Clinical Policy: Non-Calcium Containing Phosphate Binders

Reference Number: PA.CP.PMN.04
Effective Date: 01/18
Last Review Date: 04/18

Coding Implications
Revision Log

Description
The following are non-calcium containing phosphate binders requiring prior authorization: ferric citrate (Auryxia®), lanthanum carbonate (Fosrenol®), sevelamer carbonate (Renvela®), sevelamer hydrochloride (RenaGel®), sucroferric oxyhydroxide (Velphoro®).

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

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

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness® that non-preferred non-calcium containing phosphate binders is **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. Prescribed by or in consultation with a nephrologist, or member is on dialysis;
3. Member meets one of the following (a or b):
   a. Auryxia, Fosrenol, Renagel, Velphoro: age ≥ 18 years;
   b. Renvela: age ≥ 6 years;
4. Member meets one of the following (a, b, c, or d):
   a. Failure (e.g., serum phosphorus > 5.5 mg/dL) of a 4 week trial of calcium acetate at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   b. Hypercalcemia as evidenced by recent (within the previous 30 days) corrected total serum calcium level > 10.2 mg/dL;
   c. Plasma parathyroid hormone (PTH) levels < 150 pg/mL on 2 consecutive measurements in the past 180 days;
   d. History of severe vascular and/or soft-tissue calcifications;
5. For Auryxia, Renagel, or Velphoro: failure (e.g., serum phosphorus > 5.5 mg/dL) of a 4-week trial of Fosrenol (generic is preferred) or Renvela (generic is preferred) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for Fosrenol and Renvela*

6. Dose does not exceed:
   a. Auryxia: 12 tablets (2,520 mg ferric iron) per day;
   b. Fosrenol: 4,500 mg per day;
   c. Renagel: 13 g per day;
   d. Renvela: 14 g per day;
   e. Velphoro: 3,000 mg per day (6 tablets per day).

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

C. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;If request is for a dose increase, new dose does not exceed one of the f ollowing (a, b, or c):
   a. Auryxia: 12 tablets (2520 mg ferric iron) per day;
   b. Fosrenol: 4500 mg per day;
   c. Renagel: 13 g per day;
   d. Renvela: 14 g per day;
   e. Velphoro: 3000 mg per day (6 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. 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 – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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	**Hyperphosphatemia** 2 capsules PO TID with meals; titrate to phosphorus < 6 mg/dL and calcium < 9.5 mg/dL	1,500 mg/day total elemental calcium
lanthanum (Fosrenol®)	**Hyperphosphatemia** 1,500 mg PO daily in divided doses; titrate by 750 mg/day every 2 to 3 weeks based on serum phosphorus level	4,500 mg/day
sevelamer carbonate (Renvela®)	**Hyperphosphatemia** *Starting dose for adult dialysis patients based on serum phosphorus level* If serum phosphorus is: > 5.5 to < 7.5 mg/dL: 0.8 g PO TID w/ meals ≥ 7.5 mg/dL: 1.6 g PO TID w/ meals *Starting dose for pediatric patients (6 years and older) based on body surface area (BSA)* ≥ 0.75 to < 1.2: 0.8 mg PO TID w/ meals ≥ 1.2: 1.6 g PO TID w/ meals *Starting dose for patients switching from calcium acetate to Renvela based on calcium acetate 667 mg/capsule dosing schedule* • Calcium acetate 1 cap PO TID: Renvela 0.8 g PO TID w/ meals • Calcium acetate 2 caps PO TID: Renvela 1.6 g PO TID w/ meals • Calcium acetate 3 caps PO TID: Renvela 2.4 g PO TID w/ meals	14 g/day
ferrous sulfate, ferrous fumarate,	**Iron Deficiency Anemia** 100 to 200 mg elemental iron PO daily in 2 to 3 divided doses (or daily with extended release tablets)	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ferrous gluconate		

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 onstruction; known hypersensitivity to sevelamer hydrochloride or to any of the excipients
  - Renvela: bowel obstruction
  - Velphoro: none reported
- Boxed warning(s): none reported

Appendix D: General Information

- Examples of positive response to therapy:
  - Reduction in serum phosphorus from pretreatment level
  - Maintenance of serum phosphorus level ≤ 5.5 mg/dL, increased hemoglobin

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
ferric citrate (Auryxia)	Iron Deficiency Anemia	1 tablet PO TID with meals. Adjust dose as needed to achieve and maintain hemoglobin goal.	12 tablets/day
ferric citrate (Auryxia)	Hyper-phosphatemia	2 tablets PO TID with meals; titrate by 1 to 2 tabs/day at 1-week or longer intervals based on serum phosphorus level	12 tablets/day
lanthanum (Fosrenol)	Hyper-phosphatemia	1,500 mg PO daily in divided doses; titrate by 750 mg/day every 2 to 3 weeks based on serum phosphorus level	4,500 mg/day
sevelamer carbonate (Renvela)	Hyper-phosphatemia	*Starting dose for adult dialysis patients based on serum phosphorus level* If serum phosphorus is: > 5.5 to < 7.5 mg/dL: 0.8 g PO TID w/ meals ≥ 7.5 mg/dL: 1.6 g PO TID w/ meals	14 g/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Starting dose for pediatric patients (6 years and older) based on body surface area (BSA) ≥ 0.75 to < 1.2: 0.8 mg PO TID w/ meals ≥ 1.2: 1.6 g PO TID w/ meals *Starting dose for patients switching from calcium acetate to Renvela based on calcium acetate 667 mg/capsule dosing schedule* • Calcium acetate 1 cap PO TID: Renvela 0.8 g PO TID w/ meals • Calcium acetate 2 caps PO TID: Renvela 1.6 g PO TID w/ meals • Calcium acetate 3 caps PO TID: Renvela 2.4 g PO TID w/ meals	
sevelamer hydrochloride (Renagel)	Hyper-phosphatemia	*Starting dose based on serum phosphorus level* • 5.5 to < 7.5 mg/dL: Renagel 800 mg - 1 tab PO TID; 400 mg - 2 tabs PO TID w/meals • 7.5 to < 9 mg/dL: Renagel 800 mg - 2 tabs PO TID; 400 mg - 3 tabs PO TID w/meals • ≥ 9 mg/dL: Renagel 800 mg - 2 tabs PO TID; 400 mg - 4 tabs PO TID w/meals *Starting dose for patients switching from calcium acetate to Renagel based on calcium acetate 667 mg/capsule dosing schedule* • Calcium acetate 1 cap PO TID: Renagel 800 mg - 1 tab PO TID; 400 mg - 2 tabs PO TID • Calcium acetate 2 caps PO TID: Renagel 800 mg - 2 tabs PO TID; 400 mg - 3 tabs PO TID • Calcium acetate 3 caps PO TID: Renagel 800 mg - 3 tabs PO TID; 400 mg - 5 tabs PO TID	13 g/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
sucroferric oxyhydroxide (Velphoro)	Hyper-phosphatemia	500 mg PO TID with meals	3,000 mg/day

IV. Product Availability

Drug	Dosage Forms and Strengths
Auryxia (ferric citrate)	Tablets: 210 mg ferric iron, equivalent to 1 g ferric citrate
Fosrenol (lanthanum carbonate)	Chewable tablets: 500 mg, 750 mg, and 1000 mg Oral powder: 750 mg and 1000 mg.
Renvela (sevelamer carbonate)	Tablets: 800 mg Powder: 0.8 g and 2.4 g packet
RenaGel (sevelamer hydrochloride)	Tablets: 400 mg and 800 mg
Velphoro (sucroferric oxyhydroxide)	Chewable tablets: 500 mg

V. References

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Reviews, Revisions, and Approvals	Date	Approval Date
2Q18 annual review: Added trial duration of 4 weeks per guideline recommendations for monitoring frequency; Added additional requirement for trial of generic Fosrenol or generic Renvela; Criteria added for new indication for Auryxia: for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. References reviewed and updated	01.16 18	
1Q 2019 annual review: age requirement added for all agents; references reviewed and updated.	01.19	