Veltassa® (patiromer) – Expanded indication, new strength

- On October 2, 2023, the FDA approved Vifor Pharma's Veltassa (patiromer), for the treatment of hyperkalemia in adults and pediatric patients ages 12 years and older.
    - Veltassa was previously approved for treatment of hyperkalemia and the safety and efficacy in pediatric patients had not been established.
- Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.
- In addition to the expanded indication, the FDA approved a new strength of Veltassa (single-use packets containing 1 gram). Veltassa is also available as 8.4 grams, 16.8 grams and 25.2 grams packets.
- The approval of Veltassa for the expanded indication was based on open-label, single-arm study in pediatric patients 12 to 17 years of age with chronic kidney disease (CKD) and hyperkalemia. The aim of the study was maintaining serum potassium in the target range (3.8 mEq/L to < 5.0 mEq/L).
    - The mean change in serum potassium from baseline to day 14 was -0.5 mEq/L (95% CI: -0.8, -0.2). The proportion of patients 12 to 17 years of age with a serum potassium within the normal range was 50% at day 14.
- The recommended starting dose of Veltassa for pediatric patients ages 12 years and older is 4 grams orally once daily. The dose can be titrated based on serum potassium level at 1-week or longer intervals, in increments of 4 grams.
    - The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily in adults and pediatric patients aged 12 years and older.
    - Refer to the Veltassa drug label for complete adult dosing.