Clinical Policy: Electrolyte Depleter Agents

Reference Number: OH.PHAR.PPA.62
Effective Date: 01.01.2020
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

ELECTROLYTE DEPLETERS FOR HYPERPHOSPHATEMIA

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	NON-PREFERRED "NON-PREFERRED"
CALCIUM ACETATE (generic of PhosLo® gelcap) CALCIUM CARBONATE PHOSLYRA® solution (calcium acetate)	SEVELAMER (generic for Renagel®, Renvela®)	AURYXIA® (ferric citrate) tablets ELIPHOS® (calcium acetate) LANTHANUM CARBONATE (generic of Fosrenol®) VELPHORO® (sucroferric oxyhydroxide)

FDA Approved Indication(s)

- Non-calcium containing phosphate binders (Auryxia, Fosrenol, Renvela, Renagel, and Velphoro) are indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis or with end stage renal disease (ESRD).

- Auryxia is also indicated for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis.

- Phoslyra, Phoslo, Eliphos and calcium carbonate are indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis or with end stage renal disease (ESRD).

Policy/Criteria

Provider must submit documentation (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 Auryxia ® tablets, Eliphos®, lanthanum carbonate (Fosrenol®), Velphoro® are **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 ESRD;
2. Member meets one of the following (a or b):
   a. Auryxia, Fosrenol, Renagel, Velphoro: age ≥ 18 years;
   b. Renvela: age ≥ 6 years;
3. If medication is a step therapy required agent member must have had an inadequate clinical response to a trial no less than 7 days of at least one preferred medication unless one of the following:
   a Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. If medication is a non-preferred agent member must have had an inadequate clinical response to a trial of no less than 7 days of at least two preferred or step therapy medications unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval

Approval duration: 12 months

B. **Iron deficiency anemia** (must meet all):

1. Request is for Auryxia;
2. Diagnosis of iron deficiency anemia with CKD not on dialysis;
3. Failure of a 4-week, adherent trial of alternative oral iron therapy (e.g., ferrous sulfate, ferrous fumarate, ferrous gluconate), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 12 tablets (2,520 mg ferric iron) per day.

Approval duration: 12 months

II. 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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
ESRD: end-stage renal disease
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcium acetate (PhosLo® gelcap)	**Hyperphosphatemia** 2 capsules PO TID with meals; titrate to phosphorus < 6 mg/dL and calcium < 9.5 mg/dL	2,000 mg/day total elemental calcium
Phoslyra® solution (calcium acetate)	**Hyperphosphatemia** 10 mL PO TID with meals initially for dialysis patients;titrate to phosphorus < 6 mg/dL and calcium < 9.5 mg/dL	2,000 mg/day total elemental calcium
calcium carbonate	**Hyperphosphatemia** 1,000 to 2,000 mg PO TID with meals; titrate to phosphorus < 6 mg/dL and calcium < 9.5 mg/dL	2,000 mg/day total elemental calcium
ferrous sulfate, ferrous fumarate, ferrous gluconate	**Iron Deficiency Anemia** 100 to 200 mg elemental iron PO daily in 2 to 3 divided doses (or daily with extended release tablets)	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Auryxia: iron overload syndromes (e.g., hemochromatosis)
  - Fosrenol: bowel obstruction, ileus, and fecal impaction
  - Renagel: bowel obstruction; known hypersensitivity to sevelamer hydrochloride or to any of the excipients
  - Renvela: bowel obstruction
  - Velphoro: none reported

- Boxed warning(s): none reported

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.