Oscar Clinical Guideline: Velphoro (sucroferric oxyhydroxide) (PG179, Ver. 2)

Velphoro (sucroferric oxyhydroxide)

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

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.

To manage hyperphosphatemia, patients with advanced CKD or ESRD undergoing dialysis often require phosphate-binding medications like Velphoro (sucroferric oxyhydroxide) in addition to dietary phosphate

restriction and dialysis. Velphoro binds to dietary phosphorus in the gastrointestinal tract, preventing its absorption into the bloodstream and thereby reducing serum phosphorus levels.

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** 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) - 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 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 clinically significant 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
- Anemia of Chronic Disease
- Chronic Heart Failure (CHF)
- Chronic Lymphocytic Leukemia
- Colorectal Neoplasms
- Crohn's Disease (CD)
- Heart Failure
- Hip Arthropathy
- Hip Fracture
- Hypoalbuminemia
- Inflammatory Bowel Diseases (IBD)
- Iron Deficiency (ID)
- Iron Deficiency Anaemia in Childbirth
- Iron Deficiency Anemia (IDA)
- Knee Arthropathy
- Multiple Myeloma (MM)
- Non-Hodgkin's Lymphoma (NHL)
- Osteoarthritis (OA)
- Perioperative Blood Conservation
- Restless Legs Syndrome (RLS)
- Ulcerative Colitis

- Unexplained Anemia (UAE)
- Variola Major (Smallpox)

References

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Clinical Guideline Revision / History Information

Original Date: 9/21/2023
Reviewed/Revised: 09/18/2024