

New Hepatitis C Medication Sparks Debate on Innovation and Cost

In late 2013, the pharmacy marketplace was alerted to the likelihood of significantly increased costs to treat hepatitis C resulting from the FDA's approval of two new drug therapies, Olysio and Sovaldi. As a result, in 2014, plan sponsors and insurers have absorbed significantly higher costs thus far for hepatitis C drug therapy, creating a controversy on the trade-offs between innovation and cost that has caught the attention of some in Congress.

Background

In 2013, the FDA approved two new oral drugs for the treatment of hepatitis C — Olysio and Sovaldi. Clinically, there is little debate these oral therapies are superior to the injectable medications already on the market. The cure rates approach 90%, side effects are lower, and duration of treatment shorter. By all accounts, Sovaldi and Olysio represent a welcomed breakthrough in innovation for those afflicted by hepatitis C and the physicians who treat them.

Cost of Innovation

The challenge these new therapies pose is related to cost and prevalence. Historically, most specialty drugs treat diseases with relatively low incidence. However, this is not the case with hepatitis C. The Centers for Disease Control indicates that roughly 3.2 million people in the US have chronic hepatitis C. The infection is most prevalent among those persons born between 1945 and 1965, the majority of whom were likely infected during the 1970s and 1980s. There is another population segment that is hepatitis C positive, but currently undiagnosed and asymptomatic. These prevalence rates are of high concern to plan sponsors, insurers, Medicare, and Medicaid agencies grappling with how to address the approximate \$1,000 per dose cost of Sovaldi as a growing number of individuals meet the clinical criteria for this drug therapy. The estimated cost for a course of therapy is around \$85,000. This cost does not include the cost of one or more other specialty drugs recommended in combination with Sovaldi.



Notwithstanding the high cost of these new hepatitis C drugs, the bottom line is that they can achieve a cure rate of up to 90% with a shorter therapy duration than older drugs — 12 weeks vs. 24 or 48-week regimens.

Congressional Interest

The cost of Sovaldi in the US has attracted Congressional attention. In March of this year, several ranking Democrats on the House of Representative's (House) Energy and Commerce Committee [requested](#) that biotechnology company, and maker of Sovaldi, Gilead Sciences, brief their staff on how pricing for the drug was set and associated cost implications on public health. The Energy and Commerce Committee has jurisdiction over Medicaid and shares jurisdiction over Medicare with the Ways and Means Committee. While the House is currently controlled by Republicans, the pricing of Sovaldi has attracted bipartisan attention in the Senate. In July, Senators Ron Wyden (D-OR) and Chuck Grassley (R-IA) [requested](#) a more detailed explanation of the pricing of Sovaldi in both the US and other countries, along with supporting documentation. Senator Wyden is the chair of the Senate Finance Committee and Senator Grassley is a senior member and former chair of the committee — which has jurisdiction over Medicaid and Medicare. It remains to be seen what will come of these congressional inquiries.

Future Innovation

Other hepatitis C drugs under development have the potential for cure rates exceeding 90%. Some are expected to be approved by the FDA in 2015 and provide Sovaldi with competition that could result in lower costs for hepatitis C drugs.

Marketplace Overview

The marketplace is responding quickly to this issue. We have begun to see state Medicaid agencies limit treatment to only the most severe cases as they struggle to address funding issues. This practice has sparked lawsuits from individual patients. On the plan sponsor front, we are learning about potential coverage reviews and other utilization management initiatives being considered by PBMs and health plans. These include possibly excluding certain of these specialty drugs from coverage as a PBM negotiation tactic to extract pricing concessions from pharmaceutical manufacturers. With respect to Sovaldi, in particular, some PBMs are taking a wait-and-see approach and will determine whether to exclude this drug from coverage as new hepatitis C drugs enter the market in 2015.

Comment. Keeping perspective is critical in making objective decisions about the costly coverage of these drugs. This requires plan sponsors to strike a delicate balance between the cost of these drugs and the higher cost of covering a liver transplant or other costly complications under their medical plan. Liver transplants average about \$600,000 per patient. Plan sponsors need to weigh the interrelationship between pharmacy plan coverage and costs, and their impact on medical plan costs in making decisions about drug coverage and other strategic issues.

Next Steps

We will continue to monitor and update you as the management of this and other therapeutic classes of specialty medications evolve. Additional new drug therapies for hepatitis C are expected to be released in the near future, which will likely impact the overall strategies of plan sponsors, health plans, and PBMs in managing specialty drugs. All health care stakeholders will be keeping a close eye on the outcome of this important issue as a precedent for managing new specialty medications entering the marketplace to treat other common diseases and conditions.

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