Mavyret Is Highly Effective Against Hep C in Those With a Drug-Use History

A pooled analysis of numerous clinical trials and real-world studies reached this conclusion.

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People who currently use drugs or have a history of doing so, including those taking medication-assisted treatment (MAT) to treat opioid use disorder, have a high hepatitis C virus (HCV) cure rate following direct-acting antiviral treatment with Mavyret (glecaprevir/pibrentasvir).

Mavyret is approved to treat all genotypes of HCV and can be used in combination with MAT. The regimen can be completed in as little as eight weeks, including among those with compensated cirrhosis (the milder form of the severe liver disease).

Alessio Aghemo, MD, of Humanitas University and Research Hospital in Rozzano, Italy, presented results from a pooled analysis of clinical trials and real-world studies of Mavyret at The Liver Meeting, the Annual Meeting of the American Association for the Study of Liver Diseases, in Boston this month.

Specifically, the study pooled results from 13 Phase III clinical trials of Mavyret and observational studies of the treatment that are ongoing in nine European nations.

For the clinical trials, drug use was defined as the self-reported injection of street drugs, while in the real-world studies, this definition encompassed use of any street drugs.

Recent drug use was defined as drug use within the past 12 months, a positive urine drug screen (in the clinical trials only) or both prior to an individual's screening for the trial or study in question. Former drug use was defined as self-reported drug use 12 months or more prior to screening and, in the clinical trials, a negative urine drug screen.

The pooled study population included adults with genotypes 1 through 6 of HCV, those who had and had not been treated for the virus previously, and individuals either without cirrhosis or with compensated cirrhosis.

In the real-world studies, participants received 8, 12 or 16 weeks of treatment depending on their HCV genotype, cirrhosis status and prior experience with treatment for the virus.

The analysis included data on 4,645 people. Of this group, 300 (6.5%) reported recent drug use, including 151 in clinical trials and 149 in real-world studies; 1,271 (27.4%) reported former drug use, including 803 in clinical trials and 468 in real-world studies; and 3,074 (66.2) reported no history of drug use, including 1,840 in clinical trials and 1,234 in real-world studies.

A total of 56.5% of the participants were men. The average age was 50 years old. Fifty-two percent of the participants had genotype 1 of HCV, 81.5% were being treated for the first time and 83.9% did not have cirrhosis. A total of 6.3% of those in clinical trials and 10.2% of those in real-world studies were receiving MAT.

Overall, 98.7% of the participants completed treatment. In the clinical trials, this included 96.7% of those reporting recent drug use, 98.6% of those reporting former drug use and 99.0% of those with no history of drug use. In the real-world studies, a respective 97.0%, 98.1% and 99.0% of participants in those three drug-use categories completed treatment. There was no statistically significant difference between the rate of treatment completion among those with recent drug use based on whether they were in the clinical trials or real-world studies, meaning the difference may have been driven by chance. This indicates that people can have a high rate of completion even without the more intensive monitoring and support offered in formal clinical trials.

A total of 98.1% of all participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12), which is considered a cure. Among those reporting recent drug use, 98.0% of those in real-world studies and 93.4% of those in the clinical trials were cured. Among those who formerly used drugs, a respective 97.8% and 96.6% were cured. And among those with no history of drug use, 98.8% in both groups were cured.

The overall higher cure rates seen in the real-world studies, the study authors concluded, was driven by a lower proportion of participants lost to follow-up.

There were no statistically significant differences in cure rates based on sex, nor were there any significant differences in treatment completion rates based on sex, the length of treatment with Mavyret or the use of MAT.

Mavyret was well tolerated, with just 2.5% of the participants experiencing serious adverse health events and 0.6% experiencing adverse health events that led to the discontinuation of treatment. The most common adverse event was headache in the clinical trials (15.0% experienced this) and abnormal weakness or lack of energy in the real-world trials (2.3% experienced this). One person with a history of drug use experienced a health event associated with decompensated cirrhosis (the more severe form of the liver disease).

To read the conference abstract, click here.

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