

ADVANCES IN HEPATOLOGY

Current Developments in the Treatment of Hepatitis and Hepatobiliary Disease

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Roadblocks to Accessing Direct-Acting Antiviral Agents for Treatment of Hepatitis C Virus Infection



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G&H What are the major roadblocks to accessing the recently approved direct-acting antiviral agents for treatment of hepatitis C virus infection?

DB Recently, 2 new medications were approved for the treatment of hepatitis C virus infection: Harvoni (Gilead), which combines ledipasvir and sofosbuvir, and Viekira Pak (AbbVie), which combines ombitasvir, paritaprevir, and ritonavir in 1 tablet, plus a tablet of dasabuvir. Both of these drugs are highly effective for patients with genotype 1 hepatitis C virus infection, which accounts for approximately 75% of hepatitis C virus cases in the United States.

However, despite the efficacy of these drugs, not all patients can access them. One of the major barriers separating patients from these medications is the pharmacy benefit management (PBM) companies hired by insurance companies to process and pay for prescription drugs. The indications for these hepatitis C virus drugs that are listed on insurance company formularies do not necessarily coincide with the indications approved by the US Food and Drug Administration (FDA). These commercial enterprises are restricting access by creating their own rules for treatment.

G&H What is the relationship between PBM companies and insurers?

DB An insurance company hires a PBM company to determine the criteria for providing a certain medication. Patients are often unaware of the existence of the PBM company; patients are usually under the impression that

they purchased insurance and that the insurer covers the needed medication. However, for many medications, the prescriber has to submit a request for preauthorization from the PBM company in order for the patient's insurance to provide coverage.

G&H What problems are being caused by restrictions in access to direct-acting antiviral drugs?

DB Many PBM companies are entering into agreements with pharmaceutical companies, leading to restrictions on which direct-acting antiviral (DAA) agent will be covered by the insurer. The problem with this restriction is that it is not always clear at the outset which DAA agent might be best for a particular patient. The result is extra work for the health care provider and a potential delay in getting patients the medication that they need. This approach means that doctors, in many cases, can no longer decide what medications are best for their patients. That decision is being made by someone who does not know the patient and is not directly caring for the patient.

G&H Do you think that the financial bottom line is guiding these decisions?

DB Absolutely. All of the available DAA agents are effective, and their efficacy is approximately equivalent. There may be certain clinical scenarios that dictate the use of one drug combination over another. However, the cost factor is limiting access.

G&H Could you give an example of the criteria being used to determine access?

DB Many companies will pay for the medications only if the patient has bridging fibrosis or cirrhosis. The FDA did not approve the medications with these restrictions; rather, the FDA approved these medications for all hepatitis C virus patients, regardless of the degree of fibrosis. In addition, studies show that treating patients with less advanced disease is not only cost-effective but also improves all-cause mortality at 5 years among patients with hepatitis C virus infection.

G&H How has this approach been justified when it is at odds with the medical evidence and FDA indication?

DB One argument in favor of these restrictions is that if all patients were treated, the cost to the health care system would be too high. However, this argument does not reflect reality because not all patients will be treated at the same time or even in the same year. Yes, the costs will be high in the next few years, but the greater-than-90% cure rates and long-term health gains surely justify the expense.

These treatments are the results of decades of research, and patients have been hearing about their impending arrival for a long time. These medications were curative in more than 90% of clinical trial patients. Now patients are being denied access to potentially lifesaving drugs. We have the tools to treat our patients, but we cannot access them.

G&H Is the pricing of these drugs also a roadblock to patient access?

DB We have heard many reports about the high price of these drugs. However, no one really knows the actual cost of these medications. The prices are high, but what is actually paid for one of these drugs is different from the price tag that we hear about. There are discounts and rebates that physicians and patients do not know about. We hear that the full duration of treatment costs \$100,000, but the actual price may be 30% to 40% less. We do not have transparency. At the same time, it is hard to understand why the price cannot be lowered and why access cannot be expanded. Restricting access creates a disincentive to the lowering of prices. All of these different components of pharmaceuticals are interdependent. Patients are hurt by these factors because they are denied care for reasons that are not of their own making.

G&H Has the American Association for the Study of Liver Diseases taken a stance about access to DAA agents?

DB Yes. The American Association for the Study of Liver Diseases (AASLD) wrote a guidance document for the treatment of hepatitis C virus infection recommending that all patients receive treatment and that patients with bridging fibrosis or cirrhosis be made a priority. Unfortunately, many payors ignored the first statement and misinterpreted the second statement to mean that they will only provide treatment to those with advanced fibrosis and cirrhosis. To the best of my knowledge, it is the position of the AASLD that all patients with hepatitis C virus be given the opportunity to have their disease treated.

G&H Do you treat patients who are not able to access these medications?

DB Absolutely. This scenario is extremely common. With hepatitis C virus infection, there is a difference between symptoms and the degree of disease seen on biopsy. A person may have mild disease but be very symptomatic, experiencing fatigue, an inability to concentrate, and generally feeling unwell. These patients need treatment of their symptoms as well as treatment of their disease, but they are often unable to access treatment with the new DAA agents.

I run a division of liver disease that includes many patients with hepatitis C virus infection, and the health care providers in the division see this situation almost every day. For the past several years, we have been telling patients about the new drugs that are coming. Now we are telling patients that these drugs are available and we think they should have these drugs, but their insurance company is not going to pay for them.

The usual process is that we submit a request for the medication, and the request is either approved or denied. If it is denied, then we submit an appeal, which also may be denied. If that occurs, we submit a second appeal and try to speak to someone at the insurance company, and sometimes we are able to get the treatment approved. This process can take 6 to 8 weeks and requires time and effort that most health care providers do not have because they work at busy practices.

G&H Could you give an example of a specific patient in this situation?

DB Sure. A 55-year-old man came to see me for a screening colonoscopy. He was offered a hepatitis C virus screening test per the law in New York State. The patient was otherwise healthy but tested positive for hepatitis C virus infection. He had F2 disease (ie, only a moderate degree of fibrosis), which is not enough to warrant treatment according to the policies of many insurance companies. His wife was concerned about transmission through sex and through living in the same household. So now we have

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the scenario of a person being diagnosed with a disease that is curable, but he cannot be treated because he is “not sick enough” according to his insurance provider. The new diagnosis introduced a stressful element into his home, leading to issues with his spouse, and he and his wife do not understand why he cannot obtain the necessary treatment. He said to me, “I was better off not knowing.”

G&H Are you doing anything to try to improve access?

DB Yes. I have been trying to reach out to elected officials and any other influential people who may be able to help fight this battle. I have spoken with individuals at pharmaceutical companies and with medical directors at various insurance companies.

G&H Have you made any progress in enabling better access?

DB The medical directors cannot or will not change their policies. Sometimes a decision for an individual patient may be changed, but the written policy of what is covered is not readily changed. Therefore, the likelihood that a patient will be able to obtain these medications depends on the doctor that he or she is seeing and the insurance provider that he or she has.

G&H Are advocacy groups trying to change the situation?

DB Yes, but these efforts must be done regionally because each payor determines criteria by state. There are no national organizations fighting for access, which is problematic. Many grassroots efforts are ongoing, and some headway is being made here and there, but in many places no headway is being made at all. Therefore, whether or not a patient can access treatment may depend not only on his or her disease status but also on his or her zip code.

Dr Bernstein receives research funding from and is a consultant for AbbVie, BMS, Janssen, Merck, and Gilead. He is also on the speakers bureaus of Merck, Gilead, and AbbVie.

Suggested Reading

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