Reference number(s)
2048-D

Initial Step Therapy; Post Step Therapy Prior Authorization Velphoro

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Velphoro	sucroferric oxyhydroxide

Indications

FDA-approved Indications

Velphoro is indicated for the control of serum phosphorus levels in adults and pediatric patients 9 years of age and older with chronic kidney disease (CKD) on dialysis.

Initial Step Therapy

If the patient has filled a prescription for at least a 30-day supply of calcium acetate (e.g., PhosLo) within the past 120 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Coverage Criteria

Chronic Kidney Disease

Authorization may be granted when the requested drug is being prescribed to control serum phosphorus levels in adult and pediatric patients 9 years of age and older with chronic kidney disease (CKD) who are receiving dialysis when ONE of the following criteria are met:

- The patient has experienced an inadequate treatment response to calcium acetate (e.g., PhosLo).
- The patient has experienced an intolerance to calcium acetate (e.g., PhosLo).
- The patient has a contraindication that would prohibit a trial of calcium acetate (e.g., PhosLo).
- It has been determined that calcium acetate (e.g., PhosLo) is NOT appropriate for the patient (e.g., due to hypercalcemia, arterial calcification, adynamic bone disease, low parathyroid hormone [PTH] levels, or age).

Duration of Approval (DOA)

- 2048-D: DOA: 12 months

References

1. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; August 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed September 24, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/24/2024).
4. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2017;7:1–59.

Document History

Written by: UM Development (KM)

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External Review: 08/2017, 02/2018, 04/2019, 02/2020, 02/2021, 02/2022, 03/2023, 02/2024, 02/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed to control serum phosphorus levels in an adult or pediatric patient 9 years of age or older with chronic kidney disease who is receiving dialysis? [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has the patient experienced an inadequate treatment response to calcium acetate (e.g., PhosLo)? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Has the patient experienced an intolerance to calcium acetate (e.g., PhosLo)? [If Yes, then no further questions. If No, then go to 4.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of calcium acetate (e.g., PhosLo)? [If Yes, then no further questions. If No, then go to 5.]	Yes	No
5	Has it been determined that calcium acetate (e.g., PhosLo) is NOT appropriate for the patient (e.g., due to hypercalcemia, arterial calcification, adynamic bone disease, low parathyroid hormone [PTH] levels, or age)? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is to control serum phosphorus levels in a patient with chronic kidney disease who is on dialysis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your

			review. [Short Description: Diagnosis]
2.	Approve, 12 Months	Go to 3	
3.	Approve, 12 Months	Go to 4	
4.	Approve, 12 Months	Go to 5	
5.	Approve, 12 Months	Deny	Your plan only covers this drug if you have tried calcium acetate (e.g., PhosLo) and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy]