



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Phosphate Binders Drug Quantity Management Policy – Per Rx
- Calcium acetate capsules, gels, tablets (generic only)
 - Fosrenol® (lanthanum carbonate chewable tablets and oral powder – Takeda, generic to chewable tablets only)
 - Phoslyra® (calcium acetate oral solution – Fresenius)
 - Renagel® (sevelamer hydrochloride tablets – Genzyme, generic)
 - Renvela® (sevelamer carbonate tablets and powder for oral suspension – Genzyme, generic)
 - Velphoro® (sucroferric oxyhydroxide chewable tablet – Fresenius)

REVIEW DATE: 04/22/2024

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CIGNA NATIONAL FORMULARY COVERAGE:

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, gels, 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.

Sevelamer Hydrochloride (Renagel)

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 per 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 packets 1,000 mg powder packets
Phoslyra® (calcium acetate oral solution) [obsolete]	667 mg/5 mL oral solution
Sevelamer hydrochloride tablets (generic only)	400 mg tablets
Renagel® (sevelamer hydrochloride tablets, generic) [brand obsolete]	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.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Calcium acetate capsules, gelcaps, tablets (generic only)	667 mg tablets	360 tablets	1,080 tablets
	667 mg capsules	360 capsules	1,080 capsules
	667 gelcaps	360 gelcaps	1,080 gelcaps
Fosrenol®	500 mg chewable tablets	90 tablets	270 tablets

(lanthanum carbonate chewable tablets [generic], oral powder)	750 mg chewable tablets	90 tablets	270 tablets
	1,000 mg chewable tablets	90 tablets	270 tablets
	750 mg powder packets	90 packets	270 packets
	1,000 mg powder packets	90 packets	270 packets
Phoslyra® (calcium acetate oral solution) [obsolete]	667 mg/5 mL oral solution	1,800 mL	5,400 mL
Sevelamer hydrochloride tablets (generic only)	400 mg tablets	450 tablets	1,350 tablets
Renagel® (sevelamer hydrochloride tablets, generic) [brand obsolete]	800 mg tablets	270 tablets	810 tablets
Renvela® (sevelamer carbonate tablets, powder for oral suspension, generic)	800 mg tablets	270 tablets	810 tablets
	0.8 gram powder packet	180 packets	540 packets
	2.4 gram powder packet	90 packets	270 packets
Velphoro® (sucroferric oxyhydroxide chewable tablet)	500 mg chewable tablet	120 tablets	360 tablets

Phosphate Binders Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Calcium acetate 667 mg capsules, gelcaps, or tablets

No overrides recommended.

Lanthanum carbonate 500 mg chewable tablets (Fosrenol, 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 a dose of 2,000 mg per day, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery; OR

B) For a dose of 2,500 mg per day, approve 150 tablets per dispensing at retail or 450 tablets per dispensing at home delivery; OR

C) For a dose of 3,500 mg per day, approve 210 tablets per dispensing at retail or 630 tablets per dispensing at home delivery.

Note: Requests for 3,000 mg per day or 4,000 mg per day, direct the patient to *lanthanum carbonate 1,000 mg chewable tablets (Fosrenol, generic)*. Requests for 3,750 mg per day or 4,500 mg per day, direct the patient to *lanthanum carbonate 750 mg chewable tablets (Fosrenol, generic)*.

Lanthanum carbonate 750 mg chewable tablets (Fosrenol, 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 a dose of 3,750 mg per day, approve 150 tablets per dispensing at retail or 450 tablets per dispensing at home delivery; OR

B) For a dose of 4,500 mg per day, approve 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.

Note: Requests for 2,000 mg per day, 2,500 mg per day or 3,500 mg per day, direct the patient to lanthanum carbonate 500 mg chewable tablets (Fosrenol, generic). Requests for 3,000 mg per day or 4,000 mg per day, see lanthanum carbonate 1,000 mg chewable tablets (Fosrenol, generic).

Lanthanum carbonate 1,000 mg chewable tablets (Fosrenol, generic)

1. If the patient requires a dose of 4,000 mg per day to reduce plasma phosphate levels to < 6 mg/dL, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.

Note: Requests for 2,000 mg per day, 2,500 mg per day or 3,500 mg per day, direct the patient to lanthanum carbonate 500 mg chewable tablets (Fosrenol, generic). Requests for 3,750 mg per day or 4,500 mg per day, see lanthanum carbonate 750 mg chewable tablets (Fosrenol, 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 a dose of 3,750 mg per day, approve 150 packets per dispensing at retail or 450 packets per dispensing at home delivery; OR

B) For 4,500 mg per day, approve 180 packets per dispensing at retail or 540 packets per dispensing at home delivery.

Note: Requests for 3,000 mg per day or 4,000 mg per day, direct the patient to Fosrenol 1,000 mg powder packets.

Fosrenol 1,000 mg powder packets

1. If the patient requires a dose of 4,000 mg per day to reduce their plasma phosphate level to < 6 mg/dL, approve 120 packets per dispensing at retail or 360 packets per dispensing at home delivery.

Note: Requests for 3,750 mg per day or 4,500 mg per day, direct the patient to Fosrenol 750 mg powder packets.

Phoslyra 667 mg/5 ml oral solution

No overrides recommended.

Sevelamer hydrochloride 400 mg tablets (generic only)

No quantity overrides are recommended.

Note: Requests for other doses, direct the patient to sevelamer hydrochloride 800 mg tablets (Renagel, generic).

Sevelamer hydrochloride 800 mg tablets (Renagel, generic)

1. If the patient requires more than 7,200 mg per day to reduce their serum phosphorus level to < 5.5 mg/dL, approve the requested quantity, not to exceed 510 tablets per dispensing at retail or 1,530 tablets per dispensing at home delivery.

Note: This override allows for a maximum dose of up to 13,000 mg per day.

Sevelamer carbonate 800 mg tablets (Renvela, generic)

1. If the patient requires more than 7,200 mg per day to reduce their serum phosphorus level to < 5.5 mg/dL, approve the requested quantity, not to exceed 540 tablets per dispensing at retail or 1,620 tablets per dispensing at home delivery.

Note: This override allows for a maximum dose of up to 14,000 mg per day.

Sevelamer carbonate 0.8 gram powder packets (Renvela, generic)

No overrides recommended.

Note: Requests for doses over 4,800 mg per day (more than 6 packets per day), direct the patient to sevelamer carbonate 2.4 gram powder packets (Renvela, generic).

Sevelamer carbonate 2.4 gram powder packets (Renvela, generic)

1. If the patient requires more than 7,200 mg per day to reduce their serum phosphorus level to < 5.5 mg/dL, approve the requested quantity, not to exceed 180 packets per dispensing at retail or 540 packets per dispensing at home delivery.

Note: This override allows for a maximum dose of up to 14,000 mg per day.

Velphoro 500 mg chewable tablets

1. If the patient requires more than 2,000 mg per day to maintain an acceptable serum phosphorus level, approve the requested quantity, not to exceed 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.

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

REFERENCES

1. Calcium acetate capsules [prescribing information]. Berkeley Heights, NJ: Hikma; September 2020.
2. Calcium acetate gels [prescribing information]. Princeton, NJ: Sandoz; October 2023.
3. Calcium acetate tablets [prescribing information]. Congers, NY: Chartwell; December 2022.
4. Fosrenol® chewable tablets and oral powder [prescribing information]. Lexington, MA: Takeda; December 2023.
5. Phoslyra oral solution [prescribing information]. Waltham, MA: Fresenius; September 2020.
6. Renagel® 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]. Bridgewater, NJ: sanofi-aventis; June 2023.
9. Velphoro® chewable tablets [prescribing information]. Waltham, MA: Fresenius; February 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	04/06/2023
Annual Revision	No criteria changes.	04/22/2024

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