Clinical Policy Title:	Non-Calcium Phosphate Binders
Policy Number:	RxA.130
Drug(s) Applied:	Auryxia®, Fosrenol®, Renvela®, Renagel®, Velphoro®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

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®).

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.

Dosing Information

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®)	Hyperphosphatemia	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®)		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®)		*Starting dose for adult dialysis patients based on serum phosphorus level* If serum phosphorus is: > 5.5 to < 7.5 mg/dL: 0.8	14 g/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		> 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	
sevelamer hydrochloride (Renagel®)	Hyperphosphatemia	*Starting dose based on serum phosphorus level* • 5.5 to < 7.5 mg/dL: Renagel 800 mg - 1 tab PO TID; • 7.5 to < 9 mg/dL: Renagel 800 mg - 2 tabs PO TID; • 9 mg/dL: Renagel 800 mg - 2 tabs PO TID;	13 g/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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; • Calcium acetate 2 caps PO TID: Renagel 800 mg - 2 tabs PO TID; Calcium acetate 3 caps PO TID: Renagel 800 mg - 3 tabs PO TID;	
sucroferric oxyhydroxide (Velphoro®)	Hyperphosphatemia	500 mg PO TID with meals	3,000 mg/day

Dosage Forms

- ferric citrate (Auryxia®): Tablets 210 mg ferric iron (equivalent to 1 g ferric citrate)
- lanthanum (Fosrenol®): Tablets, chewable: 500 mg, 750 mg, 1,000 mg ; Oral powder: 750 mg, 1,000 mg
- sevelamer carbonate (Renvela®): Tablets: 800 mg ; oral powder, packet: 0.8 g, 2.4 g
- sevelamer hydrochloride (Renagel®): Tablets: 800 mg
- sucroferric oxyhydroxide (Velphoro®): Tablets, chewable: 500 mg iron

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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 generic lanthanum or generic sevelamer carbonate 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 (6 tablets) per day

Approval Duration
Commercial: 12 months
Medicaid: 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new 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 (6 tablets) per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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

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

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
- Serious cases of dysphagia, bowel obstruction, bleeding gastrointestinal ulcers, colitis, ulceration, necrosis, and perforation have been associated with sevelamer use, some requiring hospitalization and surgery.

References

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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Line of Business Policy Applies to was updated to "All lines of business". 2. Dose strength of Renagel was updated. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. APPENDIX B language updated to ''Below are suggested therapeutic alternatives….''. 5. Reference was reviewed and updated	1/19/2021	03/09/2021