

Innovating and Expanding Access to Hepatitis C Treatments



Key points:

- Hepatitis C affects 3.2 million Americans and kills more people each year than HIV/AIDS in the United States.¹
- Approved by the U.S. Food and Drug Administration (FDA) in December 2013 and by the European Commission in January 2014, Gilead's Sovaldi® (sofosbuvir) 400 mg tablets in combination with other antiviral agents for the treatment of chronic hepatitis C (genotypes 1, 2, 3, and 4) offers a potential cure with a short-term course of therapy, an important consideration.
- Gilead's latest innovation, the once-daily single tablet regimen Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg), has further advanced treatment for patients with genotype 1 hepatitis C infection by providing high cure rates with as little as eight or 12 weeks of therapy, without the need for interferon injections or ribavirin.
- The price of Gilead's hepatitis C treatments reflects the significant clinical, economic and public health value of these drugs, and is comparable to, or in many cases less than, the cost of older, less effective regimens.
- In the United States and around the world, Gilead is working to increase access to its medicines for all people who can benefit from them, regardless of where they live or their ability to pay.

Approximately 3.2 million Americans are currently living with chronic hepatitis C, an infection caused by the hepatitis C virus.¹ Hepatitis C slowly destroys the liver over time and can lead to serious and potentially life-threatening complications, including liver cancer and the need for liver transplants.² In addition to serious liver damage, the complications of untreated hepatitis C can include Type 2 diabetes, rheumatologic disorders and thyroid disease.^{3,4,5}

Since the discovery of the virus in 1989, effectively treating hepatitis C has been a challenge. For years, the only available treatment options were ineffective for many patients and often difficult to tolerate.⁶ Initial treatment regimens involved up to a year of weekly interferon injections and ribavirin tablets, which can cause side effects such as depression, nausea, severe reductions in certain blood cells and flu-like symptoms.⁷ These often difficult-to-tolerate treatment regimens, combined with low cure rates, caused many patients to stop treatment before it was completed.⁸

Significant Advances in the Treatment of Hepatitis C

Gilead has led two medical breakthroughs in hepatitis C treatment in the last year:

- In December 2013, the FDA approved Gilead's Sovaldi for use in combination with other antiviral medicines for the treatment of chronic hepatitis C (genotypes 1, 2, 3 and 4). The Sovaldi regimen offers a potential cure with a short-term course of treatment.
- In October 2014, the FDA approved Gilead's Harvoni, the first and only hepatitis C treatment to provide a complete regimen in a single tablet, taken orally once daily for eight, 12 or 24 weeks. Harvoni combines Sovaldi with Gilead's ledipasvir, an NS5A inhibitor. Harvoni provides a potential cure for patients with the most common form of hepatitis C in the United States (genotype 1). Eight weeks of treatment can be considered for treatment-naïve patients without cirrhosis who have baseline HCV viral loads below 6 million IU/mL.

Value of Innovative Hepatitis C Therapies

Unlike other serious chronic diseases, hepatitis C has the ability to be cured. The price of Gilead's hepatitis C treatments reflects the significant clinical, economic and public health value that Sovaldi and Harvoni offer to patients, their families and healthcare systems, and is comparable to, or in many cases less than, the cost of older, less effective regimens.

Gilead's medicines are also cost-effective over the long term. By quickly curing a vast majority of patients, Gilead's hepatitis C treatments may lessen the frequency of healthcare visits and hospitalizations, and lower the need for medications to manage side effects and complications.

Ensuring Patient Access to Care in the United States and Globally

To assist eligible hepatitis C patients in the United States with access to Harvoni and Sovaldi, Gilead provides the [Support Path™](#) program. Through this program, the majority of commercially insured patients will be able to access Harvoni and Sovaldi for just a \$5 co-pay per month. In addition, Support Path can help patients find alternative forms of financial assistance that may be available through independent non-profit organizations. And for eligible patients with no other insurance options, The Support Path Patient Assistance Program will provide Harvoni and Sovaldi at no charge.

On a worldwide basis, Gilead is developing programs and partnerships to help ensure access to Sovaldi and Harvoni for patients who can benefit from them. In September 2014, Gilead announced licensing agreements with seven India-based generic pharmaceutical manufacturers to expand access to our hepatitis C medicines in 91 developing countries, which represent more than half of the global hepatitis C-infected population. The company is also working with national governments to provide branded Sovaldi and Harvoni in low- and middle-income countries, utilizing tiered pricing based on a country's disease burden and economic means. [Learn more](#) about Gilead's global access programs.

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References

- ¹ Ly K et al. The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007. *Ann Intern Med.* 2012; 156(4):271-278.
- ² US Centers for Disease Control and Prevention. Hepatitis C Factsheet. Available at: <http://www.cdc.gov/hepatitis/hcv/pdfs/hepcgeneralfactsheet.pdf>.
- ³ Negro F et al. Hepatitis C virus and type 2 diabetes. *World J Gastroenterol.* 2009 Apr 7;15(13):1537-47.
- ⁴ American College of Rheumatology. HCV and Rheumatic Disease. February 2013.
- ⁵ Antonelli A et al. Thyroid disorders in chronic hepatitis C. *The American Journal of Medicine.* 2004 Jul 1;117(1):10-13.
- ⁶ Gaetano JN. Benefit-risk assessment of new and emerging treatments for hepatitis C. *Drug Healthc Patient Saf.* 2014;6:37-45.
- ⁷ Product label of PEGASYS, peginterferon alfa-2a.
- ⁸ LaFleur J et al. High rates of early treatment discontinuation in hepatitis C-infected US veterans. *BMC Res Notes.* 2014.