Clinical Policy Title:	Non-Calcium Phosphate Binders
Policy Number:	RxA.130
Drug(s) Applied:	Auryxia®, Renagel®, Velphoro®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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. Age ≥ 18 years;
4. 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.
5. For Auryxia®, Renagel®, or Velphoro®: Trial and 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;
6. Dose does not exceed:
   a. Auryxia®: 12 tablets (2,520 mg ferric iron) per day;
   b. Renagel®: 13 gm per day;
   c. 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. Trial and failure of 4 weeks 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. Member is currently receiving medication that has been authorized by RxAdvance or the member has 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. Renagel®: 13 g per day;
   c. Velphoro®: 3,000 mg (6 tablets) per day.

Approval Duration
Commercial: 12 months
Medicaid: 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.

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	11/26/2021	01/17/2022

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...". 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