

**Clinical Pharmacy Program Guidelines for Renvela**

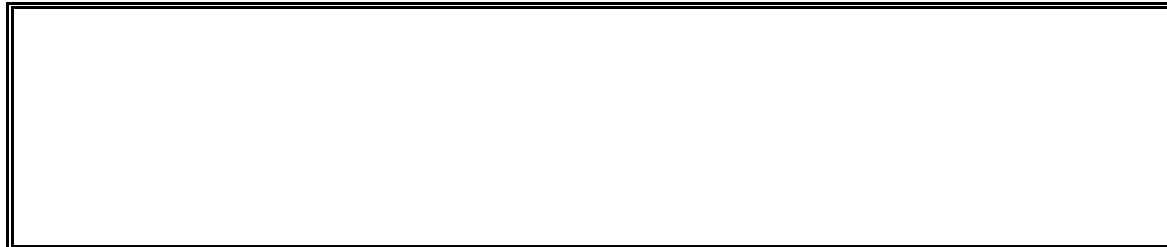
Program	Step Therapy
Medication	Renvela (sevelamer carbonate)
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

**1. Background:**

Renvela is a phosphate binder indicated for the control of serum phosphorus in patients with chronic kidney disease on dialysis.

**2. Coverage Criteria:**

<p><b>A. <u>Automated Step Therapy Criteria</u></b></p> <p>1. A claim for <b>Renvela</b> will process at the point of sale if the patient’s drug fill history shows an 8 week trial of calcium acetate tablets or capsules.</p> <p><b>B. <u>Requests That DO NOT Meet Automated Step Criteria</u></b></p> <p>1. <b>Renvela</b> will be approved for patients who have not met the automated step criteria when <u>one</u> of the following circumstances is met:</p> <p>a. The patient did not exhibit an adequate response to treatment with calcium acetate as evidenced by a phosphorus level &gt; 5.5mg/dL while on calcium acetate therapy</p> <p align="center"><b>-OR-</b></p> <p>b. The patient experienced an intolerance/adverse reaction to previous therapy with calcium acetate</p> <p align="center"><b>-OR-</b></p> <p>c. The patient has a documented contraindication to treatment with calcium acetate</p> <p><b>Authorization will be issued for 12 months.</b></p>
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**3. References:**

1. Renvela® Prescribing Information. Genzyme, March 2017.
2. Clinical Pharmacology Gold Standard. 2012.
3. Facts and Comparisons 4.0; 2012.
4. Qunibi WY. The CARE Study and Cardiovascular Calcification. Hyperphosphatemia Consultancy Panel. *Managed Care* March. 2006;15(3 Suppl):S1-5.
5. Otoo A, Little, G. Controversies in the Management of Hyperphosphatemia In Patients with End Stage Renal Disease. *Managed Care*. 2006;15(3 Suppl):S5-8.
6. National Kidney Foundation K/DOQI. Clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Pharmacotherapy*. 2005;25(12):1687-707.
7. Storms L.E, Chicella M.F, Dice J.E. Sevelamer for Pediatric End-Stage Renal Disease. *Pharmacotherapy* March 2006;26(3):410-413.
8. Delmez J, et al. A randomized, double-blind, cross-over design study of sevelamer hydrochloride and sevelamer carbonate in patients on hemodialysis. *Clinical Nephrology* December 2007;68(6):386-91.

Program	Step Therapy –Renvela (sevelamer carbonate)
<b>Change Control</b>	
Date	Change
9/2009	New policy
9/2012	Revision
12/2016	Annual review, updated policy template and added standard authorization duration of 12 months
11/2017	Annual review. Updated references.