Zemplar® (paricalcitol) – Expanded Indications

- On October 18, 2016, the FDA announced the approval of AbbVie's Zemplar (paricalcitol) capsules for pediatric patients 10 years and older for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) stages 3 and 4 and CKD stage 5 in patients on hemodialysis or peritoneal dialysis.
    - Previously, Zemplar capsules were not indicated in pediatric patients.
- Zemplar is also available generically as capsules and an injectable solution.
    - The injectable solution is indicated for the prevention and treatment of secondary hyperparathyroidism associated with CKD stage 5.
- The efficacy of Zemplar in patients 10-16 years of age was demonstrated in a clinical study of 36 patients with CKD stages 3 and 4. The primary efficacy endpoint was the proportion of patients achieving two consecutive ≥ 30% reductions from baseline in iPTH levels.
    - A statistically significantly greater proportion of Zemplar patients achieved the primary endpoint vs. placebo (28% vs. 0%, respectively; $p < 0.05$).
- The recommended dose of Zemplar capsules in patients 10-16 years of age is as follows:
    - CKD stages 3 and 4: 1 mcg administered orally three times per week.
    - CKD stage 5: dose (mcg) = baseline iPTH (pg/mL) / 120. Administer orally three times per week.
    - The Zemplar dose should be individualized and titrated based on iPTH, serum calcium and phosphorus levels to maintain an iPTH level within target range.
    - Consult package label for recommended adult dosages.