Mavyret® (glecaprevir/pibrentasvir) – Label update

- On September 26, 2019, the FDA announced the approval of AbbVie's Mavyret (glecaprevir/pibrentasvir), for an 8-week duration for the treatment of adults and children ages 12 years and older or weighing at least 45 kg who have chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection and compensated cirrhosis and have not been previously treated for HCV.
    - This approval shortens the treatment duration from 12 weeks to 8 weeks in this patient population.
- Mavyret is also approved for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with 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.
- Mavyret is the first 8-week treatment approved for all treatment-naïve adult and certain pediatric patients with HCV genotypes 1 through 6 both without cirrhosis and with compensated cirrhosis.
- The approval of Mavyret for treatment duration of 8-weeks in this population was based on EXPEDITION-8, a single-arm, open-label study in 343 treatment-naïve patients with genotype 1, 2, 3, 4, 5 or 6 chronic HCV infection and compensated cirrhosis.
    - The overall sustained virologic response (SVR12) or cure rate was 98% (335/343).
- Mavyret carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- The recommended dose of Mavyret for all HCV patients is three tablets taken orally at the same time once daily with food (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg).
    - Refer to the Mavyret drug label for the recommended treatment duration based on the patient population.