



Drug Quantity Management – Per Rx Phosphate Binders

Table of Contents

| | |
|--|---|
| National Formulary Medical Necessity | 1 |
| Conditions Not Covered..... | 3 |
| Background..... | 3 |
| References | 5 |
| Revision History..... | 5 |

Product Identifier(s)

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National Formulary Medical Necessity

Drugs Affected

- Calcium acetate tablets, capsules, gelcaps – generic
- Fosreno[®] (lanthanum carbonate chewable tablets and oral powder – generic [chewable tablets only])
- Phoslyra[™] (calcium acetate oral solution)
- Renagel[®] (sevelamer hydrochloride tablets –generic)
- Renvela[®] (sevelamer carbonate tablets and powder for oral suspension –generic)
- Velporo[®] (sucroferric oxyhydroxide chewable tablet)

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of phosphate binders. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

| Product | Strength and Form | Maximum Quantity per Rx |
|---|---------------------------|-------------------------|
| Calcium acetate capsules, gelcaps, tablets (generic only) | 667 mg tablets | 360 tablets |
| | 667 mg capsules | 360 capsules |
| | 667 gelcaps | 360 gelcaps |
| Fosrenol® (lanthanum carbonate chewable tablets [generic], oral powder) | 500 mg chewable tablets | 90 chewable tablets |
| | 750 mg chewable tablets | 90 chewable tablets |
| | 1,000 mg chewable tablets | 90 chewable tablets |
| | 750 mg powder pack | 90 powder packets |
| | 1,000 mg powder pack | 90 powder packets |
| Phoslyra™ (calcium acetate oral solution) | 667 mg/5 mL oral solution | 1,800 mL |
| Sevelamer hydrochloride tablets (generic only) | 400 mg tablets | 450 tablets |
| Renage® (sevelamer hydrochloride tablets, generic) | 800 mg tablets | 270 tablets |
| Renvela® (sevelamer carbonate tablets, powder for oral suspension, generic) | 800 mg tablets | 270 tablets |
| | 0.8 gram powder packet | 180 powder packets |
| | 2.4 gram powder packet | 90 powder packets |
| Velphoro® (sucroferric oxyhydroxide chewable tablet) | 500 mg chewable tablet | 120 tablets |

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Calcium acetate 667 mg capsules, gelcaps, or tablets

No overrides recommended.

Note: The quantity limit allows for maximum recommended dosing of up to 12 capsules/gelcaps/tablets per day.

Fosrenol 500 mg chewable tablets (generic)

1. If the individual requires a higher dose to reduce their plasma phosphate level to < 6 mg/dL, approve the following quantity (A, B, or C):

A) For 2,000 mg/day, approve 120 tablets per dispensing; OR

B) For 2,500 mg/day, approve 150 tablets per dispensing; OR

C) For 3,500 mg/day, approve 210 tablets per dispensing.

Note: Requests for 3,000 mg/day or 4,000 mg/day, see *Fosrenol 1,000 mg chewable tablets (generic)*.

Requests for 3,750 mg/day or 4,500 mg/day, see *Fosrenol 750 mg chewable tablets (generic)*.

Fosrenol 750 mg chewable tablets (generic)

1. If the individual requires a higher dose to reduce their plasma phosphate level to < 6 mg/dL, approve the following quantity (A or B):

A) For 3,750 mg/day, approve 150 tablets per dispensing; OR

B) For 4,500 mg/day, approve 180 tablets per dispensing.

Note: Requests for 2,000 mg/day, 2,500 mg/day or 3,500 mg/day, see *Fosrenol 500 mg chewable tablets (generic)*. Requests for 3,000 mg/day or 4,000 mg/day, see *Fosrenol 1,000 mg chewable tablets (generic)*.

Fosrenol 1,000 mg chewable tablets (generic)

1. If the individual requires a dose of 4,000 mg/day to reduce plasma phosphate levels to < 6 mg/dL, approve 120 tablets per dispensing.

Note: Requests for 2,000 mg/day, 2,500 mg/day or 3,500 mg/day, see *Fosrenol 500 mg chewable tablets (generic)*. Requests for 3,750 mg/day or 4,500 mg/day, see *Fosrenol 750 mg chewable tablets (generic)*.

Fosrenol 750 mg powder packets

1. If the individual requires a higher dose to reduce their plasma phosphate level to < 6 mg/dL, approve the following quantity (A or B):

A) For 3,750 mg/day, approve 150 powder packets per dispensing; OR

B) For 4,500 mg/day, approve 180 powder packets per dispensing.

Note: Requests for 3,000 mg/day or 4,000 mg/day, see *Fosrenol 1,000 mg powder packets*.

Fosrenol 1,000 mg powder packets

1. If the individual requires a dose of 4,000 mg/day to reduce their plasma phosphate level to < 6 mg/dL, approve 120 powder packets per dispensing.

Note: Requests for 3,750 mg/day or 4,500 mg/day, see *Fosrenol 750 mg powder packets*.

Phoslyra 667 mg/5 ml oral solution

No overrides recommended.

Note: The quantity limit allows for maximum recommended dosing of up to 60 mL/day.

Sevelamer hydrochloride 400 mg tablets (generic only)

No quantity overrides are recommended.

Note: Requests for other doses, use Renagel 800 mg tablets and see *Renagel 800 mg tablets*.

Renagel 800 mg tablets (generic)

1. If the individual requires more than 7,200 mg/day to reduce their serum phosphorus level to < 5.5 mg/dL, approve up to 510 tablets per dispensing.

Note: This will allow for maximum dose of up to 13,000 mg/day.

Renvela 800 mg tablets (generic)

1. If the individual requires more than 7,200 mg/day to reduce their serum phosphorus level to < 5.5 mg/dL, approve up to 540 tablets per dispensing.

Note: This will allow for maximum dose of up to 14,000 mg/day.

Renvela 0.8 gram powder packets (generic)

No overrides recommended.

Note: Requests for doses over 4,800 mg/day (6 packets per day), see *Renvela 2.4 gram powder packets (generic)*.

Renvela 2.4 gram powder packets (generic)

1. If the individual requires more than 7,200 mg/day to reduce their serum phosphorus level to < 5.5 mg/dL, approve up to 180 powder packets per dispensing.

Note: This will allow for maximum dose of up to 14,000 mg/day.

Velphoro 500 mg chewable tablets

1. If the individual requires more than 2,000 mg/day to maintain an acceptable serum phosphorus level, approve up to 180 tablets per dispensing.

Note: This will allow for a maximum dose of up to 3,000 mg per day.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Phosphate binders are indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.¹⁻⁹ Fosrenol, sevelamer hydrochloride, and sevelamer carbonate are non-calcium based phosphate binders; Phoslyra contains calcium acetate as the binding agent.⁴⁻⁸ Velphoro is an iron-based product.⁹ Age indications and available dosage forms vary across the class.¹⁻⁹

Dosing

Calcium Acetate

The recommended initial dose of calcium acetate for the adult dialysis patient is two capsules, gelcaps, or tablets with each meal.¹⁻³ The dose is gradually increased to lower serum phosphorus levels to the target range, as long as hypercalcemia does not develop. Most patients require three to four capsules with each meal.

Fosrenol

The recommended initial total daily dose of Fosrenol is 1,500 mg (to be divided and take with or immediately after meals).⁴ The dose is titrated every 2 to 3 weeks until an acceptable serum phosphate level is reached. Serum phosphate levels should be monitored, as needed during dose titration and on a regular basis thereafter. In clinical studies of patients with end stage renal disease (ESRD), Fosrenol doses up to 4,500 mg were evaluated. Most patients required a total daily dose between 1,500 mg and 3,000 mg to reduce plasma phosphate levels to < 6.0 mg/dL. Doses were generally titrated in increments of 750 mg/day.

Phoslyra

The recommended initial dose of Phoslyra for the adult dialysis patient is 10 mL with each meal.⁵ The dose is gradually increased to lower serum phosphorus levels to the target range, as long as hypercalcemia does not develop. The dose is titrated every 2 to 3 weeks until an acceptable serum phosphorus level is reached. Most patients require 15 to 20 mL with each meal.

Renagel/Sevelamer Hydrochloride

For patients not taking a phosphate binder, the recommended starting dose is 800 mg to 1600 mg, administered as one or two 800 mg Renagel tablets or one to four 400 mg sevelamer hydrochloride tablets with meals based on the serum phosphorus level.^{6,7} For patients switching from calcium acetate, see Table 1. For all patients, dosage is adjusted based on the serum phosphorus concentration with a goal of lowering serum phosphorus level to ≤ 5.5 mg/dL. The dose is increased or decreased by one tablet per meal at 2-week intervals as necessary. The average dose in a Phase III trial designed to lower serum phosphorus to ≤ 5.0 mg/dL was approximately three Renagel 800 mg tablets per meal. The maximum average daily Renagel dose studied was 13,000 mg.

Table 1. Starting Dose for Patients on Dialysis who are Switching from Calcium Acetate to Sevelamer HCl Tablets.^{6,7}

| Calcium Acetate 667 mg tablet | Sevelamer HCl 400 mg tablet | Renagel 800 mg tablet |
|-------------------------------|-----------------------------|-----------------------|
| 1 tablet per meal | 2 tablets per meal | 1 tablet per meal |
| 2 tablets per meal | 3 tablets per meal | 2 tablets per meal |
| 3 tablets per meal | 5 tablets per meal | 3 tablets per meal |

Renvela

The recommended starting dose of Renvela is 0.8 grams to 1.6 grams taken orally with meals based on serum phosphorus levels.⁸ The dose is titrated by 0.8 grams three times a day (TID) with meals at 2-week intervals as necessary to achieve target serum phosphorus levels. Based on clinical studies, the average prescribed adult daily dose of sevelamer carbonate is approximately 7.2 grams per day. The highest daily adult dose of sevelamer carbonate studied was 14,000 mg/day in patients with chronic kidney disease on dialysis.

Velphoro

The recommended starting dose of Velphoro is three tablets (1,500 mg) per day, administered as one tablet (500 mg) TID with meals.⁹ Serum phosphorus levels should be monitored and doses titrated in increments or decrements of 500 mg (one tablet) per day as needed until an acceptable serum phosphorus level is reached, with regular monitoring afterwards. Based on clinical studies, on average patients required three to four tablets (1,500 mg to 2,000 mg) a day to control serum phosphorus levels. The highest daily dose studied in a Phase III clinical trial in patients with ESRD was six tablets (3,000 mg) per day.

Availability

The availability of the phosphate binders are provided in Table 2.

Table 2. Phosphate Binders Availability.¹⁻⁹

| Product | Strength and Form |
|---|---------------------------|
| Calcium acetate capsules, gelcaps, tablets (generic only) | 667 mg tablets |
| | 667 mg capsules |
| | 667 gelcaps |
| Fosrenol® (lanthanum carbonate chewable tablets [generic], oral powder) | 500 mg chewable tablets |
| | 750 mg chewable tablets |
| | 1,000 mg chewable tablets |
| | 750 mg powder pack |
| | 1,000 mg powder pack |
| Phoslyra™ (calcium acetate oral solution) | 667 mg/5 mL oral solution |
| Sevelamer hydrochloride tablets (generic only) | 400 mg tablets |
| Renage® (sevelamer hydrochloride tablets, generic) | 800 mg tablets |
| Renvela® (sevelamer carbonate tablets, powder for oral suspension, generic) | 800 mg tablets |
| | 0.8 gram powder packet |
| | 2.4 gram powder packet |
| Velphoro® (sucroferric oxyhydroxide chewable tablet) | 500 mg chewable tablet |

References

1. Calcium Acetate capsules [prescribing information]. Berkeley Heights, NJ: Hikma; September 2020.
2. Calcium Acetate gelcaps [prescribing information]. Princeton, NJ: Sandoz March 2013.
3. Calcium Acetate tablets [prescribing information]. Congers, NY: Chartwell; May 2019.
4. Fosrenol® chewable tablets and oral powder [prescribing information]. Lexington, MA: Takeda; May 2020.
5. Phoslyra oral solution [prescribing information]. Waltham, MA: Fresenius Medical Care; September 2020.
6. Renage® tablets [prescribing information]. Cambridge, MA: Genzyme; April 2020.
7. Sevelamer hcl tablets [prescribing information]. Mahwah, NJ: Glenmark; June 2020.
8. Renvela® tablets and oral suspension [prescribing information]. Cambridge, MA: Genzyme; April 2020.
9. Velphoro® chewable tablets [prescribing information]. Waltham, MA: Fresenius Medical Care; February 2020.

Revision History

| Type of Revision | Summary of Changes | Approval Date |
|------------------|---|---------------|
| Annual Revision | <p>Renage 400 mg tablets: Brand Renage 400 mg tablets were removed (obsolete) and generic sevelamer hydrochloride 400 mg tablets were added.</p> <p>Sevelamer hydrochloride 400 mg tablets: Maximum quantity limit per Rx was increased to 450 tablets to accommodate up to 5 tablets per meal per day.</p> <p>Renage 800 mg tablets: Maximum quantity limit per Rx was increased to 270 tablets to accommodate up to 3 tablets per meal per day.</p> <p>Criteria</p> <p>Calcium acetate 667 mg tablets, capsules, gelcaps: Note was changed from 2,000 mg of elemental calcium to (the equivalent) 12 tablets/capsules/gelcaps.</p> <p>Fosrenol 1,000 mg chewable tablets (generic): Note was changed to add 2,000 mg/day and to clarify the listed units are per day.</p> <p>Phoslyra 667 mg/5 mL oral solution: Note was changed from 2,000 mg of elemental calcium to (the equivalent) 60 mL/day.</p> <p>Sevelamer hydrochloride 400 mg tablets: New criteria: No quantity overrides are recommended. Requests for other doses, use Renage 800 mg tablets and see criteria for Renage 800 mg tablets.</p> | 04/06/2022 |

| | | |
|--|--|--|
| | <p>Renagel 800 mg tablets: Previous criteria was for doses > 4,800 mg; new criteria is for doses > 7,200 mg/day. The maximum quantity remains unchanged as “up to 510 tablets per dispensing”.</p> <p>Renvela 0.8 g powder packets: Note was changed to: Requests for doses over 4,800 mg/day (6 packets per day), see Renvela 2.4 g powder packets.</p> | |
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