Phosphate Binders (Branded)

Policy # 00451
Original Effective Date: 01/01/2015
Current Effective Date: 10/19/2016

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 branded phosphate binders [including, but not limited to Phoslo® (calcium acetate), Phoslyra® (calcium acetate), Fosrenol® (lanthanum carbonate), Renagel® (sevelamer hydrochloride), Renvela® (sevelamer carbonate), Auryxia® (ferric citrate), and Velphoro® (sucroferric oxyhydroxide)]‡ to be eligible for coverage when the patient selection criteria are met.

Patient Selection Criterion
Coverage eligibility for branded phosphate binders will be considered when the following patient selection criteria are met:

- For calcium based phosphate binder requests (e.g. Phoslo, Phoslyra) 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.

- For NON-calcium based phosphate binder requests (e.g. Fosrenol, Renagel, Renvela, Velphoro, Auryxia, etc):
  - 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 patient receiving active vitamin D or vitamin D analogs).

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of branded 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. **

Background/Overview
Phosphate binders are often used in patients with chronic kidney disease (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
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Phosphate binder should be used in patients with CKD. There are currently generic phosphate binders available that contain calcium acetate.

**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, Phoslo, Phoslyra, Fosrenol, Renagel, Renvela, Auryxia, and Velphoro.

**Rationale/Source**

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 a brand name phosphate binder over the available generic phosphate binder products.

**References**


**Policy History**

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10/02/2014 Medical Policy Committee review
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.

Next Scheduled Review Date: 10/2017

*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 rationally 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, "rationally 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.
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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.