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Mercer Government Human Services Consulting

GHSC FLASH

On August 3rd, the Food and Drug Administration (FDA) approved Mavyret™ (mav-EH'-rit), a new product manufactured by Abbvie for the treatment of hepatitis C virus (HCV). Mavyret™ is approved for the treatment of all six major HCV genotypes for both treatment naïve and treatment experienced patients. Mavyret™ is a combination of two new HCV antivirals, glecaprevir and pibrentasvir. An estimated 95% of patients with chronic hepatitis C in the U.S. could be candidates for treatment with Mavyret™. The list price of Mavyret™ is significantly lower than the list price for other HCV antiviral regimens.

INDICATION AND USE

Mavyret™ is indicated for use for adult patients with genotypes 1–6 hepatitis C. For treatment naïve patients without cirrhosis, Mavyret™ is approved for an 8-week regimen. For patients with compensated cirrhosis, a condition in which a patient's liver is damaged but still works fairly well, a 12-week course of Mavyret™ is required.

Some treatment-experienced patients will also be candidates for Mavyret. Depending on the previous treatment used and the genotype of the HCV infection, the Mavyret treatment regimen could be 8, 12, or 16 weeks.

The Mavyret™ regimen consists of three tablets daily, with food, and no ribavirin is required. Mavyret™ is indicated only for patients without cirrhosis or patients with compensated cirrhosis. The drug is not indicated for patients whose disease has progressed to decompensated cirrhosis. Patients with late stage chronic kidney disease can safely use Mavyret™, which is important since sofosbuvir-based regimens such as Harvoni®, Epclusa®, and Vosevi® are not recommended in this population.

In clinical trials, the overall cure rate, as measured by SVR12, was 98% across all patients and ranged between 92% and 100% depending on the specific population treated. Importantly, SVR12 was achieved in 99% of genotype 1 patients who received the 8-week regimen.

PLACE IN THERAPY

Mavyret™ is being marketed as both first line therapy and as an option for patients who have failed on one of the other common antiviral regimens. Mavyret™'s short duration of therapy for treatment naïve patients will make it a desirable treatment choice. Mavyret will compete directly with Harvoni® and Zepatier® for genotype 1 and 4 patients and will compete with Epclusa® for treatment of the other genotypes. In some instances, treatment experienced patients and their providers will have the opportunity to choose between Vosevi® and Mavyret™.

COST

Mavyret™'s list price based on Wholesale Acquisition Cost (WAC) is $13,200 per a 28-day prescription. The list price of an 8-week course of Mavyret™, $26,400, is significantly lower than an 8-week regimen of Harvoni® ($63,000), a 12-week course of Zepatier® ($54,600) or a 12-week course of Epclusa® ($74,760).

Mavyret™ is a game changer in the Hepatitis C market. Its approval for a short 8-week regimen for treatment naïve patients across all genotypes coupled with a list price that is less than half of the competition will position it well for preferred placement on Medicaid fee-for-service (FFS) and managed care formularies. Abbvie representatives have stated publicly that they are focusing on getting coverage approved through the Medicaid, Medicare, and Veterans Administration markets.