Oscar Clinical Guideline: Lanthanum Carbonate Chewable tablet (Fosrenol) (PG177, Ver. 2)

Lanthanum Carbonate Chewable tablet (Fosrenol)

Summary

Lanthanum carbonate chewable tablet (Fosrenol) is a non-calcium, metal-based phosphate binder. It is indicated to reduce serum phosphate levels in patients with ESRD. 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 patients 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.

The use of lanthanum carbonate (Fosrenol) can help to control serum phosphorus levels in patients 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. Therefore, it is used as part of a comprehensive treatment plan that may include:

1. Dietary Changes: limit intake of foods high in phosphate, such as dairy products, certain meats, and processed foods.
2. Dialysis: a treatment that replicates some of the functions of healthy kidneys by removing waste and excess substances like phosphate from the blood.
3. Phosphate Binders: medications, such as lanthanum carbonate (Fosrenol), bind to dietary phosphate in the gastrointestinal tract, preventing its absorption and thereby reducing serum phosphate levels.

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.

"**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.

"**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.

Medical Necessity Criteria for Initial Authorization

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. The member has a diagnosis of end-stage renal disease (ESRD); ***AND***
4. 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***
5. The member is unable to use, or has tried and failed **ONE** of the following:
    a. Calcium acetate (PhosLo); ***or***
    b. Sevelamer carbonate (Renvela); ***AND***
6. The member does **NOT** have documented evidence of bowel obstruction, including ileus and fecal impaction; ***AND***
7. 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 treatment of hyperphosphatemia in ESRD.

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

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating **BOTH** of the following criteria:

1. The requested medication is prescribed by or in consultation with a nephrologist; ***AND***
2. The member has experienced a reduction in serum phosphate levels with lanthanum carbonate (Fosrenol) treatment, validated by clinical documentation showing:
    a. Serum phosphate level reduced to <5.5 mg/dL; ***or***
    b. A reduction in serum phosphorus concentration from baseline.

Experimental or Investigational / Not Medically Necessary

Lanthanum carbonate (Fosrenol) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be 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. Fosrenol (lanthanum) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; May 2023.
3. Fosrenol (lanthanum) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; December 2023.
4. 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.
5. 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.
6. 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
7. 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
8. Lanthanum carbonate chewable tablets [prescribing information]. Warren , NJ: Cipla USA Incl; January 2022.

Clinical Guideline Revision / History Information

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