Harvoni: What You Need to Know about the Newest Hepatitis C Treatment

October 10, 2014 By Lucinda K. Porter RN

This is an historic day.The FDA approved *Harvoni*, a drug for chronic hepatitis C virus (HCV) infection with high cure rates and mild side effects. Understandably, patients are anxious to get started on treatment. However, there are things you need to know about Harvoni before you can start.

Gilead Sciences' Harvoni 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 ledipasvir, an NS5A inhibitor.

What You Need to Know

Here is a brief summary of Harvoni. I've provided the prescribing information for those who want to read more.

- Harvoni is approved for treatment of genotype 1 HCV infection in adults.
- Cure rates range from 94% to 99%.
- It is a single pill taken daily, with or without food.
- Patients who have never been treated for HCV, whether they have cirrhosis or not, take Harvoni for 12 weeks.
- Treatment-naÃ¯ve patients without cirrhosis whose pre-treatment viral load (HCV RNA) is less than 6 million IU/mL may be considered for **8 weeks of treatment**. This is about 40% of eligible patients.
- Patients without cirrhosis who have failed treatment with either peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin, take Harvoni for 12 weeks.
- Patients with cirrhosis who have failed treatment with either peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin, take **Harvoni for 24 weeks**.
- Harvoni was not approved for HIV/HCV co-infection despite high cure rates in clinical trials.

Drug Interactions

Harvoni interferes with some other drugs. Let your doctor and pharmacist know all the drugs (prescription and nonprescription) and supplements that you are taking.

- Do not take Harvoni with drugs/herbs that are P-gp inducers (e.g., rifampin, St. John's wort).
- Other drugs that may interact: antacids and other acid-reducing drugs, digoxin, anti-seizure medications, simeprevir (Olysio), rosuvastatin, HIV and TB drugs

Although some herbs and drugs have the potential to interact with Harvoni, 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. Fatigue (13 to 18 %) and headache (11 to 17%) were the most common. Nausea (6 to 9%), diarrhea (3 to 7%), and insomnia (3 to 6%) were also reported. The discontinuation rate due to side effects was very low (0 to 1 %).

Increases in bilirubin, lipase, and creatine kinase were observed.

Here is a huge change: HARVONI 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 Harvoni? Harvoni's efficacy rates are excellent, ranging from 94 to 99%. Harvoni has a high barrier to drug resistance.

Harvoni is expensive.The wholesale acquisition cost of twelve weeks of Harvoni is $94,000, or $1125 a pill. Approximately 40% of patients will have 8 weeks of treatment at the bargain price of $63,000. Patients with cirrhosis who failed prior treatment will need 24 weeks of treatment, with a price tag of $188,000.

Will insurance cover Harvoni? Probably, but not for everyone. My guess is that there will be push back from state Medicaid programs, and some insurers. This past year, more than 30 states instituted stringent preauthorization regulations. For example, some states force patients to qualify for HCV treatment by proving they have cirrhosis.

The other tricky issue is that we are coming to the end of the year, and insurance companies may stall drug approval, hoping to push the problem on to another insurer if it looks like you are changing insurance plans January 2015. Also, be aware of your plan's deductibles and co-pays. If you have to meet a deductible, you will have to meet it again January 1. To save money and frustration, I highly recommend working with Gilead's patient assistance program.

On a personal note, this drug cured me, which I got via a clinical trial. I am grateful to be cured. Although this is a major step forward, we still have a long way to go. We have to deal with the price, the unjust way HCV treatment is granted, stigma, and healthcare inequities. We also have to acquire better treatment options for other genotypes, and reach the millions of people who still have not been diagnosed. Harvoni is a good first step, but it is not a giant leap for humankind.

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