Linzess® (linaclotide) – New indication

- On June 12, 2023, Ironwood Pharmaceuticals announced the FDA approval of Linzess (linaclotide), for the treatment of functional constipation (FC) in pediatric patients 6 to 17 years of age.
- Linzess is the first FDA-approved prescription therapy for FC in this patient population.
- Linzess is also approved for the treatment of irritable bowel syndrome with constipation in adults and chronic idiopathic constipation in adults.
- The approval of Linzess for the new indication was based on a randomized, double-blind, placebo-controlled study in 328 pediatric patients 6 to 17 years of age with FC. Patients received Linzess or placebo. The primary endpoint was the 12-week change from baseline in spontaneous bowel movements (SBM) frequency rate.
    - The least squares 12-week mean change from baseline in SBM frequency rate was 2.6 with Linzess and 1.3 with placebo (treatment difference 1.3, 95% CI: 0.7, 1.8).
- Linzess carries a boxed warning for risk of serious dehydration in pediatric patients less than 2 years of age.
- The most common adverse reaction (≥ 2%) with Linzess use in pediatric patients 6 to 17 years of age with FC is diarrhea.
- The recommended dose of Linzess for the treatment of FC in pediatric patients is 72 mcg orally once daily.
    - Refer to the Linzess drug label for dosing for its other indications.