Oscar Clinical Guideline: Velphoro (sucroferric oxyhydroxide) (PG179, Ver. 3)

Velphoro (sucroferric oxyhydroxide)

Summary

Chronic kidney disease (CKD) is a progressive condition characterized by gradual loss of kidney function over time. As CKD advances, the kidneys have difficulty eliminating waste products from the bloodstream. One of these waste products is phosphorus, an essential mineral needed for bone health, energy production, and other cellular functions.

In advanced CKD and end-stage renal disease (ESRD), impaired kidney function leads to hyperphosphatemia, or abnormally elevated blood phosphorus levels. If left uncontrolled, hyperphosphatemia can cause serious complications like abnormal bone mineralization, vascular calcification, and increased risk of cardiovascular mortality.

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).

Velphoro (sucroferric oxyhydroxide) is approved for the control of serum phosphorus in those 9 years of age and older with CKD on dialysis. While Velphoro (sucroferric oxyhydroxide) can help control elevated blood phosphorus levels, it does not cure CKD or restore normal kidney function. It is one component of a comprehensive treatment plan for advanced CKD and ESRD which may also include:

1. Dietary phosphorus restriction.
2. Dialysis to remove excess phosphorus.
3. Other phosphate binder medications.

Definitions

"Chronic Kidney Disease (CKD)" is a progressive condition characterized by gradual loss of kidney function over time.

"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.

"Hemodialysis" is a type of dialysis where a machine filters wastes, salts, and fluid from the blood when the kidneys are no longer healthy enough.

"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.

"Peritoneal Dialysis" is a type of dialysis where fluid is put into the abdomen to absorb wastes and fluid from small blood vessels.

"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 Velphoro (sucroferric oxyhydroxide) medically necessary when ALL of the following criteria are met:

1. Velphoro (sucroferric oxyhydroxide) is prescribed by or in consultation with a nephrologist*; AND*
2. The member is 9 years of age or older*; AND*
3. The member has a diagnosis of chronic kidney disease (CKD) on dialysis*; AND*
4. The member has documented evidence of:
    a. Hyperphosphatemia, characterized by a serum phosphate level greater than (>) 5.5 mg/dL) in adults or above age-appropriate upper limit of normal in pediatric members*; and*
    b. Inadequate control of serum phosphate despite adherence to dietary restrictions and optimized dialysis regimen*; AND*
5. The member is currently undergoing hemodialysis or peritoneal dialysis*; AND*
6. The member has tried and failed prior treatments as follows:
    a. For adults (18 years and older) - the member is unable to use, or has tried and failed TWO (2) of the following:
        i. Calcium acetate (PhosLo)*; and/or*
        ii. Lanthanum carbonate chewable tablet (Fosrenol)*; and/or*
        iii. Sevelamer (Renvela)*; or*
    b. For pediatrics (9 to 17 years old, with a body surface area of at least 0.75m^2) - the member is unable to use, or has tried and failed sevelamer carbonate (Renvela)*; AND*
7. Velphoro (sucroferric oxyhydroxide) is prescribed at a dose that does not exceed 3,000 mg per day (6 tablets per day).

If the above prior authorization criteria are met, Velphoro (sucroferric oxyhydroxide) will be approved for up to 12 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if the member has recent (within the last 3 months) clinical documentation showing:

1. Velphoro (sucroferric oxyhydroxide) continues to be prescribed by or in consultation with a nephrologist*; AND*
2. The member has experienced clinical benefit from Velphoro treatment, as evidenced by:
    a. Serum phosphate level reduced to target range (3.5-5.5 mg/dL for adults or age-appropriate range for pediatrics)*; or*
    b. A reduction in serum phosphorus concentration from baseline.

Experimental or Investigational / Not Medically Necessary

Velphoro (sucroferric oxyhydroxide) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Anemia. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of anemia.
- Anemia of Chronic Disease. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of anemia of chronic disease.
- Chronic Heart Failure (CHF). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of CHF.
- Chronic Lymphocytic Leukemia (CLL). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of CLL.
- Colorectal Neoplasms. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of colorectal neoplasms.
- Crohn's Disease (CD). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of CD.
- Hip Arthropathy. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of hip arthropathy.
- Hip Fracture. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of hip fracture.
- Hypoalbuminemia. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of hypoalbuminemia.
- Inflammatory Bowel Diseases (IBD). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of IBD.
- Iron Deficiency (ID). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of ID.
- Iron Deficiency Anemia (IDA) in Childbirth. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of IDA in childbirth.
- Iron Deficiency Anemia (IDA). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of IDA.
- Knee Arthropathy. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of knee arthropathy.
- Multiple Myeloma (MM). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of MM.
- Non-Hodgkin's Lymphoma (NHL). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of NHL.
- Osteoarthritis (OA). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of OA.

- Perioperative Blood Conservation. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of perioperative blood conservation.
- Restless Legs Syndrome (RLS). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of RLS.
- Ulcerative Colitis. There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of UC.
- Unexplained Anemia (UAE). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of UEA.
- Variola Major (Smallpox). There are no high quality studies to support the safety and efficacy of Velphoro (sucroferric oxyhydroxide) for the management of small pox.

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Clinical Guideline Revision / History Information

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