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Comparison of Hepatitis C Treatment Costs

Estimates of Net Prices and Usage in the
U.S. and Other Major Markets



Introduction

A new generation of Hepatitis C treatments has generated significant public attention since 2013, partly due to their remarkable clinical profile as “cures”, but also due to their costs. Total treatment costs are based on both the price and the number of treated patients. While it is understood and accepted that list prices are not what is actually paid for medicines, very little discussion has focused on net prices that manufacturers and intermediaries have negotiated.

In previous reports, including Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020, the IMS Institute has estimated net spending and prices through analysis of company SEC filings with IMS proprietary data sources and methods. Due in part to the media coverage of the list prices, a number of market participants, including public and private payers, and manufacturers, have taken the highly unusual step of disclosing the net prices for some of these Hepatitis C products. We have focused exclusively on two Gilead products because of the more complete disclosure of net prices by the company, governments or private payers than was the case for the other manufacturers in the market, and because the products generally represent the highest share of treated patients in these countries.

In this study we also include a country comparison of the treated prevalence, or how many of the infected population in a country are being treated. Infection rates and treatment rates differ, sometimes significantly, but together they inform payers as they negotiate based on their total cost exposure.

The study was conducted independently by the IMS Institute with funding support from the Pharmaceutical Care Management Association (PCMA), the national association representing America's pharmacy benefit managers (PBMs).

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Key Findings

Analysis of Net Prices and Usage

- The list prices of the newer Hepatitis C treatments vary widely across countries while the net prices are very similar between the U.S. and other developed markets.
- Current rates of treatment are based on multiple factors including diagnosis rates and policies which limit treatment to the most severe cases.
- The most striking treatment and epidemiological differences are the relatively higher rates of treatment in Japan and Spain, and the low rate of treatment in Italy, which has the highest rate of infection.
- In 2015, 5.8% of infected patients in the countries studied were treated and likely cured.

Budget Impact and Implications

- The budget impact of HCV treatments across countries has been significant.
- Older treatments were used to treat substantially fewer patients, resulted in more significant side effects, were generally less effective, and were priced lower on a list price basis.
- If current rates of treatment continue, it will still be a decade or more in most countries before the infected population is reduced significantly enough to consider it an eradicated disease.
- With current treatment rates, even at discounted prices, significant costs (and budgetary impact) from HCV treatments can be expected to continue for some time.
- The extent to which curative treatments will offset other health system costs typically associated with HCV infection, such as cirrhosis, liver cancer and the need for transplants, remains to be seen and further analysis will be required.

Methodology

This study measures estimated net prices paid by Medicare Part D plans in the U.S. and negotiated government reimbursed prices in other countries. The study also measures the prevalence and treated population in the U.S. for Medicare beneficiaries/enrollees and that found in comparator countries.

Prices

Price comparisons look only at products consistently available in multiple countries, where credible net price sources were available and therefore focus on the two most widely used products, Sovaldi and Harvoni.

List prices were compiled from public sources. Net (negotiated) prices were compiled from the public disclosures of market participants (manufacturers, payers or governments) and obtained from published media reports.

Net prices in the U.S. were based on statements by commercial plans, and net prices in Medicare part D and in commercial plans were noted to be approximately the same.

Prices in Japan are negotiated by manufacturers with the Ministry of Labor Health and Welfare (MLHW) and list prices are understood to represent net prices after negotiation.

When prices were reported in local currencies, prices were converted to U.S. dollars using 2015 exchange rates. However specific media reports also reported in U.S. dollars and exchange rates were not disclosed.

Treated Patients and Prevalence

Treatment volumes are based on IMS MIDAS, a unique platform for assessing worldwide healthcare markets which integrates IMS Health's national audits into a globally consistent view of the pharmaceutical market. The IMS MIDAS measure of standard units represents a number of pills.

Treated patients were estimated by factoring the number of pills by the most common approved dosing (1 pill per day for 12 weeks). There are known to be a subset of patients who are treated for shorter durations (8 weeks instead of 12), or longer durations (pre-transplant prophylaxis patients for up to a year), but for the purposes of this analysis, data were not adjusted or factored to reflect these patients.

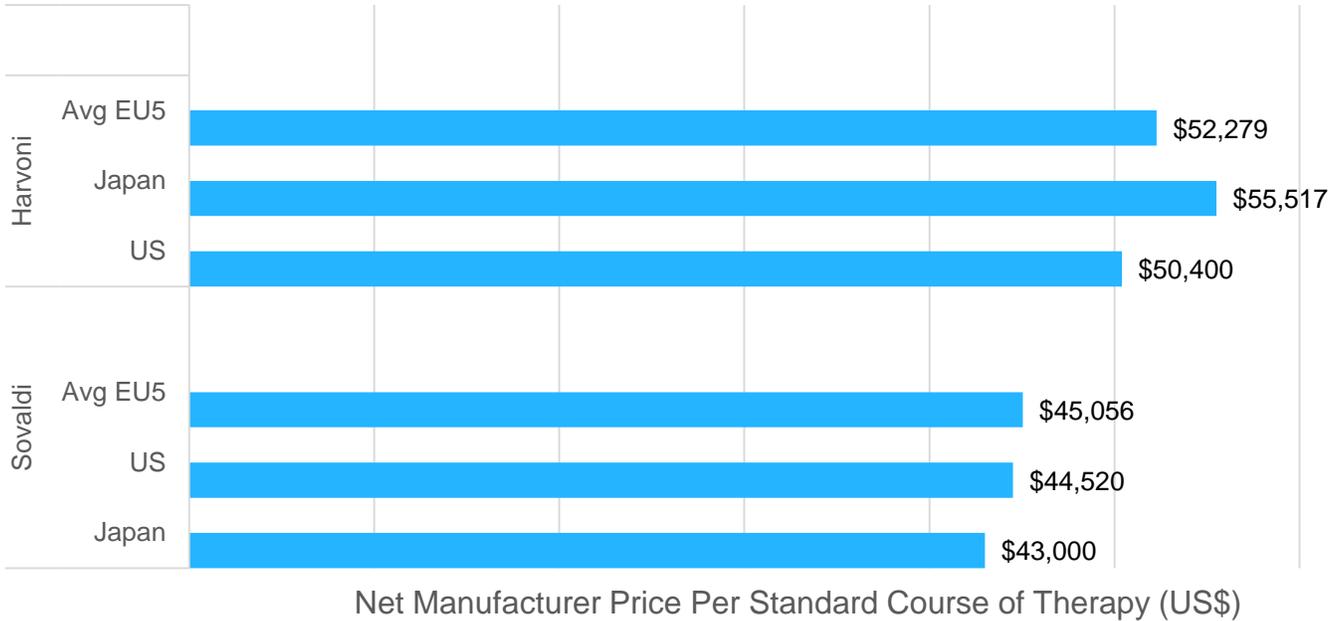
IMS Health audited data has been adjusted to reflect company reported treated patient volumes where the two differ.

Treated patient analyses are based on all available HCV therapies in a country, excluding therapies approved as "add-on" for use in regimens but which would not be used alone.

Prevalence data was compiled from the most current available public sources ranging from 2013 to 2016.

Prices of Hepatitis C treatments after negotiation were largely similar across most developed markets

Net Prices Per Course of Treatment 2015

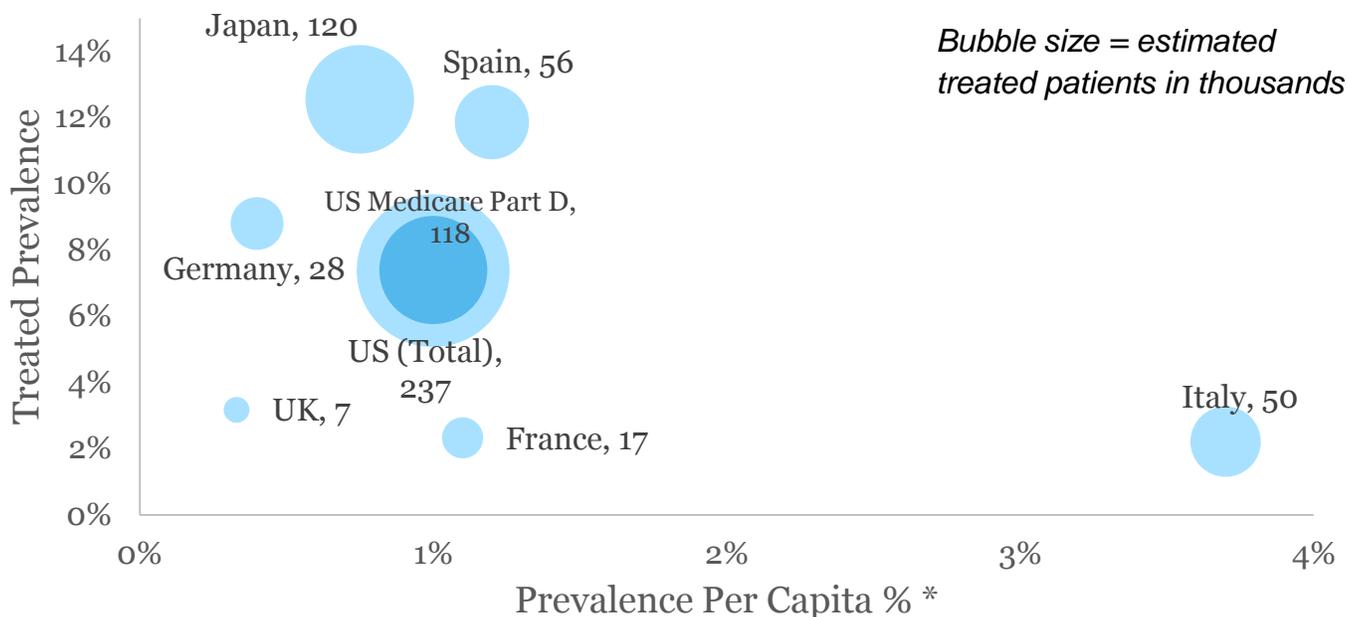


- Net prices in the U.S. for Sovaldi are below the European average price \$45,055, and within 5% of average prices for Harvoni, \$52,279.
- Price concessions are evolving rapidly and confidential rebates have been publicly disclosed.
- Average discounts are 15-20% off list prices, except in the U.S. where discounts of 45-55% have been disclosed for Sovaldi and Harvoni (see sources).
- Most countries have negotiated specific price levels while others have negotiated prices contingent on levels of utilization.
- One factor significantly affecting prices of these drugs is the treatment duration, which can be as short as 8 weeks or as long as 48 in some cases, but is compared here with a uniform 12 week course of treatment.

Chart Notes: Net prices based on compiled public statements of market participants, intermediaries or governments. Course of treatment defined as 1 pill per day for 12 weeks.

Treatment volumes are highest in the U.S., Japan, Spain and Italy with wide variations across developed markets

Prevalence, Treatment Rates and Treated Patients 2015



Source: IMS MIDAS, IMS Institute for Healthcare Informatics, 2015; See sources table for prevalence information.

- Disease prevalence estimates reflect the underlying rate of disease in a population.
- Prevalence in the countries analyzed ranges from 0.3% of the population infected in the U.K. to 3.0-4.4% in Italy.
- Japan and Spain have both made official statements supporting their commitment to funding widespread treatment.
- Germany and the U.S. have demonstrated the next highest levels of treatment of their infected populations.
- The U.S. Medicare Part D program accounts for half of estimated prevalence and treatment volumes.
- Italy has the highest rate of infection of the analyzed countries, while treatment rates in 2015 were far lower than other markets. Reported manufacturer price concessions in Italy were made conditional upon increased treatment volumes, suggesting that treatment rates may increase in future.
- In 2015, over 527,000 patients were treated across these countries, with cure rates over 90%, reducing the infected population by 5.8%.

Chart Notes: *Mid-point of published prevalence per capita estimates. Prevalence estimates in 2015 are the most current available, ranging from 2013 to 2015 (see sources). Treated prevalence is the estimated number of treated patients divided by estimated disease prevalence.

Treated patient estimates based on IMS audited volumes of all newer generation Hepatitis C treatments, excluding those whose label applies for add-on therapy to other treatments. Treated patient estimates are based on 12-week regimen and are adjusted for some products based on comparison to manufacturer statements of patient volumes if different from IMS audited volumes.

Overall country cost exposure is understood to be significant

Estimated Total Net Expenditures on Treated Patients US\$BN in 2015

Country	Average Net Cost of a 12 week course of treatment	Treated population	Total Net Spending on Treated patients (US\$BN)
US (Total)	46,169	236,874	10.9
Japan	49,259	119,610	5.9
US Medicare Part D	46,169	118,437	5.5
Top 5 Europe (D,F,E,I,UK)	48,667	158,452	7.7

- HCV treatment costs are substantial and represent a dramatic shift in the allocation of healthcare resources in a short period of time since the newest generation products were introduced in late 2013.
- These eight countries are estimated to have spent \$25.7 billion on HCV treatments.
- Consistent with having the largest treated population, the United States also has the highest total net expenditures on HCV treatments, with half of that in the Medicare part D program.
- Japan and Spain's announced priority for HCV treatment has translated into nearly double the treated prevalence of other developed markets.
- Country exposure to HCV costs are a factor of disease prevalence, policies that inform treatment decisions, as well as negotiated price levels.

Chart notes: Treatment costs are the average of Harvoni/Sovaldi net costs. Treated population are based on IMS Health audited volumes for all modern HCV treatments excluding add-on treatments.

Sources

Estimated Prevalence by Country

Country	Prevalence Estimate	Estimate year	Source
France	1.1%	2013	Diagnosis, management and prevention of hepatitis C. World Gastroenterology Organisation. 2013 4. Available from: http://www.worldgastroenterology.org/guidelines/global-guidelines/hepatitis-c/hepatitis-c-english
Germany	0.4%	2013	Diagnosis, management and prevention of hepatitis C. World Gastroenterology Organisation. 2013 4. Available from: http://www.worldgastroenterology.org/guidelines/global-guidelines/hepatitis-c/hepatitis-c-english
Italy	3.0-4.4%	2013	Ciccozzi M. Phylogeny and phylodinamic of Hepatitis C in Italy. Paper presented at International Conference on Epidemiology & Evolutionary Genomics. Orlando, FL. 2013 Aug 21-23. Available from: http://www.omicsgroup.com/conferences/ACS/conference/pdfs/3485-Speaker-Pdf-T.pdf
Japan	0.6-0.9%	2013	Bennett H, Waser N, Johnston K, et al. A review of the burden of hepatitis C virus infection in China, Japan, South Korea and Taiwan. <i>Hepatology</i> . 2015 Jul;9(3):378-90. doi: 10.1007/s12072-015-9629-x. Epub 2015 Jun 13.
Spain	1.2%	2014	Strategic Plan for the Treatment of Hepatitis C National Health System. General Secretary of Health and Consumers. Spain. 2015 May 21. Available from: http://www.msssi.gob.es/ciudadanos/enfLesiones/enfTransmisibles/docs/plan_estrategico_hepatitis_C.pdf
U.K.	0.33%	2015	Hepatitis C in the UK 2015 report. Public Health England. 2015 July. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/448710/NEW_FINAL_HCV_2015_IN_THE_UK_REPORT_28072015_v2.pdf
U.S.	0.8-1.2%	2014	Viral Hepatitis - Statistics & Surveillance. Centers for Disease Control and Prevention. 2016 May 19. Available from: http://www.cdc.gov/hepatitis/statistics/

About the IMS Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care. With access to IMS Health's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS Health information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

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