

Policies Repository



Policy Title Sevelamer Carbonate (Renvela)

Policy Number FS.CLIN.84

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Sevelamer Carbonate (Renvela)** is indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

The use of Sevelamer Carbonate (Renvela) requires prior authorization (ie clinical pharmacy and/or Medical director review).

Policy Description **Sevelamer Carbonate (Renvela)** is a non absorbed molecule that binds phosphate through ionic and hydrogen bonding. By binding phosphate in the dietary tract and decreasing absorption, sevelamer carbonate lowers the phosphate concentration in the serum.

Policy Guideline Inclusion **Sevelamer Carbonate (Renvela)** is approved for the control of serum phosphorus in patients with chronic kidney disease on dialysis when **any** of the following inclusion criteria are met:

- Documentation of a trial and failure/contraindication/intolerance/allergy to calcium acetate
- Documentation of hypercalcemia (corrected serum calcium of >10.2mg/dL [2.54mmol/L])
- Documentation of plasma parathyroid hormone (PTH) levels <150pg/mL(16.5pmol/L)
- Documentation of severe vascular and/or other soft tissue calcification

Policy Guideline Exclusion **Sevelamer Carbonate (Renvela)** is denied when **any** of the following exclusion criteria are present:

- No documentation of chronic kidney disease with dialysis
- No documentation of **one** of the following
 - A trial and failure/contraindication/intolerance/allergy to calcium acetate

- Hypercalcemia (corrected serum calcium of >10.2mg/dL [2.54mmol/L])
- Plasma parathyroid hormone (PTH) levels <150pg/mL (16.5pmol/L)
- Severe vascular and/or other soft tissue calcification

Policy List of Applicable Drugs

| Brand Name | Generic Name |
|------------|---------------------|
| Renvela | Sevelamer Carbonate |

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Facts and Comparisons Website [Renvela]. Available at www.factsandcomparisons.com. Accessed July 23, 2010.

National Kidney Foundation Clinical Practice Guidelines for bone metabolism and disease in chronic kidney disease. Available at www.kidney.org. Accessed October 10, 2008.

Qunibi W, Hootkins R, McDowell L, et al. Treatment of hyperphosphatemia in hemodialysis patients: The calcium acetate renagel evaluation (CARE study). *Kidney International* 2004. 65; 1914-1926.

Qunibi W, Moustafa M, Muenz LR, et al. A 1-year randomized trial of calcium acetate versus sevelamer on progression of coronary artery calcification in hemodialysis patients with comparable lipid control: The calcium acetate renagel evaluation-2 (CARE-2) study. *Am J Kidney Dis* 2008. Jun; 952-65.

Renvela [package insert]. Cambridge, MA: Genzyme. March 2010

Policy Link to Related Policies

Printed

08/23/2010 13:16:42

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