Mavyret® (glecaprevir/pibrentasvir) – New indication

- On June 11, 2025, AbbVie announced the FDA approval of Mavyret (glecaprevir/pibrentasvir), for the treatment of adult and pediatric patients 3 years and older with **acute or chronic hepatitis C virus** (HCV) genotype 1, 2, 3, 4, 5 or 6 infection, without cirrhosis or with compensated cirrhosis (Child-Pugh A).
    - Mavyret was previously approved for this indication for chronic HCV only.
- Mavyret is the first direct acting antiviral FDA approved for acute HCV.
- Mavyret is also approved for the treatment of adult and pediatric patients 3 years and older 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.
- The approval of Mavyret for the expanded indication was based on a single-arm, open-label study in 286 adults with documented acute HCV infection. Patients received Mavyret for 8 weeks.
    - **Overall sustained virologic response at 12 weeks (SVR12) was 96%**; no patients experienced virologic failure. Two patients who did not achieve SVR12 likely were reinfected with HCV based on having different HCV genotypes or subtype clades between the baseline and follow-up periods.
- The use of Mavyret in pediatric patients with acute HCV infection is supported by extrapolation of safety and efficacy data from adult patients with acute HCV infection and adult and pediatric patients with chronic HCV infection.
    - It is expected that adult and pediatric patients with acute HCV infection have similar disease response to treatment. No clinically meaningful differences in Mavyret exposures are expected among pediatric patients with acute HCV infection and pediatric patients with chronic HCV infection.
- Mavyret carries a boxed warning for risk of hepatitis B virus (HBV) reactivation in patients coinfected with HCV and HBV.
- Refer to the Mavyret drug label for complete dosing and administration recommendations.