Costly Hepatitis C Treatments Help Drive 12 Percent Drug Spending Jump

By Roni Caryn Rabin | November 20, 2014

After several years of modest increases, American spending on medications is projected to shoot up by 12 percent this year, pushing the nation’s drug bill to between $375 billion and $385 billion, according to a report by the IMS Institute for Healthcare Informatics.

Several factors are driving the spending spike, including the introduction of expensive new hepatitis C drugs and fewer drug patent expirations than in previous years, the report found. Such expirations typically lead to savings as cheaper generics replace brand-name drugs.

The 11.7 percent rise is a dramatic departure from the more modest average increases of 3.6 percent in annual drug spending during the past five years.

The report anticipates the pace of spending increases will slow to 7 to 9 percent in 2015, as the impact of the new hepatitis C drugs declines, less expensive biosimilar products become available and several brand-name drugs — such as cancer drug Gleevec and the antipsychotic Abilify — are replaced by generics.

“We expect this bubble of innovation around hepatitis C will pass, so we won’t see such a contribution to growth in outer years,” said Murray Aitken, executive director of IMS Health. “We think the spike in growth will moderate next year, and further moderate in 2016.”

Drug costs are projected to increase between 3 percent and 5 percent in 2016, he said. The new hepatitis C drug Sovaldi, made by Gilead Sciences and approved in December 2013, costs $1,000 a pill, with a 12-week course of treatment running about $84,000. Another hepatitis C drug — Harvoni — approved by the FDA in October, costs $1,125 a pill, or $94,500 for a 12-week course of treatment.

An estimated 3 to 4 million Americans have hepatitis C and are potentially eligible for treatment. Hepatitis drug treatments accounted for $8 billion of the approximately $40 billion in projected
increased drug spending this year.

“The hepatitis C drugs are Exhibit A when you look at escalating drug costs,” said Brian Henry, a spokesman for Express Scripts, the country’s largest pharmacy benefits manager. “You never had a drug that costs that much that can treat so many people.” The price of Sovaldi “caught payers by surprise,” he said.

Innovative new therapies, especially in the area of cancer, have also pushed up costs. The Affordable Care Act, which expanded access to health care and medications, may also have played a role, along with a new emphasis on preventive care and adherence to medications, Aitken said.

This KHN story can be republished for free (details).

Holly Campbell, director of communications for the drug industry trade group, PhRMA, said the cost of developing drugs has skyrocketed, pointing to a report this week by the Tufts Center for the Study of Drug Development that estimated the price of bringing a drug to market at $2.6 billion. The process can take a decade, the report said.

“These most recent findings underscore the ongoing challenges our industry faces,” Campbell said.

An AARP report noted the increase in prices of brand-name drugs. The report found that the prices of 227 brand name prescription drugs used by many older Americans increased by 12.9 percent on average last year, well above the 1.5 percent rate of inflation, bringing the average cost of a brand-name drug used regularly to $3,000.

“We have started to hear from members who have to decide between taking a drug they need and paying their electric bill,” said Leigh Purvis, director of health service research at the AARP Public Policy Institute and a co-author of the report.

But, she added, the impact goes beyond seniors. “This is a concern not just for our members but for everyone.”

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Gilead's hepatitis C drugs largely cost-effective in U.S.: study

BY ANDREW M. SEAMAN
Mon Mar 16, 2015 5:04pm EDT

(Reuters Health) - New hepatitis C drugs that shorten treatment times are largely cost-effective despite their hefty U.S. price tags, according to two new analyses.

The widespread use of a combination of drugs that include Gilead Sciences Inc's Sovaldi, known generically as sofosbuvir, will nonetheless be a significant cost for the U.S. healthcare system, researchers wrote.

Sovaldi's initial $84,000 price drew widespread criticism last year, and insurers have since pressed Gilead and rival AbbVie Inc to offer steep discounts on the treatments.

One analysis published on Monday in the Annals of Internal Medicine found treatment involving Sovaldi cost-effective for people with the most common type of hepatitis C, known as genotype 1, compared with older treatments.

It was funded by CVS Health, one of the largest U.S. pharmacy benefits managers, and was based on Gilead's 2014 pricing, before it began to offer greater discounts.

The new drugs cost $12,825 for every healthy year of life patients gained over older treatments, the researchers said. That was below the usual cutoff of $50,000 per healthy year of life gained for cost-effectiveness.

Senior author Dr. Niteesh Choudhry cautioned that the analysis looks at benefits over the course of a person's life, while the cost of treatment is paid upfront.

"We look over the long term and it takes a long time for these dollars to be incorporated," said Choudhry, of Brigham and Women's Hospital in Boston.

A second analysis published in the same journal found that treating all eligible U.S. hepatitis C patients over the next five years, at 2014 prices, would cost an additional $65 billion more than older and less-effective treatments.

Based on reduced 2015 prices, the researchers said, the costs would total an additional $20 billion
over the next five years.

Treating the patients with the new drugs would also prevent about $16 billion in healthcare spending in the future, the researchers said. The study was funded by the National Institutes of Health.

"These drugs are good value for the money," said lead author Jagpreet Chhatwal, from the University of Texas MD Anderson Cancer Center in Houston.

Gilead offers a combination drug known as Harvoni, which combines Sovaldi and the company's ledipasvir. AbbVie's Viekira Pak, which was approved in the United States in late 2014, was not evaluated in either of the analyses.

(Reporting by Andrew M. Seaman; Editing by Dan Grebler)
Hepatitis C Drugs Will 'Strain Budgets' at Current Prices: Study

By Amy Norton
HealthDay Reporter

MONDAY, March 16, 2015 (HealthDay News) -- New hepatitis C drugs promise cure rates above 90 percent, but could prove to be budget-busters for public and private health insurers, a new analysis finds.

Recently approved drugs for chronic hepatitis C have been heralded as a breakthrough that could make the liver disease "rare" in the United States. But with prices topping $1,000 per pill, government and private insurers are balking -- often putting limits on which patients qualify for coverage.

Now two new studies in the March 16 Annals of Internal Medicine conclude that for individual patients, treatment with the pricey pills is "cost-effective." That's a calculation that takes into account the years of better health and quality of life people will likely enjoy.

The bad news? One study estimates that state governments and insurers will have to dig up an extra $65 billion over five years to get the drugs to every eligible American.

And that won't be offset by the money saved by avoiding hepatitis C complications -- which amounts to about $16 billion.

"One of the arguments has been that these expensive drugs will ultimately save us money," said study leader Jagpreet Chhatwal. "But our data show that's clearly not the case."

He stressed, however, that none of this means that patients should not be getting the new drugs -- which include the oral drug sofosbuvir (Sovaldi) and a combination of sofosbuvir and ledipasvir marketed as Harvoni.

"We know these drugs are good, and patients need treatment," said Chhatwal, an assistant professor at the University of Texas M.D. Anderson Cancer Center. "High costs shouldn't be an obstacle."

Hepatitis C is a viral infection that causes inflammation in the liver; for most people the infection becomes chronic. According to the U.S. Centers for Disease Control and Prevention, about 3.2 million Americans have chronic hepatitis C.

Without treatment, about 15 percent to 30 percent of those people will develop cirrhosis (scarring) of the liver, according to the CDC. Smaller numbers develop liver cancer.

But for decades, the only treatment for the disease involved the injection drug interferon -- which had to be taken for up to a year, and often caused fatigue and flu-like side effects. And, the cure rate was only 40 percent to 50 percent, according to the U.S. Food and Drug Administration.

But in just the past year, several hepatitis C pills have been approved -- all with high cure rates and big price tags. Gilead Sciences makes both Sovaldi and Harvoni; while AbbVie markets a drug called Viekira Pak.
Treatment with Sovaldi typically lasts just 12 weeks, but that adds up to $84,000. Harvoni can be given for as few as eight weeks, but costs even more per pill, for a grand total of over $93,000.

Chhatwal’s team used a simulation model to estimate the costs of giving the two drugs to all eligible Americans, compared to interferon-based regimens. The researchers found that the new drugs would cost an extra $65 billion in the next five years.

But the cost savings -- in averted cases of cirrhosis, liver transplants and deaths -- came in at only $16 billion.

"There's no question that treating any individual patient with these drugs is cost-effective, because cure rates are over 90 percent -- approaching 100 percent," said Dr. Eugene Schiff, director of the Schiff Center for Liver Diseases at the University of Miami Miller School of Medicine.

"Even in relatively milder cases, people have fatigue related to the (virus)," Schiff said. "You get rid of the virus, and they feel better, they function better, their quality of life improves."

Schiff said that new hepatitis C drugs from other companies are in the pipeline, and competition should help drive down prices. And, he added, some insurance companies and state Medicaid programs have been striking exclusivity deals with drug makers in exchange for reduced prices.

But many patients still face barriers to getting the new drugs, Schiff explained.

"As a physician," he said, "I'm frustrated because I can't treat the majority of the patients I see."

Most state Medicaid programs have restrictions on coverage, including limiting the drugs to people with more-severe liver disease, according to Medicaid Health Plans of America (MHPA).

That's a particularly important issue because many Americans with hepatitis C are low-income or in prison, according to MHPA. The virus is most often transmitted through injection-drug use or contact with infected blood.

In another study, Chhatwal’s team estimated that with the new drugs on the market, hepatitis C could become a "rare" disease in the United States within 20 years.

But that all depends on people having access to the medications, Chhatwal said. To him, the situation highlights a bigger issue: Unlike many other countries, the United States has no system for regulating drug prices.

"I think patients suffer because of that," Chhatwal said.

**More information**

The U.S. Centers for Disease Control and Prevention has more on hepatitis C.

**SOURCES:** Jagpreet Chhatwal, Ph.D., assistant professor, health services research, University of Texas M.D. Anderson Cancer Center, Houston; Eugene Schiff, M.D., director, Schiff Center for Liver Diseases, University of Miami Miller School of Medicine; March 16, 2015, *Annals of Internal Medicine*

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Public Citizen, Newt Gingrich Suggest Gov't Buy Patents For Expensive, Life-Saving Rx

It's not common for Public Citizen and Newt Gingrich to agree on policy, but it seems they both think it would be a good idea for the government to buy the patent rights for expensive, life-saving drugs, then make the drugs available to everyone. The policy -- rejected by the pharmaceutical lobby as government price controls -- is the latest idea for dealing with high-priced, large-volume drugs such as Sovaldi that health plans and providers fear are going to break the healthcare system.

Public Citizen President Robert Weissman testified Wednesday (Dec. 3) before the Senate Veterans Affairs Committee on proposals to deal with the price of specialty medications, such as Gilead Science's hepatitis C drugs Sovaldi and Harvoni. A 12-week course of Harvoni costs $94,500, and it is estimated that 3.2 million are infected with hepatitis C.

One solution, Weissman said, is for the government to buy the patents from Gilead and make treatment available to everyone for the same amount of money, or potentially less, than government programs otherwise would spend to make treatment available to fewer people by rationing it. Weissman said he doesn't prefer this approach because it costs the government close to what it would have paid, but it's better than nothing because it achieves universal coverage, including people with private insurance, instead of only treating the sickest individuals.

"Here's how the patent buyout approach might work: Gilead is paid $100 billion right now. Treatment is made available to everyone who needs it, as soon as suppliers can ramp up," Weissman prepared testimony states. "With a marginal cost of production of say, $200, the cost of providing medicine to each of 3 million patients is only an additional $600 million."

The day before Weissman testified, former House Republican Speaker Newt Gingrich described a similar approach when he was asked about hepatitis C drug costs at an event sponsored by the Academy of Managed Care Pharmacy.

"I think there are some drugs where it may either lead the government to buy the patent rights to figure out some way to make it a public commodity, because it is so expensive if it stays at a monopoly level," Gingrich said.

Gingrich emphasized that the policy should be reserved for drugs that are "very life-changing," and he said individuals should pay for drugs that are marginally better than those already on the market.

Another solution suggested by Weissman is for the government to apply a law that permits it to use patented inventions if it pays reasonable compensation to the patent owner. Under this scenario, the federal government would authorize generic drug manufacturers to make and sell the product.

Weissman said the scope of the government use could vary. The generic drugs could be used to treat hepatitis C patients served only by a particular agency, such as the Department of Veterans Affairs, or for hepatitis C patients under all government programs, including Medicaid and Medicare. Or, a new program could be created that would cover all Americans.

Under this solution, the government would have the ability to negotiate purchases from generic makers anywhere in the world that satisfy quality considerations, he said, and likely could obtain a course of a treatment at a cost of several hundred dollars per patient. "A significant, additional expense would be incurred in paying royalties to Gilead, but overall costs would remain a tiny fraction of current prices," Weissman said. "With these reduced prices, treatment could easily be provided to all."
Pharmaceutical Research and Manufacturers of American spokesman Robert Zirkelbach said buying patents is a form of government price controls.

"This would have the same effect as government price controls as it would inhibit the development of new treatments and potential cures against the most costly and challenging diseases," he said. -- John Wilkerson, Michelle M. Stein

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For a patient with hepatitis C, a potentially deadly disease, the prospect of finding a cure with minimal side effects is a really big deal. Also a big deal is the cost of Sovaldi (sofosbuvir), an oral drug approved by the Food and Drug Administration in December 2013 for the treatment of chronic hepatitis C. Sovaldi has been priced by its manufacturer, Gilead, at $1,000 per pill, or an estimated $84,000 for its entire 12-week regimen. It joins the treatment arsenal with several older drugs generally thought either to be less effective or to have more side effects, and another newly approved drug to be taken in combination with other drugs. More drugs are expected to gain approval within the year.

Sovaldi’s price tag has drawn attention in part because an estimated 3 million Americans have the hepatitis C virus and could be considered candidates for new drugs. Patients will clearly benefit from a long-awaited cure, and public and private payers could potentially see a reduction in health care spending over the long term if Sovaldi successfully cures this disease and fewer patients require high-cost liver transplants. But private insurers and public programs will face significant budgetary pressures if a large number of patients receive this treatment at current prices.

To date, attention has focused on cost implications for private health plans, Medicaid, and the Department of Veterans Affairs (VA). For example, UnitedHealth reported that the cost of Sovaldi was “multiple times” its expectations. State Medicaid officials and Medicaid plans have warned that the cost of the new treatments will pose significant fiscal challenges to state budgets and plan payment rates, even though Medicaid receives a 23.1 percent rebate (discount) for all brand drug purchases. The VA has decided to cover the drug and secured from Gilead a discount of 44 percent, one that applies to certain other federal purchasers, but is targeting treatment to the sickest patients while waiting for less expensive drugs to become available.

Less attention has been paid to the cost implications for Medicare, where coverage of Sovaldi will fall under Part D, the program’s outpatient prescription drug benefit administered by private plans. Given the drug’s effectiveness, most if not all of Part D plans will likely cover Sovaldi. The anticipated impact on costs to Medicare will be revealed to CMS later this month, when plans submit premium bids for 2015. Plans will increase their bids to cover the expected costs of new treatments, which will raise costs for both the federal government and Part D enrollees who pay premiums. CMS will release the average Part D premium for 2015 in August.

The cost to Medicare may be substantial. Based on our analysis of the National Health and Nutrition Examination Survey (NHANES), 350,000 Medicare beneficiaries have hepatitis C, although less than half of them are aware they have the disease. Because hepatitis C is most prevalent among baby boomers, the number of patients seeking treatment under Part D could rise unless they are cured before reaching the age of Medicare eligibility. HHS is currently encouraging at-risk individuals to get hepatitis C screening, which could boost the number of people, including Medicare beneficiaries, seeking a cure. Medicare may soon begin to cover the cost of Hepatitis C screening for those at risk, which could further increase the number of beneficiaries seeking Medicare-covered treatments.

Estimating Medicare Costs For Sovaldi: Two Scenarios

To estimate the potential cost to Medicare, we looked at two scenarios for how many Medicare beneficiaries might be treated with Sovaldi. In each scenario, we assume a 12-week course of treatment of Sovaldi, by itself, at a total price of $84,000.
In the first scenario, we assume that 25,000 Medicare beneficiaries — or roughly 10 percent of Part D enrollees with the hepatitis C virus and about one-fourth of enrollees who have been diagnosed — are treated with Sovaldi. At this level of treatment, Medicare spending would increase by about $2 billion in new Part D drug costs in 2015 over 2014 — a 3 percent increase in federal Part D outlays and Part D premiums from this drug alone.

The second scenario assumes 75,000 Part D enrollees get treated, equivalent to most of those who are aware they have the virus, but far less than the 350,000 infected beneficiaries. This higher rate of treatment would mean about $6.5 billion more in Part D drug spending, an increase of about 8 percent in both federal Part D outlays and enrollee premiums — a bigger increase than in any year since 2008.

These estimates of new costs to Medicare might be conservative. Medicare costs could be considerably higher because doctors often prescribe Sovaldi in conjunction with other medications. In addition, the cost to Medicare would be higher if a larger number of beneficiaries are diagnosed and treated than we assumed. But it is also possible that costs could be lower than our estimates if fewer people get treated, if new equally effective drugs become available at a lower cost, or if Part D plans are able to negotiate lower prices.

# A Lack Of Leverage For Medicare Drug Plans

Yet, it is likely to be hard for plans (and thus for Medicare) to have an impact on price in the case of Sovaldi. In Part D, price negotiations are conducted by private plan sponsors on the premise that they can leverage lower prices from pharmaceutical companies by trading volume for discounts, as well as by deciding whether to cover the drug and at what level of cost sharing. This approach works best when multiple drugs achieve similar outcomes. But what happens when a newly approved drug lacks direct competitors, based on its high cure rate and low rate of side effects? Absent competitive pressures, [Part D sponsors have little negotiating power](#).

The high price of Sovaldi is expected to have cost implications for Medicare beneficiaries seeking treatment. Even with coverage under Medicare Part D, patients receiving the treatment are likely to incur high out-of-pocket costs, paying as much as $7,000 in cost sharing over a 12-week period for Sovaldi, taking into account the deductible, coinsurance, coverage gap, and the 5 percent coinsurance above the catastrophic limit. Total out-of-pocket costs would be even higher for Part D enrollees who take Sovaldi in combination with other drugs.

Furthermore, if the high cost of Sovaldi leads plans to impose prior authorization restrictions to manage utilization, some patients could face barriers to getting treatment at any cost. However, the publicity over a [recent denial of coverage](#) by a Part D plan — and its subsequent reversal — highlights the potential pitfalls for plans in exercising this type of utilization management.

**Potential savings and who would get them.** The intense focus on the costs of treatment for Medicare and patients does not take into account the potential for longer-term savings. Clinical evidence suggests that successful treatment of the disease may reduce costs associated with liver disease down the road. [Milliman](#) has estimated that Medicare beneficiaries with hepatitis C have three times the average overall medical costs as other Medicare beneficiaries. If these higher costs were eliminated or substantially reduced, the savings achieved over a longer term could offset the one-time cost of the drug for any given patient. However, because Part D is funded and provided separately from other Medicare benefits, these savings would accrue to Medicare, not to the stand-alone Part D plans. By contrast, Medicare Advantage drug plans could potentially realize savings over the longer term, provided beneficiaries stay in the same plan for many years.

# Policy Responses To Sovaldi And Similar Drugs

When high-priced, innovative drugs come to market with no real competitors, the federal government could consider strategies to reduce the cost to Medicare. As noted above, Medicare does not receive the discounts obtained by the VA or Medicaid; in fact, the program is explicitly prohibited by law from negotiating drug prices directly with pharmaceutical manufacturers. The public, however, has [expressed a favorable view](#) of giving the government greater authority to negotiate lower drug prices in Medicare, despite the reluctance of lawmakers to move in this direction. A limited way to change the existing ban on government negotiation could be a binding
arbitration system designed by Richard Frank and Joseph Newhouse for a scenario where a clinically important drug lacks competition from clinical alternatives.

Medicare might also consider a means of taking into account the medical savings that might result down the road from treatment with expensive drugs like Sovaldi. Medicare could design a way to hold back from the manufacturer some portion of the payment to see if savings materialize. The idea is to create a lower price, but offer a means of sharing savings if they materialize.

At a time when the nation is focused on how to control health costs, Sovaldi raises interesting and difficult questions which are likely to recur each time a highly priced breakthrough drug comes to the market with little or no competition, leaving public and private payers, and patients themselves, to absorb the costs. For now, Medicare is slated to pay top dollar to provide an important treatment that will potentially save lives. The question for policymakers is whether that is a sustainable policy for the longer term.

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[15] Richard Frank and Joseph Newhouse: http://content.healthaffairs.org/content/27/1/33.full