Mavyret™ (glecaprevir/pibrentasvir) – Expanded indication

- On April 30, 2019, the FDA approved AbbVie's Mavyret (glecaprevir/pibrentasvir), for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with:
    - Chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
    - HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.
- Previously, Mavyret was approved in adult patients only.
- The approval of Mavyret's expanded indication was based on an open-label study in 47 HCV-infected patients 12 years to less than 18 years without cirrhosis. The primary endpoint was sustained virologic response (SVR12), defined as HCV RNA less than lower limit of quantification (LLOQ) at 12 weeks after the end of treatment.
    - The overall SVR12 rate was 100% (47/47).
- Mavyret carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- The recommended oral dosage of Mavyret in adult and pediatric patients 12 years and older or weighing at least 45 kg is 3 tablets taken at the same time once daily with food (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg).
- The recommended treatment duration varies depending on the patient population. Refer to the Mavyret drug label for additional dosing recommendations.