Policies Repository

Independence Blue Cross

Policy Title	Sevelamer Carbonate (Renvela)
Policy Number	FS.CLIN.70

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

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 February 20, 2009.

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. 2007

Policy Link to Related Policies

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