Improving Patient Access to Hepatitis C Cures

A White Paper from the Hepatitis Therapy Access Physicians Working Group

Hepatitis Therapy Access Physicians Working Group

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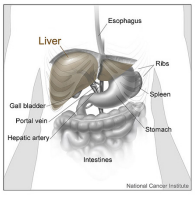
As many as 5 million Americans are infected with hepatitis C, a virus that is slowly wreaking havoc on their livers and may eventually kill them. Breakthrough medications that cure the disease are now available, but they come with a high price tag and are unaffordable for many. Complex insurance and governmental program requirements effectively ration the drugs—a move that states, employers, and insurers argue is necessary because they simply cannot afford the medications for everyone who needs them. Yet this practice may require some patients to suffer unnecessarily, while their physicians know that they could be cured with these new medications.

Background on Hepatitis

Hepatitis has several causes, but is often due to infection with one of three main hepatitis viruses known as types A, B, and C. Symptoms of infection are similar and include nausea, tiredness, abdominal pain, and jaundice (a yellowing of the skin and whites of the eyes).[1] Initially, many people with these viruses experience only mild symptoms or even no symptoms at all.

Of the three hepatitis viruses that are common in the US, type C is particularly harmful. The body usually cannot rid itself of hepatitis C without treatment. As a result, the virus remains active for many years, often unbeknownst to the individual. Over the years, the hepatitis C virus progressively damages the liver and increases the risk of various cancers, diabetes, vascular disease, nerve damage, and kidney damage, in addition to reducing quality of life. Eventually, chronic inflammation in the liver can lead to scarring or fibrosis that interferes with liver function. If fibrosis proceeds without treatment, it can lead to cirrhosis, at which point the liver is so scarred that the damage may not be reversible. Cirrhosis is associated with liver cancer and liver failure—both of which are life threatening.[2] In fact, the hepatitis C virus is the leading cause of both liver cancer and the need for liver transplantation in the US.

Progression of Chronic Hepatitis C Infection



→ **Inflammation** → **Scarring (fibrosis)** → **Cirrhosis** (healing no longer possible) → **Death**

75% of people infected with hepatitis C virus will develop chronic disease

20% of people who develop chronic disease will die due to end-stage liver disease or liver cancer

Information from Centers for Disease Control and Prevention. Liver graphic credit National Cancer Institute and Don Bliss.

Hepatitis C affects between 3 and 5 million people in the United States, most of whom do not know they have the disease.[3,4] Adults born between 1945 and 1965 are at highest risk. Individuals in this group are five times more likely to have hepatitis C than adults of other age groups and account for 75% of those with chronic infection.[1] Due to the high infection rate in this group, the number of Americans who die annually from complications related to hepatitis C is expected to triple over the next 10 years, reaching 45,000 or more.[5]

Groups at Increased Risk for Hepatitis C

- Those born between 1945 and 1965
- Those who have ever injected drugs
- Prison inmates
- Those with HIV infection
- Patients undergoing blood filtration for kidney failure
- Children born to mothers with hepatitis C
- Patients with elevated liver tests

Indeed, it is now estimated that more patients in the US die each year from hepatitis C than HIV (human immunodeficiency virus).[6] Although the risk of death is highest when hepatitis C is associated with advanced liver disease, it is unclear whether it is safe for patients to wait for treatment until their liver disease becomes advanced. Also, the chronic inflammation associated with hepatitis C is a risk factor for non-liver related deaths due to stroke.[7] In fact, patients with hepatitis C are at a significantly increased risk of death due to numerous non-liver diseases.[8]

Healthcare Costs of Hepatitis C Infection

Between the years 2001 and 2010, patients with hepatitis C accounted for more than 2.3 million outpatient visits, 73,000 emergency department visits, and 475,000 hospitalizations annually.[9] These hospitalizations and treatments add up to extraordinarily high costs. In 2011, overall costs associated with hepatitis C infection were estimated at $6.5 billion, with most of the outlay due to advanced liver diseases such as cirrhosis and liver cancer.[10] Moreover, hepatitis C is associated with problems in other organs and body systems besides the liver, including diabetes, lymphoma (type of cancer), and diseases of the kidney and vasculature (blood system), as well as decreased quality of life and increased risk of death due to any cause. The exact costs of these health conditions are unknown, but likely add another $1.7 billion annually.[11]

Costs associated with hepatitis C are expected to increase until 2025 because of the large number of baby boomers who are already infected and will experience advanced liver disease. The annual medical costs associated with hepatitis C are expected to peak at $9.1 billion in 2024, with cirrhosis accounting for more than $4.2 billion and liver cancer for $1.4 billion.[10] When indirect costs such as premature death and disability are included, the sum rises to more than $100 billion annually.[12,13]

"Most of my patients with hepatitis C want to be cured of their viral infection. Married or single, each person is concerned about infecting partners or household contacts. Many couples are eager to start a family, and have concerns about how hepatitis C would affect their babies. My patients don't want to wait until they have advanced liver disease to be cured of hepatitis C, and many have not responded or failed treatment due to side effects of the older treatments."

Robert G. Gish, MD

Treatments for Hepatitis C Infection

Since 1990, injectable biological proteins known as interferons have been used to treat hepatitis C. A major advance occurred in 2001 with the development of a long-acting interferon that could be injected weekly rather than daily or three times weekly.[14] Long-acting interferons combined with a medication known as ribavirin cure approximately 30% to 75% of patients with hepatitis C depending on the disease severity and subtype.[15,16] Although these medications mark an important step forward in the treatment of hepatitis C, they are still ineffective for a substantial portion of patients, and many others are unable to tolerate them. Moreover, these two medications are often associated with significant and, in rare cases, fatal side effects.[17] In fact, about 20% of patients stop taking these medications before they are cured because of side effects[18,19]; another 20-30% require dose changes.[19]

Beginning in 2013, a series of new medications called direct-acting antivirals dramatically changed the playing field for patients with chronic hepatitis C. These medications are truly breakthrough therapies on several levels: not only do they cure 90-99% of patients with the most frequent subtype of hepatitis C, but they are also usually well tolerated and can be taken orally as pills instead of injected.[20-23] Even patients who do not respond to interferon-based treatments can be cured with the new medications.[22] Patients additionally report improved quality of life and increased work productivity.[24] As of 2015, direct-acting antivirals have replaced interferons as the standard of care for nearly all patients with hepatitis C viral infection.[25]

Challenges with Patient Access to Hepatitis C Medications

The new direct-acting antivirals for hepatitis C are unquestionably medical breakthroughs and have decreased the cost per cure,[28] but they are still extremely expensive. States, employers, and insurers argue that they simply cannot afford the medications for everyone who needs them, so they've created a variety of coverage barriers that effectively ration the medications. This means that many people with hepatitis C may not get access to a therapy that could cure their disease.

Extensive Prior Authorization Processes

Some insurers and state Medicaid systems have developed extensive prior authorization requirements that limit the number of patients who qualify for the newest hepatitis C cures. One of the most stringent examples is the state of Illinois, which requires a 17-point prior authorization process for Medicaid patients to obtain these medications.[30]

Medication for Only the "Sickest" Patients

In many states, prior authorization requirements limit medication access to patients with stage 3 or 4 liver fibrosis, whereas others such as Illinois

Comparison of Interferon-Based and Direct-Acting Antiviral (Interferon Free) Therapies for Hepatitis C[12,16,17,26,27]

	Pegylated interferon + ribavirin	**Direct-acting antivirals** (interferon free, with or without ribavirin)
Cure rate[a]	30-75% (varies based on genotype)	90-99% (genotype 1)
Administration	Peg-interferon: injection once per week Ribavirin: pills twice daily	Pills once or twice daily[b]
Adverse events	Common; in rare cases, fatal	Much less common

[a]Defined as sustained virilogic response for 12 weeks
[b]Recommended doses and regimens vary for the available medications. See prescribing information for description.[26,27]

require patients to have stage 4 fibrosis (cirrhosis).[30] Some physicians question the ethics of making patients wait until their livers are highly or irreversibly damaged before they can obtain the needed medication. Moreover, patients whose disease is treated in the early stages are more likely to be cured.[31]

Access to Fibrosis Scans

As part of the prior authorization process, some insurers require patients to obtain specialized liver fibrosis scans to document the extent of disease.[32] However, such scans are not available in many healthcare settings, particularly for patients who do not live close to large medical centers and cannot afford to travel. Patients who cannot access scans because of logistical challenges may therefore be unable to access the newest hepatitis C antivirals.

No Substance Abuse Diagnosis or Treatment

In Illinois, prior authorization requirements stipulate that patients who have been diagnosed or treated for substance abuse in the past 12 months are ineligible for the newer direct-acting antivirals.[30] Given that needle sharing is a primary mode of hepatitis C transmission, this requirement excludes many patients, including those who are currently undergoing substance abuse treatment. Yet the requirement can prove counterproductive; patients should be rewarded, not punished, for seeking substance abuse treatment.

No Malignancy

Prior authorization requirements in Illinois also state that patients must not have had malignancy (cancer) within the last year. The plan makes exceptions for patients with liver cancer only if they have been pre-approved for a liver transplant. Neither of the two newest direct-acting antiviral medications for hepatitis C includes malignancy as a contraindication in the FDA-approved prescribing information,[26,27] so the basis for this requirement is unclear.

In some cases, this requirement may make sense. Based on the type and extent of cancer, individual patients may not be good candidates for direct-acting antiviral medications. However, in other cases, this requirement may be detrimental to patients. Direct-acting antiviral medications may prolong life in patients with liver cancer.[33,34] Hepatitis C may also be associated with a greater likelihood of developing and dying from various non-liver cancers.[35] This finding argues that curing hepatitis C may be important in patients with cancers that have been associated the virus.

Medication Compliance or Adherence

Notably, some of the prior authorization requirements set by insurers and governments are reasonable. For instance, the Illinois checklist includes several points related to the patient's compliance with or adherence to treatment. Given the expense of the new hepatitis C antiviral medications and the demand among infected patients, requirements related to treatment adherence help ensure value for payers—that is, payers need to be assured that patients are doing their part to make the treatment successful.

High Co-Pays

Another major challenge with the new hepatitis C antiviral medications is the high out-of-pocket cost for patients. Insurers typically require patients to pay a portion of the cost for their medications (so-called co-pays or cost sharing). For specialty medications like new hepatitis C antivirals, co-pays may be as high as 25% of the medication's cost.[36] For drugs that run $84,000 or more per treatment course, 25% of the cost would be $21,000 for patients whose plans exclude the antivirals from their annual out-of-pocket maximum; this extremely high co-pay would be an insurmountable hardship for most people.

Given that a disproportionate number of patients with hepatitis C are poor, many cannot even afford a co-pay of 1%, placing the direct-acting antivirals completely out of their reach. Foundations sponsored by pharmaceutical companies have set up patient assistance programs

to help defray medication costs, but many people with government insurance plans cannot utilize these.

The Costs and Value of Curing Hepatitis C

The prices of direct-acting antiviral medications for hepatitis C are established by manufacturers. These prices are very high and thereby impact patient access to treatment. Manufacturers justify the prices based on level of investment, need for return on investment, and costs of research and development. Manufacturers may attempt to offset losses on unsuccessful medications through pricing of successful medications.

Additionally, 95% of drugs developed never make it to market because they are ineffective or unsafe.[29] In many instances, state Medicaid programs, health plans, and prescription drug benefit managers have responded by negotiating lower prices. However, policymakers must ensure that the lower costs are passed on to patients by limiting inappropriate policy barriers for use.

Although the costs of hepatitis C cures are high, the costs of not curing hepatitis C are also substantial. In the absence of a cure, tens of thousands of baby boomers with hepatitis C will experience cirrhosis and liver cancer, leading to enormous increases in healthcare costs over the next several decades—at least $9 billion annually for medical expenses alone.[10,13] This looming bill will almost certainly be paid for by the government and, consequently, taxpayers, because healthcare for patients with hepatitis C is disproportionately state or federally funded through Medicare, Medicaid, and the Veterans Health Administration. Moreover, patients with hepatitis C remain carriers of the infection, which can be transmitted to other individuals under certain conditions—causing the hepatitis C patient population and the cost of treating these patients to grow.

The question facing policymakers, therefore, is whether to pay for hepatitis C patients' healthcare up front in the form of hepatitis C cures, or for years to come in the form of ongoing care for patients as their livers continue to deteriorate. Both options are costly.

Researchers have conducted cost effectiveness analyses with new hepatitis C drugs, taking into account the health benefits of curing hepatitis C, medication side effects, improvements in quality of life, medication cost, and other factors. Results of these studies indicate that the medications are cost effective.[28,37] More research is needed to better understand the health economic impact of treating hepatitis C at differing disease stages.

Another cost-related consideration is the duration of treatment with direct-acting antiviral medications. Evidence suggests that treatment durations shorter than the currently recommended 2 to 3 months may be successful for some patient subgroups.[38-40] Ideally, stakeholders including policymakers, manufacturers, and researchers would work together to ensure the conduct of treatment duration studies that could help to optimize resource use.

Getting Patients the Treatment They Need

Most people agree that patients with hepatitis C would be better off cured but disagree about how to make that happen. Many options exist, including federal purchasing of these new drugs or the development of a federally funded program like the Ryan White approach for HIV/AIDS.[41]

"My patients are shocked and upset to learn that, although a new cure for hepatitis C is available in pill form that doesn't have the side effects of other medications, they cannot obtain it until their disease has reached an advanced stage of liver damage."

Raj Vuppalanchi, MD

Thus, policymakers face difficult questions, such as:

- What are the societal benefits of curing and preventing the spread of hepatitis C?
- How can we structure sustainable insurance systems that also allow patients to get the treatments they need?
- How can we bring down the cost of hepatitis C medications? Will competition among different medication manufacturers lead to reduced prices?
- How can we develop insurance co-pays so that patients can afford the treatments they need?
- How can we ensure that hepatitis C patients will take their medications as prescribed?

Physicians and policymakers must consider these and other questions, both for current patients and for the tens of thousands of silently infected people who will develop advanced liver disease over the next several decades.

Conclusion

Millions of Americans are infected with the hepatitis C virus, which often leads to advanced liver disease. In many cases this can progress to liver cancer and possibly death. Breakthrough medications can cure hepatitis C in more than 90% of patients, but many patients cannot afford the medications, and states, employers, and insurers have set requirements designed to limit the number of patients who receive them. However, hepatitis C itself is expensive, with medical costs in the billions of dollars annually. It is difficult for physicians to watch their patients suffer with a disease that they know can be cured. Policy solutions must reconcile societal needs with the needs of current patients, as well as the needs of those who may not even know they are infected.

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Please note that the views expressed in this document do not necessarily reflect those of the institutions with which working group members are affiliated.

JOIN AFPA'S HEPATITIS THERAPY ACCESS PHYSICIANS WORKING GROUP

The mission of AfPA's Hepatitis Therapy Access Physicians Working Group is to ensure the perspectives of hepatologists, gastroenterologists, infectious diseases specialists and other clinicians treating patients suffering from hepatitis, are shared with policymakers considering issues impacting access to hepatitis therapies. Working group members collaborate in the development of educational resources and participate in advocacy initiatives designed to promote informed policymaking. Physicians interested in joining the working group or participating in an upcoming meeting should contact AfPA at www.AllianceforPatientAccess.org or call 202-499-4114.

Hepatitis Therapy Access Physicians Working Group

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This white paper is authored by the members of the Hepatitis Therapy Access Physicians Working Group and sponsored by the Institute for Patient Access.

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The Hepatitis Therapy Access Physicians Working Group is a project of the Alliance for Patient Access. The working group is supported by educational donations from: Bristol-Myers Squibb Company, AbbVie Incorporated and the Institute for Patient Access.