LOUISIANA BLUE

Phosphate Binders

Policy # 00451
Original Effective Date: 01/01/2015
Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select phosphate binders [including, but not limited to Fosrenol® (lanthanum carbonate), Renagel® (sevelamer hydrochloride), Renvela® (sevelamer carbonate), Auryxia® (ferric citrate), Velphoro® (sucroferric oxyhydroxide), generic sevelamer, or generic lanthanum carbonate]‡ to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for select phosphate binders mentioned above will be considered when the following patient selection criteria are met:

- Velphoro (sucroferric oxyhydroxide):
  - Patient is 9 years of age or older; AND
  - Patient has chronic kidney disease (CKD) and is receiving dialysis; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) calcium acetate unless there is clinical evidence or patient history that suggests the use of calcium acetate will be ineffective or cause an adverse reaction to the patient; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
  - Patient has tried and failed (e.g., intolerance or inadequate response) lanthanum carbonate OR sevelamer carbonate unless there is clinical evidence or patient history that suggests the use of lanthanum carbonate or sevelamer carbonate will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- All other requests:
  - There is clinical evidence or patient history that suggests the use of generically available calcium acetate products will be/was ineffective or will/did cause an adverse reaction to the patient (e.g., hypercalcemia, calcium x phosphate product of ≥ 55mg/dL, history/presence of severe vascular and/or soft tissue calcification and/or adynamic bone disease, normocalcemic chronic kidney disease (CKD) patient receiving active vitamin D or vitamin D analogs).
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select phosphate binder products WITHOUT clinical evidence or patient history that suggests the use of generically available calcium acetate products will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

Based on review of available data, the Company considers the use of Velphoro (sucroferric oxyhydroxide) when the patient has not tried and failed the listed preferred alternatives to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Velphoro (sucroferric oxyhydroxide) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Phosphate binders are often used in patients with CKD to control phosphate levels. There are essentially two types of phosphate binders: calcium containing phosphate binders and non-calcium containing phosphate binders. All of the available prescription phosphate binders are effective in lowering phosphate levels, and there is currently no consensus about whether any particular type of phosphate binder should be used in patients with CKD. There are currently generic phosphate binders available that contain calcium acetate, sevelamer, or lanthanum carbonate.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Examples of FDA approved phosphate binders include, but are not limited to, Fosrenol, Renagel, Renvela, Auryxia, and Velphoro.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The patient selection criterion presented in this policy takes into consideration clinical evidence or patient history that suggests the use of generically available calcium acetate products will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using select phosphate binders mentioned in this policy over the available generic calcium phosphate binder products. Furthermore, there is no demonstrated clinical advantage of using Velphoro over other generically available non-calcium-based phosphate binders such as sevelamer carbonate or lanthanum carbonate, which have comparable efficacy and safety profiles in managing hyperphosphatemia in patients with chronic kidney disease.

References

1. National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. Am J Kidney Dis 2003; 42:S1.
2. Fosrenol [package insert]. Shire US, Inc. Wayne, PA 19087. Updated 2012.
3. Renagel [package insert]. Genzyme Corporation. Cambridge, MA 02142. Updated 2011.
4. Renvela [package insert]. Genzyme Corporation. Cambridge, MA 02142. Updated 2011.
5. Velphoro [package insert]. Fresenius Medical Care. Waltham, MA 02451. Updated 2013.
6. Auryxia [package insert]. Keryx Biopharmaceuticals, Inc. Floor Boston, Massachusetts. Updated 2016.

Policy History

Original Effective Date: 01/01/2015
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10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. New policy.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Updated the policy to reflect the call tree's intent. When this policy was created, there was a generic non-calcium phosphate binder approved by the FDA. Since then, that generic has been pulled from the market. When it was pulled, the criteria was changed to include use of a generic phosphate binder unless the patient could not use a calcium product.
10/05/2017	Medical Policy Committee review

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10/18/2017	Medical Policy Implementation Committee approval. Changed title to "Phosphate Binders". Added new generics (sevelamer and lanthanum carbonate) to the policy.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Removed Phoslo® and Phoslyra® from policy as these products have been discontinued.
10/02/2025	Medical Policy Committee review
10/08/2025	Medical Policy Implementation Committee approval. Added specific criteria to Velphoro.

Next Scheduled Review Date: 10/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.