Zepatier® (elbasvir/grazoprevir) – Expanded indication

- On December 9, 2021, the FDA approved Merck's Zepatier (elbasvir/grazoprevir), for the treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.
    - Zepatier was previously approved for this indication in adult patients only.
    - Zepatier is indicated for use with ribavirin in certain patient populations.
- The approval of Zepatier for the expanded indication was based on an open-label study in 22 pediatric patients 12 years to less than 18 years with chronic HCV infection. Patients received Zepatier for 12 weeks. The primary endpoint was sustained virologic response (SVR), defined as HCV RNA less than lower limit of quantification at 12 weeks after the cessation of treatment (SVR12).
    - The SVR12 rate was 100% (22/22).
- Zepatier carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- The recommended dose of Zepatier for all patients is one fixed-dose combination tablet (containing 50 mg of elbasvir and 100 mg of grazoprevir) orally once daily. The recommended Zepatier treatment regimen and duration is based on the patient population and genotype. Refer to the Zepatier drug label for complete dosing and administration recommendations.