

DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Phosphate Binders Drug Quantity Management Policy – Per Rx
- Calcium acetate tablets, capsules, gelscaps —(generics only)
 - Fosrenol® (lanthanum carbonate chewable tablets and oral powder – Shire, generic [chewable tablets only])
 - Phoslyra™ (calcium acetate oral solution – Fresenius Medical Care)
 - Renagel® (sevelamer hydrochloride tablets – Genzyme, generic)
 - Renvela® (sevelamer carbonate tablets and powder for oral suspension – Genzyme, generic)
 - Velphoro® (sucroferric oxyhydroxide chewable tablet – Fresenius Medical Care)

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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, gelscaps, 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-

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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
Renagel [®] (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

POLICY STATEMENT

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.

Automation: None.

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
Renagel® (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® (sucroferic oxyhydroxide chewable tablet)	500 mg chewable tablet	120 tablets

CRITERIA

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 patient 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 patient 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 patient 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 patient 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 patient 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 patient 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 patient 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 patient 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 patient 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.

REFERENCES

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