Surprising Updates to the HCV Guidelines

The HCV Guidelines added the combination of Daklinza/Sovaldi for 12 weeks for genotype 3 patients without cirrhosis or 24 weeks with/without ribavirin for those with cirrhosis. What I did not anticipate was that the panel would make off-label recommendations for daclatasvir.

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Last month, the FDA approved two more drugs to treat hepatitis C. Daklinza (daclatasvir) was approved for use with sofosbuvir to treat patients with genotype 3; Technivie (ombitasvir, paritaprevir and ritonavir) was approved for use with ribavirin to treat non-cirrhotic patients with genotype 4.

I assumed that the HCV Guidelines written by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) would reflect these changes. I was not disappointed. The HCV Guidelines added the combination of Daklinza/Sovaldi for 12 weeks for genotype 3 patients without cirrhosis or 24 weeks with/without ribavirin for those with cirrhosis.

What I did not anticipate was that the panel would make *off-label* recommendations for daclatasvir. Off-label use allows physicians to prescribe approved drugs according to their clinical judgment, regardless of the indication the FDA has approved for the drug.

Let's look at recommendations for **genotype 1** patients who have never been treated for hepatitis C before. Prior to the approval of Daklinza, the guidelines recommended 3 treatment regimens:

- Harvoni
- Olysio/Sovaldi
- Viekira Pak

These may be used with/without ribavirin and the treatment lengths varied, depending on it, the patient had various factors, such as cirrhosis.

Daklinza/Sovaldi were added to the guidelines. You read that correctly - I am still talking about genotype 1 treatments.

The HCV Guidelines also recommended Daklinza/Sovaldi to treat treatment-naÃ¨ve **genotype 2**

patients who can’t take ribavirin. (Which in my mind is nearly everyone, because why should anyone take ribavirin if they didn’t have to.)

This all sounds so promising, except for one little problem. Actually, one big problem--the insurance industry. If people are having a hard time getting approval for a single expensive drug such as Harvoni, then why would an insurance company approve a combination that would cost them even more?

Quoting wholesale acquisition costs, $1125 a pill for Harvoni, a 12-week course of hepatitis C treatment would amount to $94,500. The wholesale acquisition cost of twelve weeks of Daklinza is $63,000. That would practically be a bargain if it could be prescribed without Sovaldi, which it can’t. Sovaldi costs $84,000 for a twelve-week course, so with Daklinza the total is $147,000.

Insurance companies are slow to approve off-label prescriptions, especially expensive ones. The likelihood of getting insurance approval for Daklinza/Sovaldi for genotype 1 or 2 seems low. However, maybe insurance companies will think Harvoni is a bargain now that there is a $147,000 treatment. Or am I just being delusional?

HepMag.com has an easy to use table summarizing the latest HCV Guidelines.

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