Oscar Clinical Guideline: Lanthanum Carbonate Chewable tablet (Fosrenol) (PG177, Ver. 3)

Lanthanum Carbonate Chewable tablet (Fosrenol)

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.

"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.

Clinical Indications

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:

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/or optimizing dialysis (if appropriate); *AND*
5. The member is unable to use, or has tried and failed ONE (1) 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.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Medical Necessity 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 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.

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

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

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Clinical Guideline Revision / History Information

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