FDA Approved Two New Hepatitis C Drugs for Genotypes 3 and 4

August 3, 2015 By Lucinda K. Porter RN

A mere two weeks ago, I wrote, "*In 1997, there was one hepatitis C treatment - interferon. Eventually, ribavirin was approved, and until 2011, I only had to remember the brand names of these two medications. In short, hepatitis C treatment didn't change much. Then came all the "virs" - boceprevir (Victrelis), telaprevir (Incivek), simeprevir (Olysio), sofosbuvir (Sovaldi), and ledipisvir (when combined with sofosbuvir = Harvoni). Ombitasvir, paritaprevir, ritonavir and dasabuvir (Viekira Pak, aka PrOD) caused my brain to explode, and we are just getting started*."
Four days after I wrote that, the FDA approved two more drugs to treat hepatitis C, plus added a new "vir" to the arsenal:

- Daklinza (daclatasvir) for use with sofosbuvir to treat patients with genotype 3
- Technivie (ombitasvir, paritaprevir and ritonavir) for use with ribavirin to treat non-cirrhotic patients with genotype 4. Basically, Technivie is Viekira Pak without the dasabuvir.

Here is a brief summary of each:

Daklinza

- Daklinza is used with Sovaldi (sofosbuvir) to treat hepatitis C virus genotype 3
- It is the first drug approved for genotype 3 that does not use either peginterferon or ribavirin
- Treatment involves taking one Daklinza and one Sovaldi daily for 12 weeks
- Daklinza is an NS5A inhibitor
- Daklinza is marketed by Bristol-Myers Squibb (BMS); Sovaldi is a Gilead product

Warnings: Co-administration of amiodarone with Daklinza in combination with Sovaldi is not recommended.
Adverse Events (Side Effects): The majority of reported side effects were mild, with no discontinuations due to adverse events. The most common side effects were headache (14%), fatigue (14%), nausea (8%) and diarrhea (5%).
Interactions: Daklinza is contraindicated in combination with drugs that strongly induce CYP3A, such as phenytoin, carbamazepine, rifampin, St. John's wort

Efficacy: The ALLY-3 clinical trial enrolled 152 patients with genotype 3 and compensated liver disease (101 treatment-naÃ¨ve patients and 51 treatment-experienced patients). The endpoints were sustained virologic response rates 12 weeks after completing therapy (SVR12) in each treatment group.

- Treatment-naÃ¨ve patients had 90% SVR12 rates
- Treatment-experienced had 86% SVR12 rates
- Genotype 3 patients without cirrhosis, regardless of treatment history had 96% SVR12 rates
- Patients with cirrhosis had 63% SVR12 rates

Pregnancy and Breastfeeding: The safety of Daklinza during pregnancy or breastfeeding has not been established. Consider the benefits and risks of Daklinza when prescribing to a pregnant or nursing woman.
Cost: 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. That is $1750 per day for two pills.
Will insurance cover Daklinza? I assume so, but I also assume that there will be the usual hurdles, denials, and nightmares that patients experience trying to get other costly hepatitis C medicines.
Patient Support and Assistance: Bristol-Myers Squibb's Patient Support Connect Program
(844) 44-CONNECT (844-442-6663)
Technivie

- Technivie (ombitasvir, paritaprevir and ritonavir) is used with ribavirin to treat noncirrhotic patients with genotype 4
- Technivie is taken once daily with a meal, and co-administered with twice-daily ribavirin, also taken with food. Treatment is for 12 weeks
- Ombitasvir is an HCV NS5A inhibitor. Paritaprevir is an HCV NS3/4A protease inhibitor. Ritonavir is a CYP3A4 inhibitor
- Technivie is marketed by AbbVie

Warnings: People who have severe liver problems (decompensated cirrhosis) should not take Technivie
Adverse Events (Side Effects): There were no discontinuations due to adverse events. When taken with ribavirin, the most common side effects were weakness (25-29%), fatigue (7-15%), nausea (9-14%), and insomnia (5-13%).
Interactions: Technivie is not recommended for patients who take certain medicines, such as those containing ethinyl estradiol (contraceptives). Technivie may interact with drugs such as Sustiva (efavirenz), Dilantin (phenytoin), phenobarbital, rifampin, St. John's wort, and more.
Efficacy: The PEARL-I clinical trial enrolled 42 treatment-naive and 49 treatment-experienced participants without cirrhosis with 100% SVR12 rates. Another 44 treatment-naive participants took Technivie without ribavirin. Forty of them (91 %) were cured.
Pregnancy and Breastfeeding: The safety of Technivie during pregnancy or breastfeeding has not been established. Consider the benefits and risks of Technivie when prescribing to a pregnant or nursing

woman.
Cost: The wholesale acquisition cost of twelve weeks of Technivie is $76,653.
Will insurance cover Technivie? Probably, especially since it is priced below Harvoni.
