

Glossary of Key Terms

AbbVie, Inc.	Markets and sells Viekira Pak™ and Technivie™.
American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA)	Medical societies that have issued clinical practice guidelines and best practices for treatment of hepatitis C.
Bristol Myers-Squibb Co.	Markets and sells Daklinza™.
Cirrhosis	Cirrhosis is a condition in which the liver slowly deteriorates and is unable to function normally due to chronic, or long lasting, injury. Scar tissue replaces healthy liver tissue and partially blocks the flow of blood through the liver. The buildup of scar tissue that causes cirrhosis is usually a slow and gradual process. In the early stages of cirrhosis, the liver continues to function. However, as cirrhosis gets worse and scar tissue replaces more healthy tissue, the liver will begin to fail. Chronic liver failure, which is also called end-stage liver disease, progresses over months, years, or even decades. With end-stage liver disease, the liver can no longer perform important functions or effectively replace damaged cells.
Daklinza™ (daclatasvir)	Developed by Bristol-Meyers Squibb. Approved in July 2015 for treatment of genotype 3 in combination with Sovaldi®.
Direct-acting antiviral drugs (DAA)	DAAs act against HCV by directly inhibiting viral activities including specific enzymes such as polymerase and protease. Among the DAAs are agents which specifically target the NS5A (replication complex), NS5B (polymerase) and NS3/4A (protease).
Early virologic response (EVR)	A significant or complete decline in hepatitis C RNA levels by week 12 of treatment. Failing to achieve an EVR typically means that treatment has failed and a patient will not clear the disease.
Fibrosis	The liver can regenerate most of its own cells when they become damaged. However, if injury to the liver is too severe or long lasting, regeneration is incomplete, and the liver creates scar tissue. Scarring of the liver, also called fibrosis, may lead to cirrhosis.
Genotype	Hepatitis C is divided into distinct strains known as genotypes, which vary in geographic distribution and respond differently to treatment. Also referred to as “GT.”
Genotype 1	The most common strain of hepatitis C in the United States, accounting for roughly 70%–75% of infections.
Genotype 2	The second most common strain of hepatitis C in the United States, accounting for roughly 15%–16% of infections.
Genotype 3	The third most common strain of hepatitis C in the United States, accounting for roughly 10%–12% of infections.
Gilead Sciences, Inc.	Markets and sells Sovaldi® and Harvoni®.
Gross-to-net price	The difference between the gross—wholesale—price of a drug and the net price after deducting mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs.
Harvoni® (ledipasvir/sofosbuvir)	Developed by Gilead as a fixed-dose, once daily, single tablet regimen of two agents. Approved in October 2014 for treatment of genotype 1 without interferon or ribavirin. First interferon-free therapy. Also referred to as Wave 2 and “SOF/LDV”
Incivek® (telaprevir)	Developed by Vertex. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Victrelis®.

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Interferon-alfa	The first approved therapy for hepatitis C, this injectable drug works by boosting the immune system to effectively block new cell sites to which a virus can attach. It had major drawbacks for patients because it required frequent visits to a health care provider and was often accompanied by difficult side effects. Also referred to as IFN.
Johnson & Johnson	Markets and sells Olysio™.
Merck & Co.	Marketed and sells Victrelis®.
NS5A Inhibitors	Class of drugs including ledipasvir (part of Harvoni®), ombitasvir (part of Viekira Pak™), and daclatasvir (Daklinza™), that inhibit the NS5A part of the virus that is required to create the replication complex. A unique class of antivirals that first allowed for all-oral regimens for hepatitis C.
Olysio™ (simeprevir)	Developed by Johnson & Johnson. Approved in November 2013 to treat genotype 1. The AASLD/IDSA recommended in January 2014 that it be used in combination with Sovaldi for treatment of patients not eligible for treatment with interferon. The FDA approved its use in combination with Sovaldi in November 2014.
Pegylated interferon-alfa	Interferon-alfa linked with polyethylene glycol, which prolongs its effect allowing once weekly injections. Pegylated interferon in combination with ribavirin was the standard of care for the treatment of hepatitis C for over a decade until 2014. Also referred to as PEG IFN or PEG.
Pharmasset, Inc.	Bought by Gilead in 2011, this company was the original developer of PSI-7977, the molecule that would become Sovaldi® and be component of Harvoni®.
Polymerase inhibitors	Class of drugs, including Sovaldi®, Harvoni® and Viekira Pak™ that work by disrupting the polymerase enzyme that mediates hepatitis C RNA replication.
Protease inhibitors	Class of drugs including Olysio™, Victrelis®, and Incivek®, that work by blocking the protease, which cleaves and processes viral polyproteins, an important part of hepatitis C's life cycle.
Rapid virologic response (RVR)	When hepatitis C virus is undetectable at week 4 of treatment. Reaching RVR typically signifies high likelihood that a patient has been successfully cured of the disease.
Ribavirin	An antiviral drug discovered in 1972 used for treatment of RNA viruses including hepatitis C. It was part of the standard of care until 2014 and may be a component of current DAA-based regimens. Also referred to as RBV.
Sovaldi® (sofosbuvir)	Developed clinically by Gilead. Approved in December 2013 to treat genotypes 1, 2, 3 and 4. Also referred to as PSI-7977, GS-7977, SOF, and Wave 1.
Standard of care	Treatment accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.
Sustained virologic response (SVR)	Hepatitis C virus RNA is undetectable a set time after treatment—typically 12 or 24 weeks. Signifies that a patient has likely been cured of the disease.
Technivie™ (obmitasvir/paritaprevir/ritonavir)	Developed by AbbVie. Approved in July 2015 for treatment of genotype 4.
Treatment experienced (TE)	Patient who has received treatment for a disease.
Treatment naive (TN)	Patient who has not yet received treatment for a disease.

Glossary of Key Terms—Continued

Vertex Pharmaceuticals, Inc.	Marketed and sold Incivek®.
Victrelis™ (boceprevir)	Developed by Merck. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Incivek®.
Viekira Pak™ (obitasvir/ paritaprevir/ritonavir/dasabuvir)	Developed by AbbVie as a fixed-dose regimen of three agents active against HCV. Ritonavir is included as a dose-boosting agent. Approved in December 2014 for treatment of genotype 1 without interferon or ribavirin.
Warehousing	The common, though informal, practice of doctors encouraging their patients to delay treatment close to the release date of a new therapy that is expected to be more effective or less burdensome (in terms of side effects). Typically results in a surge of patients using the new therapy.
Wholesale Acquisition Cost (WAC)	The price of a drug before any discounts, deductions, or other costs.