



The American Academy of HIV Medicine:
Representing Physicians, Physician Assistants, Nurse
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Hepatitis C Cure Access

A Cure for HCV

Hepatitis C Virus (HCV) affects 3.5 million Americans. It is the leading cause of liver cancer and liver failure.* Over 19,000 HCV-infected individuals died from HCV related causes in 2013.** In 2014, there were an estimated 30,500 cases of acute HCV infections reported in the U.S.* HCV infection rates are highest among baby boomers and injection drug users.

In 2013, the FDA approved the first effective oral medication for HCV that offered a cure in over 90% of cases. Since then, more than 5 additional Direct Acting Antiviral (DAA) regimens have become available to patients. These drugs have much higher cure rates, are more tolerable, and have far fewer harsh side effects than older treatments.

Restrictions to Access

The new HCV drugs are costly. In response to budget pressures, insurers and government payers have placed a variety of restrictions on access to the drugs. Older, less well-tolerated treatments for HCV do not have the same restrictions, despite having far more complications associated with their use.

Fibrosis Stage

The liver fibrosis (scarring) of HCV-infected patients is determined on a scale of 0-4. A score of F1 indicates mild fibrosis. F3 represents advanced fibrosis, while F4 indicates cirrhosis of the liver. Many payers have restricted access to curative Hep C regimens to patients with stages F3 or F4 only. This barrier delays the initiation of treatment in some individuals who would benefit from it, giving their HCV a chance to progress. Earlier initiation of treatment has been shown to reverse early fibrosis. The medications are less efficacious when there is cirrhosis, and may not prevent the subsequent development of liver cancer.

Substance Use

Some payers have restricted access to HCV cure treatments based on abstinence from alcohol, drug use or both (including illegal or legal drugs, such as marijuana in states where legal). Some also require a particular period of abstinence, from 1-12 months. These sobriety restrictions cause severe delays in treatment, allowing damage to the liver due to HCV to progress. There is little to no medical evidence that sobriety is necessary for successful treatment of HCV

Prescriber Limitations

Some states have limited the type of medical provider who can prescribe these drugs to only certain specialties such as Gastroenterology, Hepatology, Infectious Diseases or Liver Transplant Specialists. Other states require prescribing in consultation with a set of specific types of providers. In many cases, HIV Specialists have been excluded by these definitions despite experience in treating HCV, and ability and qualification to successfully prescribe and monitor treatment.

Recommendations on HCV Access:

HCV cure medications should be available to:

- All indicated patients regardless of fibrosis scores
- All patients with HIV co-infection
- All patients without substance use restrictions

Those with training and experience in treating HCV, including HIV specialists, should be qualified to prescribe HCV treatments and monitor patients.

HIV Co-infection

About one third of HIV-infected patients are also co-infected with HCV. HCV patients who are co-infected with HIV decline more quickly and should receive the treatment even if they have not progressed to F3 or F4 stage. Some states recognize the importance of early treatment access for co-infected individuals and waive the fibrosis stage requirement, though not all.

Treatment Guidelines

HCV treatment guidelines published jointly by the American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) state that “evidence clearly supports treatment in all HCV-infected persons except those with limited life expectancy (less than 12 months)” and also that, “treatment is best administered early in the course

disease before fibrosis progression and the development of complications.” Restrictions such as fibrosis score and sobriety requirements prevent patients from receiving treatment that complies with this standard of care. These restrictions are motivated by financial, not medical, concerns.

Real Cost of Treatment

The high initial AWP cost of the new curative HCV drugs made headlines for many months after their introduction. This perception of the cost of HCV medications has persisted, despite the decrease in price, available discounts, the introduction of competitor drugs at lower prices, and the cost effectiveness of these treatments when compared to the alternatives. Negotiated prices by coverage entities along with available rebates put the price of the drugs more in the range of \$40-\$50,000 per patient, and provides a 90% cure rate with one course of treatment.

The older treatment regimens, which

Medicaid

The high cost of these drugs has led many state Medicaid programs to employ restrictive criteria to HCV cure medications.^{***} However, Medicaid law requires that all prescription drugs of a manufacturer who enters into rebate agreements must be covered by the program. The only exceptions allowed are for safety and clinical effectiveness. If states do limit access to a drug, they must provide a written explanation to the public for the basis for the exclusion.

CMS sent a letter to the states specifically addressing these issues in 2015. CMS was clear that restrictions

had low success rates of cure, and often had to be repeated, were estimated to have cost \$250,000 per each cure achieved. Additionally, the cost of a liver transplant for patients whose HCV infection has resulted in liver failure can cost over \$300,000 on average.*

One study of the cost effectiveness of the new drugs concluded that “treating HCV infection at early stages of fibrosis appeared to improve health outcomes and to be cost-effective” despite substantial aggregate costs.^{****}

such as fibrosis score and sobriety are medically unjustified and, therefore, are inappropriate. CMS also stated that drugs available under the approved state Medicaid plan must be must also available to individuals enrolled in Medicaid managed care (MCO) arrangements.^{*****}

Currently, patients, provider, and advocate groups are raising challenges to HCV drug restrictions in several states. Other states have taken steps to widen access or remove restrictive criteria.

Real Costs:

Older HCV medications:

- \$250,000 per cure
- Cure rates of 45%
- Low tolerability among patients

New HCV medications:

- Approximately \$50,000 per cure
- Cure rates over 90%
- Much more tolerable

REFERENCES:

* Centers for Disease Control and Prevention, Hepatitis C FAQs for the Public, available at <http://www.cdc.gov/hepatitis/hcv/cfaq.htm> Updated January 8, 2016.

** Centers for Disease Control and Prevention, “Hepatitis C Kills More Americans than Any Other Infectious Disease” May 4, 2016 <http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>

*** Harvard Center for Health Law and Policy Innovation “Examining Hepatitis C Virus Treatment Access: A Review of Select State Medicaid Fee-For-Service and Managed Care Programs” 2013 http://www.chlpi.org/wp-content/uploads/2013/12/Examining_HCV_Treatment_Access_Report.pdf

**** JAMA Internal Medicine “Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naive Population” January 2016 <http://archinte.jamanetwork.com/article.aspx?articleid=2471608>

*****Centers for Medicaid and Medicare Services “Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs” 2015 <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf>