Lanthanum Carbonate Chewable tablet (Fosrenol)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

End-stage renal disease (ESRD), also known as kidney failure, is the final stage of chronic kidney disease (CKD). This condition is characterized by the kidneys' inability to function adequately to filter waste and excess fluid from the blood. One of the common complications associated with ESRD is hyperphosphatemia, which is an abnormally high level of phosphate in the blood. Normally, the kidneys help regulate phosphate levels in the body. However, in those with ESRD, the kidneys are unable to effectively remove excess phosphate, leading to elevated serum phosphate levels. This can contribute to various health issues, including bone disease, heart disease, and even death.

Hyperphosphatemia is typically managed first with lifestyle modification if the phosphate levels are no greater than (>) 5.5 mg/dl. This may include reducing phosphate in the diet (e.g., processed foods, sodas, meat and eggs). Other management strategies include optimizing dialysis if they are receiving dialysis to improve phosphate removal, and utilizing phosphate binders. Phosphate binders bind to dietary phosphate in the gastrointestinal tract and limit intestinal absorption and ultimately reducing serum phosphate levels; they are further divided into non-calcium-containing and calcium-containing binders. Non-calcium-containing binders include lanthanum carbonate (Fosrenol), sevelamer (Renvela), ferric citrate (Auryxia), and sucroferric oxyhydroxide (Velphoro). Calcium-containing phosphate binders include calcium carbonate (e.g., Tums), and calcium acetate (PhosLo, Calphron, Phoslyra).

Lanthanum carbonate chewable tablet (Fosrenol) is indicated to reduce serum phosphate levels in those with ESRD. The use of lanthanum carbonate (Fosrenol) can help to control serum phosphorus levels in those with ESRD, potentially reducing the risk of complications associated with hyperphosphatemia. It's important to note that while lanthanum carbonate (Fosrenol) can help manage serum phosphate levels, it does not cure ESRD or the underlying issues causing kidney dysfunction.

Definitions

"Dialysis" is a treatment that filters wastes, salts, and fluid from the blood when the kidneys are no longer healthy enough to do this on their own. Two main types are hemodialysis and peritoneal dialysis.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"End-Stage Renal Disease (ESRD)" is the final stage of chronic kidney disease when the kidneys can no longer function at the level needed to sustain life. Patients typically require renal replacement therapy such as dialysis or kidney transplantation.

"Hyperphosphatemia" is abnormally elevated level of phosphate in the blood, defined as a serum phosphate concentration greater than 4.5 mg/dL in patients with ESRD. For adults on dialysis, serum phosphorus >5.5 mg/dL (1.78 mmol/L) is an indication for treatment.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Phosphate Binders" are medications that bind dietary phosphate in the gastrointestinal tract to reduce absorption and lower serum phosphate levels. Examples include calcium acetate, sevelamer carbonate, sevelamer hydrochloride, and lanthanum carbonate.

"Serum Phosphate" is a measurement of the amount of phosphate in the blood, reported in mg/dL or mmol/L. Normal range is 2.5-4.5 mg/dL in adults. Levels higher than 4.5 mg/dL indicate hyperphosphatemia.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers lanthanum carbonate (Fosrenol) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a nephrologist; *AND*
2. The member is 18 years of age or older; *AND*
3. No evidence of bowel obstruction, including ileus and fecal impaction; *AND*
4. IF request is for brand Fosrenol, the member is unable to use, or has tried and failed generic lanthanum carbonate[s]*; AND*
5. Lanthanum carbonate (Fosrenol) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication*; AND*
6. The member meets the applicable Medical Necessity Criteria for Initial Clinical Review or Subsequent Clinical Review listed below.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Hyperphosphatemia in End-Stage Renal Disease

The Plan considers lanthanum carbonate (Fosrenol) medically necessary when ALL of the following criteria are met:

7. The member meets the above General Medical Necessity Criteria; *AND*
8. The member has a diagnosis of end-stage renal disease (ESRD); *AND*
9. The member has documented evidence of:
    a. Hyperphosphatemia, characterized by a serum phosphate level greater than (>) 5.5 mg/dL); *and*
    b. Inadequate control of serum phosphate despite dietary restriction and/or optimizing dialysis (if appropriate); *AND*
10. The member is unable to use, or has tried and failed ONE (1) of the following[s]:
    a. Calcium acetate (PhosLo); *or*
    b. Sevelamer carbonate (Renvela).

If the above prior authorization criteria are met, lanthanum carbonate (Fosrenol) will be authorized for up to 12 months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Hyperphosphatemia in End-Stage Renal Disease:

The Plan considers lanthanum carbonate (Fosrenol) medically necessary when ALL of the following criteria are met:

1. The member meets the above applicable General Medical Necessity Criteria and/or Initial Clinical Review; *AND*
2. The member has experienced clinical benefit from lanthanum carbonate (Fosrenol) treatment as validated by clinical documentation showing showing ONE of the following within the last 3 months:
    a. Serum phosphate level reduced to target range (3.5-5.5 mg/dL for adults)*; or*
    b. A reduction in serum phosphorus concentration from baseline.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.[s]

Experimental / Investigational, unproven[s]

Lanthanum carbonate (Fosrenol) for any other indication or use is considered experimental, investigational, or unproven.

References

1. Chen TK et al. Chronic kidney disease diagnosis and management: a review. JAMA. 2019;322(13):1294-1304
2. Chiang SS, Chen JB, Yang WC. Lanthanum carbonate (Fosrenol) efficacy and tolerability in the treatment of hyperphosphatemic patients with end-stage renal disease. Clin Nephrol. 2005 Jun;63(6):461-70. doi: 10.5414/cnp63461.
3. Fosrenol (lanthanum) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; December 2024.
4. Hutchison AJ, Maes B, Vanwalleghem J, et al. Long-term efficacy and tolerability of lanthanum carbonate: results from a 3-year study. Nephron Clin Pract. 2006;102(2):c61-71. doi: 10.1159/000088932. Epub 2005 Oct 14.
5. Hutchison AJ, Maes B, Vanwalleghem J, et al. Efficacy, tolerability, and safety of lanthanum carbonate in hyperphosphatemia: a 6-month, randomized, comparative trial versus calcium carbonate. Nephron Clin Pract. 2005;100(1):c8-19. doi: 10.1159/000084653. Epub 2005 Apr 4.
6. Ketteler M et al. Diagnosis, evaluation, prevention, and treatment of chronic kidney disease-mineral and bone disorder: synopsis of the kidney disease: improving global outcomes 2017 clinical practice guideline update. Ann Intern Med. 2018;168(6):422-430.
7. Ketteler M, Block GA, Evenepoel P, et al. Executive summary of the 2017 KDIGO Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Guideline Update: what's changed and why it matters. Kidney Int. 2017 Jul;92(1):26-36. doi: 10.1016/j.kint.2017.04.006. Erratum in: Kidney Int. 2017 Dec;92(6):1558. doi: 10.1016/j.kint.2017.10.001.
8. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. Kidney Int. 2024 Apr;105(4S):S117-S314. doi: 10.1016/j.kint.2023.10.018. PMID: 38490803.
9. 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. 2017;7(suppl 1):1-59. doi:10.1016/j.kisu.2017.04.001
10. Kovesdy CP, Lu JL, Wall BM, et al. Changes with lanthanum carbonate, calcium acetate, and phosphorus restriction in CKD: a randomized controlled trial. Kidney Int Rep. 2018;3(4):897-904. doi:10.1016/j.ekir.2018.03.011
11. Lanthanum carbonate chewable tablets [prescribing information]. Warren, NJ: Cipla USA Incl; August 2024.
12. Ogata H, Fukagawa M, Hirakata H, et al. Effect of Treating Hyperphosphatemia With Lanthanum Carbonate vs Calcium Carbonate on Cardiovascular Events in Patients With Chronic Kidney Disease Undergoing Hemodialysis: The LANDMARK Randomized Clinical Trial. JAMA. 2021 May 18;325(19):1946-1954. doi: 10.1001/jama.2021.4807.

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