

**Clinical Policy: Sucroferic Oxyhydroxide (Velphoro)**

Reference Number: HIM.PA.SP30

Effective Date: 05.17

Last Review Date: 02.20

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Sucroferic oxyhydroxide (Velphoro®) is a phosphate binder.

**FDA Approved Indication(s)**

Velphoro is indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis.

**Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Velphoro is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Hyperphosphatemia (must meet all):**

1. Diagnosis of hyperphosphatemia associated with CKD or end stage renal disease (ESRD);
2. Member is on dialysis;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, c, or d):
  - a. Failure (e.g., serum phosphorus > 5.5 mg/dL) of a 4-week trial of calcium acetate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
  - b. Hypercalcemia as evidenced by recent (within the previous 30 days) corrected total serum calcium level > 10.2 mg/dL;
  - c. Plasma parathyroid hormone (PTH) levels < 150 pg/mL on 2 consecutive measurements in the past 180 days;
  - d. History of severe vascular and/or soft-tissue calcifications;
5. Failure (e.g., serum phosphorus > 5.5 mg/dL) of a 4-week trial of lanthanum (generic Fosrenol) or sevelamer hydrochloride (generic Renvela) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 3,000 mg (6 tablets) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

**II. Continued Therapy**

**A. Hyperphosphatemia (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 3,000 mg (6 tablets) per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

2. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

3. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CKD: chronic kidney disease  
 ESRD: end-stage renal disease

FDA: Food and Drug Administration  
 PTH: parathyroid hormone

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
calcium acetate	2 capsules PO TID with meals; titrate to phosphorus < 6 mg/dL and calcium < 9.5 mg/dL	1,500 mg/day total elemental calcium
lanthanum (Fosrenol®)	1,500 mg PO daily in divided doses; titrate by 750 mg/day every 2 to 3 weeks based on serum phosphorus level	4,500 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sevelamer carbonate (Renvela <sup>®</sup> )	<p><i>Starting dose for adult dialysis patients based on serum phosphorus level</i></p> <p>If serum phosphorus is:</p> <p>&gt; 5.5 to &lt; 7.5 mg/dL: 0.8 g PO TID w/ meals</p> <p>≥ 7.5 mg/dL: 1.6 g PO TID w/ meals</p> <p><i>Starting dose for pediatric patients (6 years and older) based on body surface area (BSA)</i></p> <p>≥ 0.75 to &lt; 1.2: 0.8 mg PO TID w/ meals</p> <p>≥ 1.2: 1.6 g PO TID w/ meals</p> <p><i>Starting dose for patients switching from calcium acetate to Renvela based on calcium acetate 667 mg/capsule dosing schedule</i></p> <ul style="list-style-type: none"> <li>• Calcium acetate 1 cap PO TID: Renvela 0.8 g PO TID w/ meals</li> <li>• Calcium acetate 2 caps PO TID: Renvela 1.6 g PO TID w/ meals</li> <li>• Calcium acetate 3 caps PO TID: Renvela 2.4 g PO TID w/ meals</li> </ul>	14 g/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

#### *Appendix C: Contraindications/Boxed Warnings*

None reported

#### *Appendix D: General Information*

- Examples of positive response to therapy:
  - Reduction in serum phosphorus from pretreatment level
  - Maintenance of serum phosphorus level ≤ 5.5 mg/dL, increased hemoglobin

### **V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Hyperphosphatemia	500 mg PO TID with meals	3,000 mg/day

### **VI. Product Availability**

Tablets, chewable: 500 mg iron

### **VII. References**

1. Velphoro Prescribing Information. Waltham, MA: Fresenius Medical Care North America; April 2018. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/205109s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205109s006lbl.pdf). Accessed October 30, 2018.

2. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kidney Dis 42:S1-S202, 2003 (suppl 3).
3. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–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.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at <http://www.clinicalpharmacology-ip.com/>.
5. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–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 2017; 92(1):26-36.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.17	
1Q18 annual review: added trial duration of 4 weeks per guideline recommendations for monitoring frequency; added additional requirement for trial of generic Fosrenol or generic Renvela; provided an additional measure of positive response to therapy; references reviewed and updated	11.16.17	02.18
1Q 2019 annual review: added age requirement; no significant changes; references reviewed and updated.	10.30.18	02.18
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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**Note:**

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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