

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3163-4
Program	Step Therapy – Phosphate Binders
Medication	Fosrenol®* (lanthanum carbonate), Velphoro® (sucroferric oxyhydroxide)
P&T Approval Date	2/2022, 2/2023, 2/2024, 7/2024
Effective Date	1/1/2025

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Fosrenol* (lanthanum carbonate) and Velphoro (sucroferric oxyhydroxide) are phosphate binders. Fosrenol is indicated to reduce serum phosphate in patients with end stage renal disease (ESRD) and Velphoro is indicated to control serum phosphate levels in patients with chronic kidney disease on dialysis.

This program requires a member to try either sevelamer or calcium acetate before providing coverage for lanthanum carbonate or Velphoro. Members with a history of lanthanum carbonate or Velphoro as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the below criteria.

2. Coverage Criteria^a:

<p>A. Lanthanum carbonate (generic Fosrenol*) or Velphoro will be approved based on the following criterion:</p> <ol style="list-style-type: none"> 1. History of failure after appropriate titration, contraindication or intolerance to <u>one</u> of the following: <ol style="list-style-type: none"> a) calcium acetate (eg. PhosLo) b) sevelamer carbonate (generic Renvela) <p>B. Fosrenol (brand only)* will be approved based on <u>both</u> of the following criteria:</p> <ol style="list-style-type: none"> 1. History of failure after appropriate titration, contraindication or intolerance to <u>one</u> of the following: <ol style="list-style-type: none"> a) calcium acetate (eg. PhosLo) b) sevelamer carbonate (generic Renvela) <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> 2. History of failure, contraindication or intolerance to lanthanum carbonate (generic Fosrenol) <p>Authorization will be issued for 12 months</p>

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
* Fosrenol brand chewable tablets are typically excluded from coverage.

4. References:

1. Fosrenol [package insert]. Lexington, MA: Takeda Pharmaceuticals American, Inc; December 2023.
2. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; February 2020.
3. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int.* 2024;105(4S): S117–S314. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group.

Program	Step Therapy – Phosphate Binders
Change Control	
Date	Change
2/2022	New program
2/2023	Annual review with no changes.
2/2024	Annual review. Updated references.
7/2024	Added Velphoro to program.