Opening Doors to the Latest Hepatitis C Drugs

February 4, 2014 By Lucinda K. Porter RN

At the end of 2013, the FDA approved two new drugs to treat hepatitis C: Olysio (simeprevir) and Sovaldi (sofosbuvir). Solvadi's approval was especially exciting because it was the first all-oral treatment for hepatitis C. The excitement was tempered by:

- All-oral treatment was approved for the minority of hepatitis C patients, such as those with genotype 2 or 3.
- All-oral hepatitis C treatment still includes ribavirin, a drug with challenging side effects, such as anemia, insomnia, agitation, rashes, and may cause fetal death in pregnant women.
- Solvadi's price tag--the wholesale acquisition cost of twelve weeks of Sovaldi is $84,000 or $1000 a pill.

The FDA unlocked the door for more access to all-oral hepatitis C treatment by approving Sovaldi with ribavirin for patients who cannot use interferon, and those with hepatocellular carcinoma (liver cancer) who are waiting for a liver transplant. However, the price of Sovaldi and to a lesser extent Oysio, is making it difficult for patients to get medical insurance approval for the most effective hepatitis C treatments ever. In short, the door is unlocked but a huge obstacle makes the door difficult to open.

Hepatitis C patients need help to open the door, and this week, we may have gotten some. The American Association for the Study of Liver Diseases and the Infectious Society released Recommendations for Testing, Managing, and Treating Hepatitis C. These guidelines carry huge weight, as many medical providers use this expert advice in their own practices. These guidelines are simply written and public, allowing patients access to the latest advice from leading authorities on hepatitis C.

The Recommendations cover testing, managing and treating hepatitis C. The guidelines are not complete--coming soon are "In Whom and When to Initiate Treatment," Monitoring Patients Who are On or Have Completed Treatment," and "Managing Acute Hepatitis C." However, the information on treating and retreating hepatitis C patients is so compelling, that I want everyone

to see it so they know what the experts are recommending.

I suggest you read the Recommendations to see what applies to your particular profile. However, here are a few points:

- The Recommendations offer all-oral interferon-free alternatives for all genotypes except genotype 5 and 6 hepatitis C patients.
- Solvadi and Olysio are used in combination with other hepatitis C drugs for all genotypes.
- The panel recommended using Solvadi and Olysio together for patients with genotype 1 who are unable to take interferon and for retreatment for certain patients with genotype 1. Ribavirin may or may not be used.
- The panel recommended against using boceprevir (Victrelis) or telaprevir (Incivek).
- Peginterferon plus ribavirin dual therapy is no longer recommended except as an alternative regimen for genotype 5 and 6 hepatitis C patients.

These recommendations are from some of the top experts in the U.S., but the FDA has not approved these. Medical providers are allowed to prescribe any drug that is approved, a process known as off-label. Getting insurance to cover them is an entirely different matter. If you are denied, request an appeal and either give these recommendations to the insurance company, or ask your medical provider's office to. Be persistent, and never give up.

Related Articles or Resources:

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Sovaldi's Support Path

Bloomberg News: *At $84,000 Gilead Hepatitis C Drug Sets Off Payer Revolt*

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