Mavyret® (glecaprevir/pibrentasvir) – Expanded indication, new formulation approval

- On June 10, 2021, the FDA approved AbbVie's Mavyret (glecaprevir/pibrentasvir), for the treatment of adult and pediatric patients 3 years and older 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 (PI), but not both.
- Mavyret was previously approved for these uses in adult and pediatric patients 12 years and older or weighing at least 45 kg.
- Along with the expanded indication, the FDA also approved a new oral pellet formulation and strength (50 mg/20 mg) of Mavyret.
    - Previously, Mavyret was only available as a 100 mg/40 mg tablet.
- The approval of Mavyret for the expanded indication was based on an open-label study in 80 patients aged 3 years to less than 12 year with HCV infection. Sixty-two patients received the weight-based recommended dosage. Eighteen subjects received doses lower than the recommended weight-based dosage and were not included in the efficacy assessment.
    - At 12 weeks after treatment completion, Mavyret achieved a sustained virologic response (SVR12) or cure rate of 98.4% (61/62); the patient who did not achieve SVR12 discontinued treatment due to an adverse reaction.
- Mavyret carries a boxed warning for risk of hepatitis B virus reactivation in patients coinfected with HCV and hepatitis B virus.
- Mavyret is contraindicated:
    - In patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation
    - With atazanavir or rifampin.
- Additional warnings and precautions for Mavyret include risk of hepatic decompensation/failure in patients with evidence of advanced liver disease; and risk of reduced therapeutic effect due to concomitant use of Mavyret with carbamazepine, efavirenz containing regimens, or St. John's wort.
- The recommended treatment duration and dosage for Mavyret in pediatric patients 3 years of age and older are provided in the tables below.
    - Refer to the Mavyret label for additional dosing and administration recommendations, including dosing in adult patients.

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Recommended duration

HCV genotype	Prior treatment	Treatment duration	
		No cirrhosis	Compensated cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	Treatment-naïve	8 weeks	8 weeks
1	An NS5A inhibitor without prior treatment with an NS3/4A PI	16 weeks	16 weeks
	An NS3/4A PI without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5, or 6	PRS*	8 weeks	12 weeks
3	PRS*	16 weeks	16 weeks

* PRS = Prior treatment experience with regimens containing (peg)interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

Dosing for pediatric patients 3 years and older

Body weight or age	Mavyret daily dose	Dosing of Mavyret
< 20 kg	150 mg/60 mg per day	Three 50 mg/20 mg packets of oral pellets once daily
20 kg to < 30 kg	200 mg/80 mg per day	Four 50 mg/20 mg packets of oral pellets once daily
30 kg to < 45 kg	250 mg/100 mg per day	Five 50 mg/20 mg packets of oral pellets once daily
> 45 kg OR 12 years of age and older	300 mg/120 mg per day	Three 100 mg/40 mg tablets once daily*

* Pediatric patients weighing 45 kg and greater who are unable to swallow tablets may take six 50 mg/20 mg packets of oral pellets once daily. Dosing with oral pellets has not been studied for pediatric patients weighing greater than 45 kg.

- AbbVie's launch plans for Mavyret oral pellets are pending.