Mavyret Is Safe for Those With Severely Impaired Kidneys

A recent analysis of two studies of AbbVie's hepatitis C regimen showed good results in this population.

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AbbVie's hepatitis C virus (HCV) regimen Mavyret (glecaprevir/pibrentasvir) is safe and highly effective among those with moderate to severe kidney impairment.

Presenting their findings at the Annual Meeting of the American Association for the Study of Liver Diseases in San Francisco, researchers conducted an integrated efficacy and safety analysis of Mavyret among those with Stages 3b, 4 or 5 of chronic kidney disease (CKD), including those on dialysis, who participated in the Phase III EXPEDITION-4 and EXPEDITION-5 studies.

EXPEDITION-4 was a single-arm, open-label multicenter study of Mavyret among those with genotypes 1 through 6 of hep C and Stages 4 or 5 of CKD. EXPEDITION-5 was an open-label, nonrandomized multicenter study of those with genotypes 1 through 6 of hep C and Stages 3b, 4 or 5 of CKD.

Stage 3b of CKD was defined as an estimate glomerular filtration rate (eGFR) of at least 30 but less than 45 milliliters per minute per 1.73 meters squared. Stage 4 of CKD was defined as an eGFR of at least 15 ml/min/1.73 m^2but less than 30 ml/min/1.73 m^2, and Stage 5 was defined as an eGFR of less than 15 ml/min/1.73 m^2.

All participants in EXPEDITION-4 received 12 weeks of Mavyret. Those in EXPEDITION-5 received eight, 12 or 16 weeks of Mavyret based on their hep C genotype, cirrhosis status and prior experience with hep C treatment.

The new analysis looked at 104 people treated for 12 weeks in EXPEDITION-4, and 84 people treated for eight weeks, 13 people treated for 12 weeks and four people treated for 16 weeks in EXPEDITION-5.

Of the 205 people included in the analysis, 54 percent had genotype 1 of HCV, 21 percent had genotype 2, 13 percent had genotype 3 and 12 percent had genotype 4. One person (less than 1 percent) had genotype 5, and one person had genotype 6 of the virus.

The average age of the participants was 58 years old.

Seventy-eight percent of the participants were on dialysis.

Sixteen percent of the participants had compensated cirrhosis (the milder form of the advanced liver disease) and the remainder did not have cirrhosis.

Four percent of the participants had Stage 3b of CKD, 14 percent had Stage 4 of CKD and 81 percent had Stage 5 of CKD. Forty-one percent had a history of diabetes and 89 percent had a history of cardiovascular disease.

A total of 97.6 percent (200 of 205) of the participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Of the five people (3 percent) who were not cured, none experienced virologic failure. Three people stopped Mavyret treatment prematurely—because of diarrhea, itching and intestinal blockage, respectively.

The cure rate remained high—specifically above 93 percent—among participants regardless of treatment duration, CKD stage, dialysis status and previous hep C treatment experience.

Sixty-three percent of the participants experienced an adverse health event while on treatment, including 18 percent who had serious adverse health events. None of the serious adverse health events was judged related to Mavyret.

None of the participants experienced Grade 3 or higher elevations in their ALT liver enzymes. No one experienced health events indicating that he or she had progressed to decompensated cirrhosis (the more advanced form of the severe liver disease) or had experienced drug-induced liver injury.

The eGFR of the 42 pre-dialysis participants with available data remained unchanged from the beginning of treatment to the end of treatment to four weeks after the end of treatment. The eGFR of the eight people with Stage 3b CKD remained similarly unchanged over time.

The most common adverse health events, experienced by at least 5 percent of participants, included itching (18 percent), fatigue (8 percent), nausea (7 percent), weakness or lack of energy (6 percent) and diarrhea (5 percent).
