BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

VELPHORO® (sucroferric oxyhydroxide) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Velphoro (sucroferric oxyhydroxide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Nephrologist

2. Individual is 9 years of age or older

3. Individual has a confirmed diagnosis of **chronic kidney disease on dialysis with hyperphosphatemia (phosphorus level greater than or equal to 5.5 mg/dL)** with **ANY** of the following:
    a. Evidence of bone disease
    b. Vascular and/or other soft tissue calcification

c. Elevated corrected serum calcium of greater than or equal to 10.2 mg/dL **OR** two consecutive low intact parathyroid hormone (iPTH) levels of less than 150 pg/mL, with a normal or elevated corrected serum calcium

4. Individual has completed **ALL** the following baseline tests before initiation of treatment and will have continued monitoring as clinically appropriate:
   a. Serum phosphorus
   b. Serum calcium
   c. Serum albumin
   d. Intact parathyroid hormone (iPTH)

5. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for at least **TWO** of the following:
   a. Lanthanum (generic or branded Fosrenol)
   b. Sevelamer HCl (generic or branded Renagel)
   c. Sevelamer carbonate (generic or branded Renvela)

6. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Velphoro (sucroferric oxyhydroxide) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Nephrologist

2. Individual has documentation of positive clinical response to therapy defined as the following:
   a. Achieved and maintains a serum phosphorus levels between 3.5-5.5 mg/dL (1.13-1.78 mmol/L)
   b. Achieved and maintains a serum levels of corrected total calcium between 8.4-9.5 mg/dL (2.10-2.37 mmol/L)
   c. Achieved and maintains iPTH (second-generation PTH assay) levels between 150-300 pg/mL (or 80-160 pg/mL using the bio-intact PTH assay)

3. Individual has been adherent with the medication and still requires dialysis

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

Renewal duration: 12 months

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- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-Cancer Medications**

  2. **Off-Label Use of Cancer Medications**

Description:

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

Velphoro (sucroferric oxyhydroxide) binds phosphate in the gastrointestinal (GI) tract. The bound phosphate is eliminated within the feces. Both serum phosphorus levels and calcium-phosphorus product levels are reduced as a consequence of the reduced dietary phosphate absorption.

Each Velphoro (sucroferric oxyhydroxide) contains 500 mg of iron in 2,500 mg sucroferric oxyhydroxide, a degradation product, a mononuclear iron species, can be released and a minimal amount is absorbed. The sucrose and starch components can be digested to glucose and fructose, and maltose and glucose respectively and they can be absorbed. One tablet is equivalent to 1.4 g of carbohydrates.

Serum phosphorus, hyperparathyroidism, and Chronic Kidney Disease (CKD)
Changes in bone mineral metabolism & deviations in calcium-phosphate balance occur early in CKD. These changes progress as kidney function declines. They are grouped under the term Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) which includes renal osteodystrophy and extraskeletal (vascular) calcification related to these abnormalities. Renal osteodystrophy includes osteitis fibrosa (hyperparathyroidism), osteomalacia, and adynamic bone disease. Patients with CKD-MBD are at higher risk of death.

CKD leads to hyperphosphatemia and a number of chronic disturbances of calcium-phosphate homeostasis. As kidney function declines, the ability to regulate and eliminate phosphorus declines. There are several complications from hyperphosphatemia: 1) conversion of 24-hydroxyvitamin D to 1, 25-dihydroxyvitamin D (calcitriol) is inhibited; 2) there is a decrease in the intestinal absorption of calcium leading to hypocalcemia; 3) there is development of renal bone loss; and 4) extraosseous calcification of soft tissue and vasculature occurs. Risk for death is increased with hyperphosphatemia > 6.5 mg/dL.

Low levels of calcitriol and low levels of calcium with hyperphosphatemia stimulate the secretion of parathyroid hormone (PTH). Secondary hyperparathyroidism contributes to abnormal bone metabolism in CKD. PTH secretion is regulated by extracellular calcium, extracellular phosphate, calcitriol, and fibroblast growth factor 23. A change in calcium concentration is sensed by a sensitive calcium-sensing receptor (CaSR) on the surface of parathyroid cells. A decrease in serum ionized calcium concentration produces a large increase in serum PTH concentration within minutes.

Management of the bone disorder includes maintain calcium and phosphorus balance and vitamin D supplementation. CKD patients on dialysis should have: a goal serum phosphorus level between 3.5-5.5 mg/dL (1.13-1.78 mmol/L) and a goal total serum calcium level (corrected for serum albumin) of 8.4-9.5 mg/dL (2.10-2.37 mmol/L).

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Management of secondary hyperparathyroidism in dialysis patients involves the administration of some combination of: phosphate binders (either calcium-containing or non-calcium-containing binders) such as calcitriol or synthetic vitamin D analogs or calcimimetic (cinacalcet, etelcalcetide). The goal in secondary hyperparathyroidism is either: an intact parathyroid hormone (iPTH; second-generation PTH assay) between 150-300 pg/mL or a bio-intact PTH assay between 80-160 pg/mL.

The data on phosphate binders are inconclusive as to whether there is a difference in long-term clinical outcome benefit among the phosphate binders (calcium based phosphate binders compared to non-calcium based phosphate binders). All available phosphate lowering medications (calcium salts, aluminum salts, magnesium salts, sevelamer and lanthanum carbonate) are effective in lowering serum phosphorus levels.

Calcium-based phosphate binders should not be used in the following: persistent or recurrent hypercalcemia (a corrected calcium of > 10.2 mg/dL), arterial calcification, or adynamic bone disease. They may be used in the following: hypocalcemic patients or normocalcemic patients who have no evidence of vascular calcification or adynamic bone disease.

Aluminum hydroxide should not be used for the long-term, chronic treatment of hyperphosphatemia, because of the risk for aluminum toxicity. Aluminum hydroxide may be used for short-term therapy (a single, four-week course) for severe hyperphosphatemia.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Calculation for corrected calcium:

Corrected calcium = serum calcium + 0.8 (4 – serum albumin)
Ex. Calcium 9.9 mg/dl; albumin 3.2 gm/dl
Corrected calcium = 9.9 + 0.8 (4 – 3.2)
Corrected calcium = 10.54 (or 10.5 mg/dl)

Stages of Chronic Kidney Disease (CKD):

Stage	GFR (mL/min/1.73 m^2)	
G1	≥ 90	Normal kidney or high
G2	60-89	Mildly reduced kidney function
G3 A	45-59	Mild to moderately reduced kidney function
G3 B	30-44	Moderate to severely reduced kidney function
G4	15-29	Severely reduced kidney function
G5	< 15 or on dialysis	End stage kidney failure (sometimes called established renal failure)
In the absence of evidence of kidney damage, neither G1 nor G2 fulfill the criteria for CKD		

Resources:

Velphoro (sucroferric oxyhydroxide) product information, revised by Fresenius Medical Care North America 07-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 27, 2025.

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Quarles LD, Kendrick J. Management of hyperphosphatemia in adults with chronic kidney disease. In: UpToDate, Berns JS, Taylor EN (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated July 02, 2025. Accessed September 30, 2025.

Quarles LD, Kendrick J. Management of secondary hyperparathyroidism in adult patients on dialysis. In: UpToDate, Berns JS, Taylor EN (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated January 09, 2025. Accessed September 30, 2025.

Quarles LD, Kendrick J. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: UpToDate, Berns JS, Taylor EN (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through August 2025. Topic last updated May 22, 2025. Accessed September 30, 2025.