Clinical Policy Title:	Non-Calcium Phosphate Binders
Policy Number:	RxA.130
Drug(s) Applied:	Auryxia®, sevelamer HCl 800 mg
Original Policy Date:	02/07/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

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, b, c, or d):
   a. Trial and failure (e.g., serum phosphorus > 5.5 mg/dL) of a 4-week trial of calcium acetate, 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.
4. Trial and failure lanthanum or sevelamer carbonate, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 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. Trial and failure of alternative oral iron therapy (e.g., ferrous sulfate, ferrous fumarate, ferrous gluconate) unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Am J Kidney Dis 42:S1-S202, 2003 (suppl 3). Available at: https://www.ajkd.org/article/S0272-6386(03)00905-3/fulltext. Accessed October 14, 2022.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). Kidney International 2009; 76 (Suppl 113): S1–S130. Available at: https://kdigo.org/wp-content/uploads/2017/02/KDIGO-2009-CKD-MBD-Guideline-English.pdf. Accessed on October 14, 2022.
3. Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). Kidney International 2017; 92(1):26-36. Available at: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. Accessed on October 14, 2022.
4. Renvela (sevelamer carbonate). Highlights of prescribing information [package insert]. Silver Spring, MD: U.S. Food and Drug Administration; 2020. Accessed on April 8th, 2024.
5. Auerbach M, DeLoughery TG, Means RJ, et al. Treatment of iron deficiency anemia in adults. In: Post TW, ed. *UpToDate*. UpToDate; 2024. Accessed on April 8th, 2024 https://www.uptodate.com

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. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. Reference was reviewed and updated	1/19/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, 1.B.3: Updated trial and failure criteria from 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 to Failure of 4 weeks for at least one (1) alternative oral iron therapy (e.g., ferrous sulfate, ferrous fumarate, ferrous gluconate) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".	11/26/2021	01/17/2022

3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A..4.a and I.B.3: Updated to remove maximally indicated doses. 2. References were reviewed and updated.	10/14/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed Renagel and Velphoro which no longer require a PA. 2. Added sevelamer HCl 800 mg which does require a PA. 3. I.A.3 Removed age 4. I.A.5 Removed Renagel and Velphoro removed trial duration of 4 weeks, and removed at maximally indicated doses 5. Removed dosing 6. II.A.2 Removed positive response to therapy	03/29/2024	10/19/2023