Vosevi: The Newest Hepatitis C Treatment on the Block

July 31, 2017 By Lucinda K. Porter RN

The Food and Drug Administration (FDA) recently approved Gilead Sciences' Vosevi, the newest treatment for chronic hepatitis C virus (HCV) infection for people without cirrhosis or with compensated cirrhosis (a milder form of this serious disease). Vosevi (sofosbuvir 400 mg, velpatasvir 100 mg and voxilaprevir 100 mg) is a single tablet regimen approved to retreat genotypes 1 through 6.

What You Need to Know about Vosevi

Gilead Sciences' Vosevi is one pill containing three drugs. All are direct-acting antivirals (DAAs) which means they directly interfere with hepatitis C virus replication. One drug, sofosbuvir (brand name Sovaldi), has been on the market since late 2013. It is a polymerase inhibitor. The second drug is velpatasvir, an NS5A inhibitor. You may recognize velpatasvir, as it was combined with sofosbuvir to form Epclusa. Voxilaprevir is the third drug in the mix, and it is an HCV NS3/4A protease inhibitor.

Here is a brief summary of Vosevi:

Vosevi is a single pill taken daily with food for 12 weeks. It is approved as a retreatment option for adults with genotype 1-6 hepatitis C infection, without cirrhosis or with compensated cirrhosis. Note the following retreatment recommendations:

- Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with a hepatitis C regimen containing an NS5A inhibitor.
- Genotype 1a or 3 infection and have previously been treated with a hepatitis C regimen containing sofosbuvir without an NS5A inhibitor.
- Additional benefit of Vosevi over Epclusa was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.

Warning: Vosevi carries a boxed warning concerning the risk of hepatitis B virus reactivation among those coinfected with HBV and HCV. This warning applies to all direct-acting antiviral treatments for hepatitis C.

Drug Interactions

Vosevi interferes with some other drugs. Let your doctor and pharmacist know all the drugs (prescription and nonprescription) and supplements that you are taking. The most notable drug that may interact with Vosevi is the cardiac drug, amiodarone. Do not take Vosevi with drugs/herbs that are P-gp inducers (e.g., rifampin, St. John's wort). Other drugs may interact with Vosevi, but can still be taken as long as they are taken as instructed. Some examples are acid-reducing drugs, statins, certain anti-seizure medications, and some HIV and TB drugs.

Although some herbs and drugs have the potential to interact with Vosevi, this doesn't mean you can't take drugs that may potentially interact. It usually means that your doctor or pharmacist will advise you on how to space out the timing of your medications. To see if a medication you are taking has the potential to interact with Vosevi, see the prescribing information.

Adverse Events (Side Effects)

The majority of reported side effects were mild. Fatigue, headache, diarrhea, and nausea were the most common.

Pregnancy/breastfeeding Vosevi should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Similarly, the effects of Vosevi on infants whose mothers are breastfeeding are unknown.

How effective is Vosevi? The POLARIS 1 and 4 trials reported efficacy rates of Vosevi of approximately 96 to 97 percent for everyone. Vosevi has a high barrier to drug resistance.

What is the cost of Vosevi? The wholesale acquisition cost is $74,760 for a 12-week course of treatment. This is lower than the initial sticker prices of Sovaldi or Harvoni, and the same price as Gilead's most recently approved hepatitis C treatment regimen, Epclusa. There will likely be discounts to insurance companies and state Medicaid programs as well as assistance to patients.

Will insurance cover Vosevi? My guess is very likely, although it may take a bit of time to get them up to speed. To save money and frustration, I highly recommend working with an experienced provider or a patient assistance program.

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