What You Need to Know about the Newest Hepatitis C Drug Sovaldi

December 10, 2013 By Lucinda K. Porter RN

The Food and Drug Administration (FDA) recently approved Gilead Sciences' *Sovaldi* (sofosbuvir). Hepatitis C patients have been waiting for this moment for quite some time. Now that Sovaldi is here, hepatitis C patients are anxious to get started on their treatment. However, there are things you need to know about Sovaldi before you can start.

Interferon is still part of treatment for most patients. Treatment for genotypes 2 and 3 uses Sovaldi plus ribavirin, making it the first interferon-free treatment. As expected, Sovaldi will be used with peginterferon and ribavirin for patients with genotypes 1 and 4.

Patients are disappointed, hoping that treatment would be all-oral for everyone. However, the FDA opened the door for all-oral hepatitis C treatment by sanctioning a broader application of sofosbuvir. In addition to genotype 2 and 3 patients, Sovaldi plus ribavrin may be used for patients with hepatocellular carcinoma (liver cancer) who are waiting for a liver transplant and genotype 1 patients who cannot use interferon.

Sovaldi is expensive. The wholesale acquisition cost of twelve weeks of Sovaldi is $84,000 or $1000 a pill. This does not include the cost of peginterferon, ribavirin, labs, medical costs, and drugs for side effects. Since genotype 3 patients will need 24 weeks of treatment, the cost would be $168,000. A 48-week treatment for hepatocellular carcinoma patients awaiting transplant would be just under a half a million.

Will insurance cover Sovaldi? Who knows. My guess is that they will pay for it, since it is cheaper than the medical costs related to the potential complications of hepatitis C.

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

Sovaldi with ribavirin for the treatment of adults with genotypes 2 or 3

Pros

No peginterferon

Short 12-week treatment duration for genotype 2, with limited exposure to ribavirin/ 24 weeks

of treatment for genotype 3 patients

High cure rate at around 93-95% overall for genotype 2

- Cirrhosis 60-94%
- Hardest to treat (genotype 1, cirrhosis, IL28B non-C/C, high viral load) 71%

Improved cure rate at around 84% overall for genotype 3

- Cirrhosis 60-92%
- Hardest to treat (genotype 1, cirrhosis, IL28B non-C/C, high viral load) 71%

Easier to tolerate side effect profile

Once daily pill

Highest rate of response in Blacks 87% vs. Non-blacks at 91%

Low drug-resistance profile

Fewer known drug interactions than other direct-acting antivirals (Incivek, Victrelis, and Olysio)

Cons

- Ribavirin side effects
- Cost

Sovaldi in combination with peginterferon and ribavirin for adults with genotype 1 or 4

Pros

Short 12-week treatment duration, with limited exposure to peginterferon and ribavirin, which translates into an easier to tolerate side effect profile

High cure rate at around 90% overall

- Genotype 1 89%; genotype 4 96%
- Cirrhosis 80%

- Hardest to treat (genotype 1, cirrhosis, IL28B non-C/C, high viral load) 71%

  Once daily pill

  Highest rate of response in Blacks 87% vs. Non-blacks at 91%

  Low drug-resistance profile

  Fewer known drug interactions than other direct-acting antivirals (Incivek, Victrelis, and Olysio)

Cons

- Peginterferon and ribavirin side effects
- Cost
- Treatment not approved for genotypes 5 or 6 yet

Ten years ago, I endured 48 weeks of difficult treatment and had about a 50/50 chance of clearing hepatitis C. I didn't win that bet. This year, the odds were stacked in my favor. Treatment was much easier, and shorter with only 12 weeks of treatment. And best of all, now I am cure. Despite the price, and the fact that interferon and ribavirin are still part of the hepatitis C treatment regimen, Sovaldi is a game changer.

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