

Clinical Policy: Sucroferric Oxyhydroxide (Velphoro)

Reference Number: HIM.PA.SP30

Effective Date: 05.17

Last Review Date: 02.18

Line of Business: Health Insurance Marketplace

[Revision Log](#)

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

Description

Sucroferric 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 (including 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. 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;
4. 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;
5. Dose does not exceed 3000 mg per day (6 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 (e.g., reduction in serum phosphorus from pretreatment level, maintenance of serum phosphorus level ≤ 5.5 mg/dL);
3. If request is for a dose increase, new dose does not exceed 3000 mg per day (6 tablets per day).

Approval duration: 12 months

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

1. 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

2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 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

V. References

1. Velphoro Prescribing Information. Waltham, MA: Fresenius Medical Care North America; September 2017. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=237da26c-f38c-4faa-93ad-735e71c9d0c1>. Accessed November 16, 2017.
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.; 2017. 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

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, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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