AbbVie’s Viekira Pak: What You Need to Know about the Newest Hepatitis C Treatment

December 22, 2014 By Lucinda K. Porter RN

It is official. There are now multiple medications to treat hepatitis C (Harvoni, Olysio, Sovaldi). The newest is AbbVie’s Viekira Pak, which contains three new drugs--ombitasvir, paritaprevir and dasabuvir, along with a previously approved drug, ritonavir. Ombitasvir, paritaprevir and dasabuvir are *direct-acting antivirals* (DAAs) which means they directly interfere with hepatitis C virus replication.Ombitasvir is an NS5A inhibitor,paritaprevir is an NS3/4A protease inhibitor, anddasabuvir is a non-nucleoside NS5B palm polymerase inhibitor. In short, they interfere with hepatitis C growth in three different ways.Ritonavir is a CYP3A inhibitor and it boosts the blood levels ofparitaprevir.

What You Need to Know

Here is a brief summary of Viekira Pak. For those who want more information, see the prescribing information.

Viekira Pak is approved for treatment of adults with genotype 1 HCV infection, including those with compensated cirrhosis. It is not recommended for patients who have decompensated cirrhosis, which is very advanced liver damage.

Viekira Pak is be used with or without ribavirin, depending on genotype and presence of cirrhosis.

Dosing

Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily (in the morning) + **one** dasabuvir 250 mg tablet twice daily (morning and evening) with a meal without regard to fat or calorie content.

If ribavirin is prescribed, then take the prescribed dose, usually 1000 mg - 1200 mg (weight-dependent). The dose is divided and taken twice daily with food. A daily dose of 1200 mg = 6 pills, which means taking three pills, two times daily.

- Genotype 1b, no cirrhosis - Take Viekira Pak for 12 weeks
- Genotype 1b, cirrhosis - Take Viekira Pak + ribavirin for 12 weeks
- Genotype 1a, no cirrhosis - Take Viekira Pak + ribavirin for 12 weeks
- Genotype 1a, cirrhosis - Take Viekira Pak + ribavirin for 24 weeks
- HCV/HIV coinfection - follow above dose

- Liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score â¤2), the recommended duration of Viekira Pak with ribavirin is 24 weeks.

Drug Interactions

Viekira Pak interacts with multiple drugs and supplements. A partial list includes:

- anti-seizure medications
- buprenorphine/naloxone
- cardiac drugs
- ethinyl estradiol-containing contraceptives
- HIV antivirals
- immunosuppressants
- Lovastatin
- omeprazole
- oral midazolam (Versad)
- Rifampin,
- St. John's wort

(See Prescribing Information for the full list)
Let your doctor and pharmacist know all the drugs (prescription and nonprescription) and supplements that you are taking. Potential drug-drug interaction does not 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. You may need to be closely monitored.
Women: Discontinue ethinyl estradiol-containing medications such as combined oral contraceptives, contraceptive patches or contraceptive vaginal rings prior to starting Viekira Pak. Alternative contraceptive methods are recommended.
Warning: Ribavirin causes birth defects in animals, so it cannot be used by women who are pregnant or by the male partners of women who are pregnant. This also applies to those who are trying to get pregnant. Use extreme care to avoid pregnancy while taking the drug. As a result, men and women who are having intercourse must use two forms of birth control during HCV treatment and for the next six months afterward, since ribavirin can remain in the bloodstream after people stop taking it.
HCV/HIV-1 co-infected patients treated with Viekira Pak should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance.
Adverse Events (Side Effects)
The majority of reported side effects were mild. Two percent of subjects experienced a serious adverse event (SAE). The proportion of subjects who permanently discontinued treatment due to adverse reactions was less than 1%.
The most common adverse reactions reported for Viekira Pak + ribavirin: fatigue (34%), nausea (22%),

pruritus (itching 18%), other skin reactions (16%), insomnia (14%), and asthenia (weakness 14%)
In subjects receiving Viekira Pak without ribavirin, the most commonly reported adverse reactions (greater than or equal to 5% of subjects) were nausea, pruritus and insomnia.

Lab Abnormalities

All patients should have hepatic lab testing during the first four weeks of treatment. Approximately 1% of those taking Viekira Pak had post-baseline serum ALT levels greater than five times the upper limit of normal (ULN) after starting treatment. The incidence increased to 25% among women taking a concomitant ethinyl estradiol containing medication.

Post-baseline elevations in bilirubin at least twice ULN were observed in 15% of subjects receiving Viekira Pak with ribavirin compared to 2% in those receiving Viekira Pak alone.

Hemoglobin levels in subjects treated with Viekira Pak in combination with ribavirin dropped an average of 2.4 g/dL. Decreases in hemoglobin levels occurred early in treatment (Week 1-2) with further reductions through Week 3. Less than 1% of subjects treated with ribavirin had hemoglobin levels decrease to less than 8.0 g/dL during treatment. Seven percent of subjects treated with Viekira Pak + with ribavirin underwent a ribavirin dose reduction due to a decrease in hemoglobin levels; three subjects received a blood transfusion and five required erythropoietin. One patient discontinued therapy due to anemia. No subjects treated with Viekira Pak alone had a hemoglobin level less than 10 g/dL.

How effective is Viekira Pak? Viekira Pak is highly effective, especially for those with genotype 1b.

- Genotype 1b, no cirrhosis - 100%
- Genotype 1b, cirrhosis - 99%
- Genotype 1a, no cirrhosis - 96% to 97% (prior experience with peginterferon treatment 94% to 100%)
- Genotype 1a, cirrhosis - 95%
- HCV/HIV coinfection: genotype 1b - 100%; genotype 1a - 91%
- Liver transplant recipients: genotype 1b - 100%; genotype 1a - 97%

Of those who achieved SVR12, 99% maintained their response through 48 weeks post-treatment

What does Viekira Pak cost? The wholesale acquisition cost of twelve weeks of Viekira Pak is $83,320, plus the cost of ribavirin (around $2500 for 12 weeks). Patients needing 24 weeks of treatment, with a price tag of $167,640 plus the cost of ribavirin (around $5000 for 12 weeks).

Will insurance cover Viekira Pak? Probably, but not for everyone. My guess is that because the price of Viekira Pak is high, we will see the same push back from state Medicaid programs and insurers that are occurring with Harvoni and Sovaldi.

AbbVie launched a patient support program, called the proCeed program at www.viekira.com or by calling 1-844-2-PROCEED.
