



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/17/16
LAST REVIEW DATE: 11/15/18
LAST CRITERIA REVISION DATE: 11/15/18
ARCHIVE DATE:

VELPHORO® (sucroferric oxyhydroxide) chewable tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

VELPHORO® (sucroferric oxyhydroxide) chewable tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Velporo (sucroferric oxyhydroxide) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older
2. A confirmed diagnosis of chronic kidney disease on dialysis with hyperphosphatemia (≥ 5.5 mg/dL) with **ANY** of the following:
 - Evidence of bone disease
 - Individual with vascular and/or other soft tissue calcification
 - Elevated corrected serum calcium of ≥ 10.2 mg/dL **OR** two consecutive low iPTH levels of < 150 pg/mL, with a normal or elevated corrected serum calcium
3. Individual has failure, contraindication or intolerance to at least **TWO** of the following preferred step therapy agents:
 - Preferred step therapy agents include:
 - Eliphos (calcium acetate)
 - Fosrenol (lanthanum)
 - Renagel (sevelamer HCl)
 - Sevelamer carbonate generic or brand
4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - Serum phosphorus
 - Serum calcium
 - Serum albumin
 - Intact parathyroid hormone (iPTH)

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Velporo (sucroferric oxyhydroxide) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
 - Response is defined as:
 - Achieved and maintains a serum phosphorus levels between 3.5-5.5 mg/dL (1.13-1.78 mmol/L)
 - Achieved and maintains a serum levels of corrected total calcium between 8.4-9.5 mg/dL (2.10-2.37 mmol/L)
 - Achieved and maintains intact parathyroid hormone (iPTH; second-generation PTH assay) levels between 150-300 pg/mL (or 80-160 pg/mL using the bio-intact PTH assay)
2. Individual has been adherent with the medication and still requires dialysis

VELPHORO® (sucroferric oxyhydroxide) chewable tablet (cont.)

Renewal duration: 12 months

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:
 - Conversion of 24-hydroxyvitamin D to 1, 25-dihydroxyvitamin D (calcitriol) is inhibited
 - There is a decrease in the intestinal absorption of calcium leading to hypocalcemia,
 - There is development of renal bone loss
 - Extrasosseous calcification of soft tissue and vasculature occurs
- The 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

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- 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)
 - A goal total serum calcium level (corrected for serum albumin) of 8.4-9.5 mg/dL (2.10-2.37 mmol/L)
- Management of secondary hyperparathyroidism in dialysis patients involves the administration of some combination of:
 - Phosphate binders (either calcium-containing or non-calcium-containing binders)
 - Calcitriol or synthetic vitamin D analogs
 - Calcimimetic (cinacalcet, etelcalcetide)
- Goal of secondary hyperparathyroidism is either:
 - Intact parathyroid hormone (iPTH; second-generation PTH assay) between 150-300 pg/mL
 - Bio-intact PTH assay between 80-160 pg/mL
- Phosphate binders:
 - The data 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
 - Adynamic bone disease
 - May be used in the following:
 - Hypocalcemic patients
 - 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

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Definitions:

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 (10.5 mg/dl)

Stages of 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. Package Insert. Revised by manufacturer 9/2014. Accessed 9/16/16.

Levin A, Stevens PE, Bilous RW, et al.: Kidney disease: improving Global Outcomes (KDIGO) CKD Working Group. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kind Inter Suppl 2013; 3(1): 1-150. doi:10.1038/kisup.2012.73

Sista SK and Arum SM.: Management of adynamic bone disease in chronic kidney disease: A brief review. J Clin Translational Endocrinol 2016;5: 32–35. doi.org/10.1016/j.jcte.2016.07.002
FDA-approved indication and dosage:

UpToDate: Treatment of hyperphosphatemia in chronic kidney disease. Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/treatment-of-hyperphosphatemia-in-chronic-kidney-disease?source=search_result&search=phosphate%20binders&selectedTitle=1~150

UpToDate: Management of secondary hyperparathyroidism and mineral metabolism abnormalities in dialysis patients. Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/management-of-secondary-hyperparathyroidism-and-mineral-metabolism-abnormalities-in-dialysis-patients?source=search_result&search=phosphate%20binders&selectedTitle=9~150



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UpToDate: Overview of chronic kidney disease-mineral and bone disorder (CKD-MBD). Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/overview-of-chronic-kidney-disease-mineral-and-bone-disorder-ckd-mbd?source=related_link#H21

UpToDate: Pediatric chronic kidney disease-mineral and bone disorder (CKD-MBD). Current through Sep 2017. https://www.uptodate-com.mwu.idm.oclc.org/contents/pediatric-chronic-kidney-disease-mineral-and-bone-disorder-ckd-mbd?source=search_result&search=phosphate%20binders&selectedTitle=8~150#H27



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**
 ICD-10 Code: _____ Diagnosis Description: _____

2. Yes No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. Yes No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: _____ Date: _____

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

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