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Harvoni® Utilization in the Weeks after Launch: Patterns and Implications

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There are still almost **1.5 million patients with diagnosed** hepatitis C in the U.S. who are untreated and an estimated **1.5 million who are infected and not yet diagnosed.**

Background

The extraordinary cost of treating hepatitis C has become an issue of increasing importance for health care payers, as well as state and federal budgets, since the release of sofosbuvir (Sovaldi®) in December 2013. The highly effective medication costs approximately $1,000 per pill and approximately $84,000 for a course of therapy. Historically, the substantial side effects and modest efficacy of hepatitis C treatment encouraged physicians to delay therapy until absolutely necessary, a process known as "warehousing" patients. The launch of Sovaldi led to much greater rates of treatment; roughly 100,000 hepatitis C patients in the U.S. and another 17,000 in Europe have been treated with the medication, with sales exceeding $8.5 billion worldwide. The rate of uptake of Sovaldi and the resultant costs surprised many, leading to significant budgetary shortfalls for commercial and government payers alike.

However, there are still almost 1.5 million patients with diagnosed hepatitis C in the U.S. who are untreated and an estimated 1.5 million who are infected and not yet diagnosed. Adding to payer concerns, research has shown that once treatment is initiated, not all patients complete therapy. One recent study demonstrated that real-world discontinuation rates of therapy with Sovaldi are several times greater than was seen in randomized controlled trials.[1] This is likely related to the need for a combination therapy with other anti-viral medications, such as interferon products and/or ribavirin, that pushes costs even higher. For example, a 12-week course of the combination of Sovaldi and Olysio®, a protease inhibitor, costs approximately $150,000.

Launch of Harvoni

In October 2014, a new combination therapy from Gilead, the same manufacturer that introduced Sovaldi, was approved for use in the U.S. to treat patients with hepatitis C genotype 1 infections. The new medication, Harvoni, is a fixed-dose combination of sofosbuvir and ledipasvir that is only taken once a day, and therapy can be completed in as little as eight weeks for treatment-naïve patients without cirrhosis and a low viral load (< 6 mIU/mL). The medication costs approximately $1,125 per pill and $94,500 for a 12-week course of therapy – the length of therapy recommended for treatment-naïve patients with cirrhosis. Harvoni does not require any additional

concurrent therapy (such as interferon or ribavirin) to deliver cure rates of 94 percent to 99 percent for the treatment of hepatitis C genotype 1 infections.

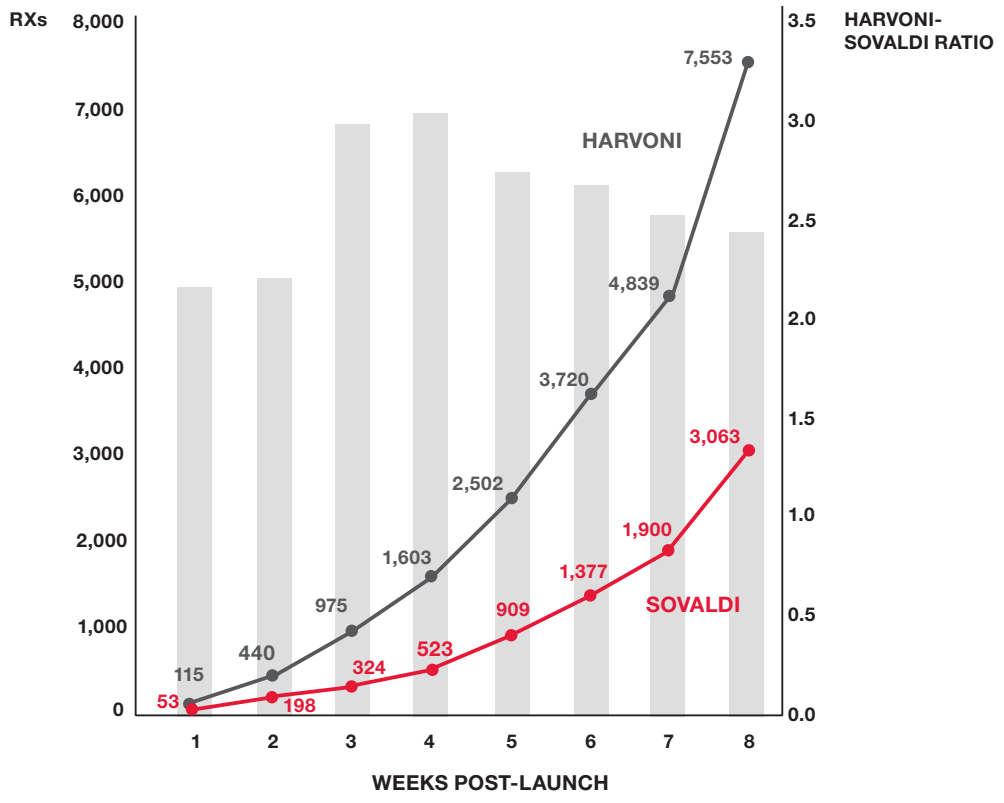
There was great anticipation in advance of the release of Harvoni; experts wondered whether a higher proportion of patients with hepatitis C would be treated, in particular those healthier and asymptomatic patients that previously often went without treatment. With the high tolerability and effectiveness of Sovaldi, some expected a considerable increase in treatment rates and related cost outlays when this simpler and less costly regimen became available.

Post-Launch Utilization Patterns

At CVS/caremark, one of the nation's largest pharmacy benefit managers with more than 65 million members, we wanted to understand the trajectory of uptake to help prepare for the budgetary implications associated with Harvoni's launch. We assessed the rates and costs of Harvoni prescriptions in the first eight weeks after market availability and studied use in CVS/caremark-covered populations. We compared Harvoni prescription rates with Sovaldi in the first eight weeks after its launch and also compared Harvoni prescribing to contemporary Sovaldi prescribing.

In the eight weeks after launch, rates of Harvoni prescribing were approximately 2.5 times the rates of Sovaldi prescribing after its launch last year. (Figure 1)

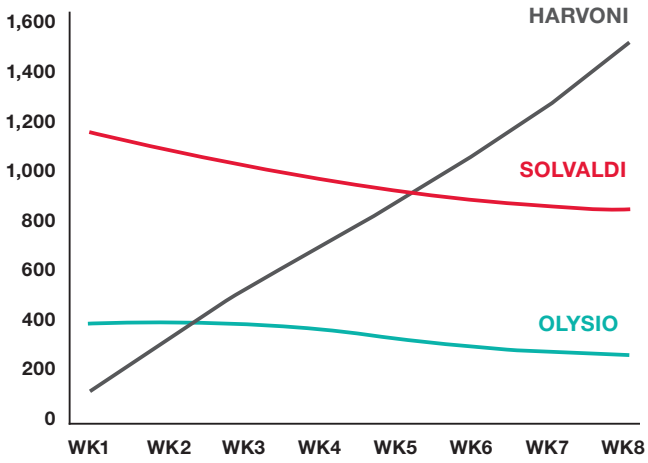
FIGURE 1. NUMBER OF HARVONI AND SOVALDI PRESCRIPTIONS DISPENSED TO CVS/CAREMARK MEMBERS IN THE EIGHT WEEKS AFTER EACH DRUG'S LAUNCH



In the eight weeks after launch, rates of **Harvoni prescribing were approximately 2.5 times the rates of Sovaldi** prescribing in the same period after its launch last year.

By the end of November, Harvoni prescribing rates eclipsed concurrent Sovaldi prescribing rates (Figure 2). Unlike Figure 1, which compares use in the eight weeks after launch of each drug, Figure 2 shows use of Harvoni, Sovaldi and Olysio during the same time period, the eight weeks after Harvoni became available. Previous studies of Sovaldi prescribing trajectories suggest that there had been a plateau and modest decline in prescribing rates of Sovaldi leading up to the Harvoni launch. In our study, there has not been a pronounced reduction in the use of Sovaldi since the launch of Harvoni. These findings suggest that a higher proportion of patients with hepatitis C are now being treated; Harvoni availability appears to have expanded the pool of treated patients rather than substituting for Sovaldi.

FIGURE 2. WEEKLY PRESCRIPTIONS FOR HEPATITIS C MEDICATIONS BETWEEN OCTOBER 13, 2014, AND DECEMBER 10, 2014



Budgetary Implications

Since the release of Sovaldi, much attention has been paid to the cost of treating hepatitis C. The new medications can offer a well-tolerated cure to the overwhelming majority of those infected, but the cure comes at a very high cost. We have posited that the critical issue with these new medications is not the per-patient cost but the size of the eligible population. High-priced specialty medications now target pools of patients measured in the millions.[2] Harvoni use has been brisk across market segments—commercial clients (i.e., employers and health plans) as well as Medicare and Medicaid. These findings suggest that payers and policymakers from all segments must actively plan for the new budget realities, as it appears that no populations will be spared.

Manufacturers have several ways to reach potential consumers of these products including direct-to-consumer advertising, the promotion of HCV testing, and copay coupons that are readily available online. All increase utilization among consumers while simultaneously jeopardizing payor management and formulary strategies.

In this analysis, we find that Harvoni uptake after launch has been swift, approximately 2.5 times as rapid as Sovaldi prescribing after its launch, and Harvoni use has already surpassed Sovaldi use overall in plan members with a CVS/caremark pharmacy benefit. Moreover, there has been only modest overall reduction in corresponding Sovaldi use to date, suggesting that there is an increase in the number of eligible patients now being treated. The consistency of Sovaldi use indicates that not only are more type 1 patients being treated, increasingly with Harvoni, but type 2-6 genotypes continue to be treated as well.

These findings have important implications for those who manage health care budgets. If the pool of treated patients is, in fact, expanding as it appears to be, these trends could lead to substantial and unplanned increases in expenditures. Such increases will likely be passed down to patients in the form of increased premiums, predicted to increase by as much as $200 to $300 per person, specifically in relation to the cost of hepatitis C treatment alone.[2]

Managing These Costs

Pharmacy benefit managers are well-positioned to develop thoughtful, clinically nuanced responses to these marketplace changes to provide high-quality, appropriate care for patients while controlling rising costs. In our evaluation, four approaches are critical.

First, CVS/caremark will use prior authorization to drive evidence-based, genotype-specific targeted therapy, both optimizing efficacy and reducing unnecessary costs. Such an approach requires genotype testing to determine appropriate therapy and better guides the right therapy to the right patients. This process ensures that people are not improperly treated, thereby eliminating waste.

Second, evaluate severity of illness to determine when to begin treatment. Some payers and a few employers are evaluating the degree of fibrosis a patient has and then deciding if it is possible to wait on therapy. These programs are based on the fact that the disease progresses slowly, and substantial progression can be prevented by therapy guided by frequent fibrosis screening tests. Fortunately, these tests are becoming less invasive than in the past. By delaying therapy, payers may benefit from the launch of new highly effective treatments and greater competition, which will drive down unit costs.

Third, thoughtful formulary placement will also be used to drive down costs for payers. There will likely be a new product available in the marketplace shortly, manufactured by AbbVie. The new product has been shown to have similar efficacy to the therapies currently available. Additional products will likely reach the market in the next 24 to 26 months. Consistent with its past practices, CVS/caremark will pursue an aggressive strategy to negotiate with manufacturers and use both formulary step edits and/or formulary product exclusions to control costs for patients and payers.

Fourth, provide adherence support to help patients complete therapy. CVS/caremark will apply a breadth of programs to support patients who start therapy to make sure they complete it. Through our specialty pharmacy, every patient has access to our Specialty CareTeams that include clinicians with specific expertise in supporting patients who have hepatitis C. We have also embedded disease management nurses with disease-specific expertise in the CareTeams. These nurses address the patient's overall condition, including comorbidities, lifestyle concerns and any non-specialty prescriptions the patient uses. We also make it easier for patients to start therapy with Specialty Connect. Specialty Connect allows patients who present specialty prescriptions to any CVS/pharmacy® retail store to receive centralized benefit guidance and CareTeam support from our specialty pharmacy. Improved access and patient-centered support is associated with substantial improvements in completion rates, enhancing patient care and reducing waste.[1]

This combination of thoughtful patient targeting, aggressive negotiation on price and patient-centered support will help ensure that the population receives the greatest benefit from these effective therapies with the lowest financial burden for payers.

Non-adherence to such costly therapy represents **great potential waste.**

References

1. Brennan TA, Lotvin A, Shrank W. Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates. Sept 2014. Available at: http://www.cvshealth.com/sites/default/files/hepatitisCutilization.pdf
2. Brennan T, Shrank W. New expensive treatments for hepatitis C infection. JAMA. 2014 Aug 13;312(6):593-4.