Tips for Getting Hepatitis C Medications

July 13, 2015 By Lucinda K. Porter RN

On July 1, 2015, Gilead announced significant changes to their hepatitis C patient assistance program. These changes affect patients who need affordable access to Sovaldi (sofosbuvir) and/or Harvoni (ledipasvir/sofosbuvir). Here are the main highlights:

"Patients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:

- *Fibrosis score restrictions*
- *Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)*
- *Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy*
- *Step-therapy requirements*
- *Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)*"

The bottom line: If your insurance company denies treatment to you, and you are unable to win an appeal, Gilead will not override that decision by providing Sovaldi or Harvoni. Gilead will continue to provide the Sovaldi and Harvoni Co-pay Coupon Program, which minimizes monthly out-of-pocket costs for eligible patients to as little as $5 per month and the Support Path Patient Assistance Program, which will provide Sovaldi or Harvoni at no charge for eligible patients.
I am deeply disturbed by these changes, but today I am not going to use this blog to criticize Gilead or insurance payers. Regular readers can probably figure out my opinions. The real issue is what to do about this...

Tips for Getting Hepatitis C Medications

- When possible, try to work with a physician or nurse practitioner who has experience with getting drug approvals. If I drive an hour to Sacramento, I will have a better chance of getting medication than if I work with the GI group in my small town.
- Be sure your medical provider has the latest HCV Guidelines so he/she can argue your case with the most current evidence.

- Work with a patient assistance program. *HepMag.com* has a list. My current favorite is the Patient Advocate Foundation's Hepatitis C CareLine. They will also work with your medical provider, so it is worth mentioning to your doctor that the CareLine offers case management services.
- If you don't have cirrhosis, consider Viekira, especially if you have genotype 1b which doesn't need ribavirin. AbbVie has negotiated more affordable medication with insurers.
- Keep trying. On July 1, some states loosened their hepatitis C treatment requirements. For instance, California's Medi-Cal program now treats women of childbearing years who may want to get pregnant, regardless of fibrosis stage. They also will treat fibrosis level stage 2 and a myriad of other situations. Also, some insurance companies are relaxing their protocols in order to avoid lawsuits, which are now emerging.
- Wait. Merck is bringing out their hepatitis C treatments fairly soon, and if the competition may drive the price down on all the drugs.
- I can't believe I am going to say this, but I am: consider purchasing generic medication from another country. For more information about how to do this safely and legitimately, read the blog by Greg Jeffreys. Note that generic Harvoni is not yet available.
- **Don't despair. Despair serves no one.** It will steal all the life out of you and will not help you get your hepatitis C medications. The "system" may deny your hepatitis C treatment, but don't let them also have your precious joy.

Here is the letter from Gilead in its entirety:
July 1, 2015
Gilead has always been an advocate for patient access to therapies in the areas in which we work. I am writing to provide you with an update regarding Support Path, our patient support program for individuals living with chronic hepatitis C.

As you may be aware, Support Path is designed to help patients in the U.S. with high co- pays or who lack adequate insurance access Sovaldi or Harvoni. The Support Path program provides assistance to patients who are uninsured or who need financial assistance to pay for the medicine.

Key components of the program include:
In the interest of facilitating patient access in the period immediately following the launch of Sovaldi and Harvoni, the Gilead Patient Assistance Program (PAP) made these medications available to virtually all patients who met financial and other program requirements. Gilead also implemented significant discounts for its HCV therapies across different payer groups. While many payers responded to these

discounts by opening access broadly, some payers have continued to restrict access despite the discounts.

As a result, our PAP criteria enabled continued restrictions by some payers by providing a generous route for them to deny access and refer patients they have chosen not to cover. While we have approved many of these patients in the past, we feel it is necessary to establish more specific guidelines for patient eligibility. Our PAP was designed to help uninsured patients with the most need, and changes are necessary to remain true to that mission. We believe these changes also will help increase access among those payers who continue to restrict access.

With that in mind, effective July 1, 2015, the following changes will be implemented. Gilead anticipates these changes will not impact the majority of patients helped by our patient support programs.

Specifically, patients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:
â¢ Fibrosis score restrictions
â¢ Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)
â¢ Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy
â¢ Step-therapy requirements
â¢ Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)

It is important to note that a very small number of patients fall into this category. Support Path experts will continue to treat each patient case individually and consider a number of variables when assessing patients for our free drug program.
â¢ The Sovaldi and Harvoni Co-pay Coupon Program, which minimizes monthly out-of-pocket costs for eligible patients to as little as $5 per month*
â¢ The Support Path Patient Assistance Program, which will provide Sovaldi or Harvoni at no charge for eligible patients

You are not eligible if you are enrolled in a government healthcare prescription drug program such as Medicaid or Medicare Part D.

For Sovaldi and Harvoni patients who are insured and have been denied coverage by their payer, Support Path can assist patients with the requirements for submitting appeals, peer reviews and understanding the process for in-person hearings if required.

Gilead continues to support open access to hepatitis C therapies - with prescribing decisions made by a physician in partnership with his or her patient. We will continue to work with payers to provide information that conveys the profile of our hepatitis C medications and the benefit of curing individuals living with the virus. We believe that payers should take the responsibility to provide coverage for their insured patients based on the treatment decisions of their healthcare providers.

Through Gilead's Support Path Program, which provides a comprehensive suite of patient assistance resources, we are committed to our mission of helping patients in financial need access our products, and to ensuring our patient assistance program reaches eligible uninsured patients.

As always, we appreciate the ongoing dialogue with our community partners and look forward to continuing to collaborate with you on efforts to expand access to life-saving therapies.

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