FDA OKs 8 Weeks of Mavyret for Hep C Treatment First-Timers

The indication for AbbVie's regimen includes those with compensated cirrhosis.

September 30, 2019 By Benjamin Ryan

The Food and Drug Administration (FDA) has granted a new approval of AbbVie's Mavyret (glecaprevir/pibrentasvir) that shortens treatment from 12 to eight weeks for those with all six genotypes of hepatitis C virus (HCV) who have not been treated previously. The new drug indication applies to adults and to children who are at least 12 years old or weigh at least 99 pounds and to those without cirrhosis or who have compensated cirrhosis, the milder form of the severe liver disease.

Mavyret was first approved in 2017.

The new indication for Mavyret makes it the first regimen approved for an eight-week course among treatment first-timers and certain children and adolescents with genotypes 1 through 6 of HCV who have compensated cirrhosis or who do not have cirrhosis.

Mavyret's efficacy was established in clinical trials that between them enrolled more than 2,500 people with genotypes 1 through 6 of hep C who were treated for 8, 12 or 16 weeks. These trials included individuals with HIV and HCV coinfection, kidney or liver transplantees and people with advanced kidney disease, including those on dialysis.

The most common adverse health events in these trials were headache and fatigue.

Mavyret should not be taken by people with moderate or severe liver impairment (Child-Pugh B or C liver disease) or those with a history of decompensated cirrhosis. Nor should the drug be used by those taking the antibiotic rifampin or the HIV antiretroviral Reyataz (atazanavir), which is included in the combination tablet Evotaz (atazanavir/cobicistat).

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

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