Renvela® (sevelamer) – Expanded Indication

- On November 25, 2016, the FDA approved Genzyme's Renvela (sevelamer) tablets and oral suspension, for the control of serum phosphorus in adults and children 6 years of age and older with chronic kidney disease (CKD) on dialysis.
    - Previously, Renvela was approved only for use in adults.
- Renvela's expanded indication is based on a clinical study of 101 patients 6 to 18 years of age with CKD randomized to sevelamer or placebo. Sevelamer significantly reduced serum phosphorus levels through week 2 by a mean difference of -0.90 mg/dL vs. placebo (p = 0.001).
    - In this study, Renvela was less effective in children with a low baseline serum phosphorus level, which described children < 13 years of age and children not on dialysis. Given its mechanism of action, Renvela is expected to be effective in lowering serum phosphorus levels in pediatric patients with CKD.
    - Most adverse events that were reported as related, or possibly related, to sevelamer carbonate were gastrointestinal in nature. No new risks or safety signals were identified with the use of sevelamer carbonate in the trial.
- The recommended starting dose of Renvela for pediatric patients ≥ 6 years of age is 0.8 g to 1.6 g taken orally three times per day with meals based on the patient's body surface area (BSA) category.
    - The Renvela dose is titrated as needed to achieve target levels at two-week intervals based on BSA category.
    - Refer to the Renvela drug label for BSA categories.
- The recommended starting dose of Renvela for adult patients is 0.8 g to 1.6 g taken orally three times per day with meals based on serum phosphorus level.