

Gilead's Efforts to Ensure Patient Access to Sovaldi[®] for Chronic Hepatitis C



Key points:

- Approved by the U.S. Food and Drug Administration in December 2013 and by the European Commission in January 2014, Gilead's Sovaldi (sofosbuvir) represents a therapeutic advance in the treatment of appropriate patients with hepatitis C
- Sovaldi, in combination with other agents, offers a cure with a short-term course of treatment, an important consideration when comparing the cost of a drug to the lifetime cost of chronic disease
- Gilead is working with public and private payers around the world to help ensure patient access to Sovaldi as quickly as possible

For 75-85 percent of people who contract the hepatitis C virus, it becomes a chronic infection that can lead to serious and life-threatening complications including liver failure, liver cancer or liver transplantation. Beyond the devastating impact on the lives of patients, the cost and burden to societies of managing these conditions is enormous. Once a patient achieves a cure for chronic hepatitis C, the threat of these complications, along with their accompanying costs, is thought by the medical community to be greatly reduced.

Unlike long-term or indefinite treatments for other chronic diseases, Sovaldi, in combination with other agents, is a short-term therapy that resulted in high cure rates in Phase 3 clinical trials. Patients who achieve sustained virologic response 12 weeks after treatment (SVR12) are considered cured of hepatitis C. Sovaldi was priced such that the total regimen cost is comparable to the previous standard of care regimen for genotype 1 patients with hepatitis C. However, in addition to a higher cure rate, Sovaldi provides a shorter treatment duration and improved tolerability, thereby potentially reducing total treatment costs for hepatitis C when taking into account the cost of medications (including those for side effects of less effective treatment or complications from side effects) and healthcare visits.

HCV Treatment Costs

Regimen	Cost (\$)*	Duration of Therapy (weeks)
OLYSIO ^{1M} + PEGASYS [®] + ribavirin	106,673	48
INCIVEK [®] + PEGASYS + ribavirin	106,468	48
VICTRELIS [®] + PEGINTRON [®] + ribavirin	95,845	48
SOVALDI[®] + PEGASYS + ribavirin	94,078	12
OLYSIO + PEGASYS + ribavirin	86,516	24
INCIVEK + PEGASYS + ribavirin	86,312	24
VICTRELIS + PEGINTRON + ribavirin	85,257	36
VICTRELIS + PEGINTRON + ribavirin	64,825	28

*Wholesale Acquisition Cost (WAC) per patient and corresponding treatment duration for HCV Genotype 1 regimens. Excludes costs of adverse event management. Reflects WAC prices as reported by First Databank[™] (FDB) on February 27, 2014. Manufacturers change the WAC prices of their products periodically. Current WAC prices may be obtained by contacting FDB. Therapy duration based on approved dosing for complete course of therapy. Follows full prescribing information recommendations for each product. Total regimen costs assume average weight of typical patient (86.2 kg) calculated using anthropometric reference data for US adults compiled by the US Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in 2007-2010 and CDC data showing 87% of US individuals were born between 1945 and 1970 and two-thirds of this cohort are male. Ribavirin costs were based on the average generic price for capsules and tablets. Assumes no dose reduction due to adverse events and that patient takes entire regimen as indicated. Not all components may be used for the full duration. Cost for Pegasys[®] based on the cost of ProClick[™] autoinjectors and prefilled syringes, which are priced the same. Cost for Peg Intron[®] based on the cost of REDIPEN[®]s and single-dose kits (powder + diluent vials), which are priced the same.

Facilitating Patient Access in the U.S. and Beyond

Gilead offers a number of support services for patients in the United States who are uninsured, underinsured or who need financial assistance to pay for their medicine. These include the Sovaldi Co-pay Coupon Program, which limits monthly out-of-pocket costs for eligible patients with private insurance to no more than \$5 per month; and the [Support Path Patient Assistance Program](#), which provides Sovaldi at no charge for eligible patients with no other insurance options.

On a worldwide basis, Gilead is working on programs and partnerships to help ensure patients for whom treatment with Sovaldi may be appropriate have access to it. A key component of the company's treatment expansion efforts is tiered pricing based on a country's ability to pay. Gilead also considers an individual country's HCV burden, treatment needs and economic means when setting prices. [Learn more](#) about Gilead's developing world access program.