Mavyret approved as 8-week treatment for hep C, compensated cirrhosis

October 1 2019

(HealthDay)—Approval of Mavyret (glecaprevir and pibrentasvir)

tablets has been expanded to eight-week treatment for treatment-naive patients aged 12 years and older with chronic hepatitis C virus (HCV) genotypes 1 through 6 and compensated cirrhosis, the U.S. Food and Drug Administration announced last week.

Mavyret is the first eight-week treatment approved for any treatment-naive HCV patients, regardless of cirrhosis status or treatment type. The drug is now approved for all treatment-naive adult patients and certain pediatric patients (weighing at least 99 pounds) without cirrhosis and with compensated cirrhosis. Standard treatment length for compensated cirrhosis was at least 12 weeks.

Approval was based on clinical trial data from more than 2,500 patients with HCV genotype 1 through 6 infection. Patients received Mavyret for eight, 12, or 16 weeks. Patients included those with HIV coinfection, kidney or liver transplant recipients, and patients with advanced kidney disease. Sustained virologic response with Mavyret at 12 weeks posttreatment ranged from 91 to 100 percent across clinical trials.

The most commonly reported adverse reactions with Mavyret were fatigue and headache. Contraindications include patients with moderate or severe liver impairment or a history of liver decompensation as well as patients taking atazanavir and rifampin.

Approval was granted to AbbVie.

More information: More Information

treatment-hep-compensated.html