FDA OKs AbbVie’s Mavyret for Adolescents With Hepatitis C

The approval applies to those between 12 and 17 years old who have any of the six genotypes of the virus.

May 1, 2019 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved AbbVie’s Mavyret (glecaprevir/pibrentasvir) to treat all six genotypes of hepatitis C virus (HCV) among adolescents.

Mavyret was approved to treat all genotypes of HCV among adults in August 2017.

The adolescent approval is based on clinical trials including 47 adolescents with genotype 1, 2, 3 or 4 of hep C who had no cirrhosis or only a mild case. All those who received the regimen for eight or 16 weeks achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

For those adolescents with cirrhosis, a history of kidney or liver transplant, or genotype 5 or 6 of HCV, the FDA approval was supported by previous research of Mavyret conducted among adult populations.

The adverse health events seen among adolescents taking Mavyret were similar to those experienced by adults. The most common adverse events associated with the regimen are headache and fatigue.

The recommended duration of Mavyret treatment depends on whether an individual has been treated for HCV before and his or her viral genotype and cirrhosis status.

Mavyret is not recommended for those with moderate cirrhosis and is contraindicated, or not advised, for those with severe cirrhosis and those taking Reyataz (atazanavir) or Rifadin (rifampin).

To read a press release about the FDA approval, click here.
