular filtration rate [GFR] < 59 mL/min/1.73m²) through 5D (patients receiving dialysis).⁷ It is noted that data supporting the benefits of maintaining serum phosphate in the normal range in these patients are lacking. There are additional safety concerns as well and therefore, treatment should be aimed at avoiding overt hyperphosphatemia. Overall, treatments should be based on evaluation of phosphate, calcium, and parathyroid hormone levels, all considered together, due to the complexity of the interaction between these laboratory parameters. Phosphate-lowering treatment decisions in patients with CKD Stage 3a through 5D should be based on persistently or progressively elevated serum phosphate levels. No preference for a specific non calcium-based phosphate binder is provided in the KDIGO guidelines.

POLICY STATEMENT

This 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 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. 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

Phosphate Binders Preferred Step Therapy Policy product(s) is(are) covered as medically necessary when the following preferred step therapy criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Fosrenol® chewable tablets and oral powder [prescribing information]. Lexington, MA: Takeda; May 2020.
2. Phoslyra™ oral solution [prescribing information]. Waltham, MA: Fresenius; October 2015.
3. Renagel® tablets [prescribing information]. Cambridge, MA: Genzyme; May 2021.

4. Renvela® tablets and oral suspension [prescribing information]. Cambridge, MA: Genzyme; April 2020.
5. Velphoro® chewable tablets [prescribing information]. Waltham, MA: Fresenius; 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 Int.* 2009;76(Suppl 113):S1-S130.
7. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/25/2023
Annual Revision	No criteria changes.	10/23/2024

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