Epclusa: The Newest Hepatitis C Treatment

June 28, 2016 By Lucinda K. Porter RN

The Food and Drug Administration (FDA) recently approved Gilead Sciences' Epclusa, the newest treatment for chronic hepatitis C virus (HCV) infection. Epclusa (sofosbuvir 400 mg/velpatasvir 100 mg) is the first single tablet regimen approved to treat genotypes 1 through 6. It is also the first single tablet regimen approved for the treatment of patients with genotype 2 and 3 without the need for ribavirin.

It's been nearly two years since the FDA approved Harvoni, Gilead's game changing hep C drug with high cure rates and mild side effects. After Harvoni, the FDA approved Viekira Pak, Zepatier, Daklinza, and Technivie. These drugs were much more affordable than Harvoni, but weren't as easy to take.

Despite the great strides, not everyone was cured. In particular, people with genotype 3 had lower cure rates, longer treatment durations, and were stuck with ribavirin. What we needed was an effective, oral, easy-to-tolerate pan-genotypic drug, (able to cure all the genotypes). Enter in Epclusa.

What You Need to Know about Epclusa

Gilead Sciences' Epclusa is one pill containing two drugs. Both 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.

Here is a brief summary of Epclusa:

- Epclusa is approved for treatment of genotype 1-6 HCV infection in adults.
- It is a single pill taken daily, with or without food.
- Standard treatment for those without cirrhosis or with compensated cirrhosis 12 weeks. Those with decompensated (severe) cirrhosis take Epclusa plus ribavirin for 12 weeks.

Drug Interactions

Epclusa interferes with some other drugs. Let your doctor and pharmacist know all the drugs

(prescription and nonprescription) and supplements that you are taking.

Other drugs that may interact: topotecan (a chemotherapy agnet), amiodarone, antacids and other acid-reducing drugs, certain anti-seizure medications, and some HIV and TB drugs.

Do not take Epclusa with drugs/herbs that are P-gp inducers (e.g., rifampin, St. John's wort).

Although some herbs and drugs have the potential to interact with Epclusa, 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.

Adverse Events (Side Effects) The majority of reported side effects were mild, with fatigue and headache being the most commonly supported. When Epclusa was used with ribavirin in decompensated cirrhotics, the most common adverse events were fatigue, anemia, nausea, headache, insomnia, and diarrhea.

Pregnancy/breastfeeding Epclusa should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. This is big change from ribavirin's dire Black Box warnings of potential fetal damage.

How effective is Epclusa? Epclusa's efficacy rates are excellent with approximately 98 percent for everyone without decompensated cirrhosis and 94 percent when taken with ribavirin among those with decompensated cirrhosis. Epclusa has a high barrier to drug resistance. Here is a link to clinical study data about sofosbuvir/velpatasvir.

What is the cost of Epclusa? The wholesale acquisition cost of twelve weeks is $74,760 for a 12-week course of treatment. This is lower than the sticker prices of Sovaldi or Harvoni. There will likely be discounts to insurance companies and state Medicaid programs as well as financial assistance to patients.

Will insurance cover Epclusa? 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 a patient assistance program.

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