

Does Patient Cost Sharing for HCV Drugs Make Sense?

Darius N. Lakdawalla, PhD; Mark T. Linthicum, MPP; and Jacqueline Vanderpuye-Orgle, PhD

The launch of novel direct-acting antivirals (DAAs) for the treatment of hepatitis C virus (HCV) in 2013 brought the ever-present tension among innovation, drug pricing, and patient access into the media and policy-making spotlight. Although the clinical value of these drugs is clear, their high cost raised protests from insurers and health systems concerned that treating HCV patients with these highly effective new drugs would bankrupt the healthcare system. As a result, some insurers have shifted the cost burden partly onto patients with HCV by placing these therapies on high-cost specialty drug tiers within their formularies. This approach might seem appealing and “equitable” at some level, but closer reflection reveals that it would expose patients with HCV to potentially significant financial burdens at a time when they are least able to cope with them. There are better options for sharing the costs of HCV treatment among beneficiaries.

Effects of Cost Sharing on Adherence in HCV

Opponents of high cost sharing commonly argue that it reduces patient adherence and leads to worse health outcomes. Indeed, there is considerable evidence to suggest that high levels of cost sharing have such effects in a wide variety of disease areas¹: on average, 10% greater cost sharing reduces pharmaceutical spending by 2% to 6% but is also associated with lower initiation and adherence.² However, this pattern does not appear to hold in the case of HCV therapies. Although adherence data for new DAAs remain scarce, we can assess the relationship between cost sharing and adherence to older, less-effective regimens, such as pegylated interferon (Peg-IFN) alone, Peg-IFN plus ribavirin (RBV), or so-called “triple therapy”—Peg-IFN plus RBV plus older-generation DAAs boceprevir or telaprevir (BOC/TPV).

The **Figure** illustrates the relationship between adherence and cost sharing for employer-insured patients with

HCV who were prescribed older HCV regimens between 2004 and early 2014. Adherence is measured by the proportion of days covered (PDC), which measures the fraction of days on which the patient had the medication on hand—the lower the PDC, the more days of therapy patients are forced to miss. The degree of cost sharing is measured as the proportion of total drug costs, paid out of pocket, for each insurance plan and year in the data; it is broken into 4 quartiles: 1 (lowest cost-sharing plan-years) to 4 (highest).

The Figure also demonstrates how average adherence across plan-years varies across cost-sharing quartiles for different HCV regimens. It shows no economically or statistically meaningful effects of cost sharing on adherence; the only factor possibly affecting adherence appears to be regimen type, where patients may be slightly less adherent to regimens that include BOC/TPV. However, higher cost sharing does not seem to discourage adherence to earlier HCV regimens. Patients were willing to bear higher out-of-pocket costs for the older generation of drugs. Economic theory would suggest that they would be just as, if not more, willing to bear higher out-of-pocket costs for the newer, more effective and more tolerable generation of drugs.

Does High Cost Sharing for DAAs Make Sense?

In light of this, it would be tempting to conclude that high cost sharing for new DAAs is unlikely to discourage adherence. Although this might be the case, new DAAs are very expensive and likely to be considered specialty drugs for reimbursement purposes. Subsequently, patients’ actual out-of-pocket costs under high cost-sharing arrangements could be quite large, even with private insurance. High cost-sharing arrangements for these therapies would therefore impose a significant financial burden on patients who are already bearing the burden of a potentially life-threatening disease.

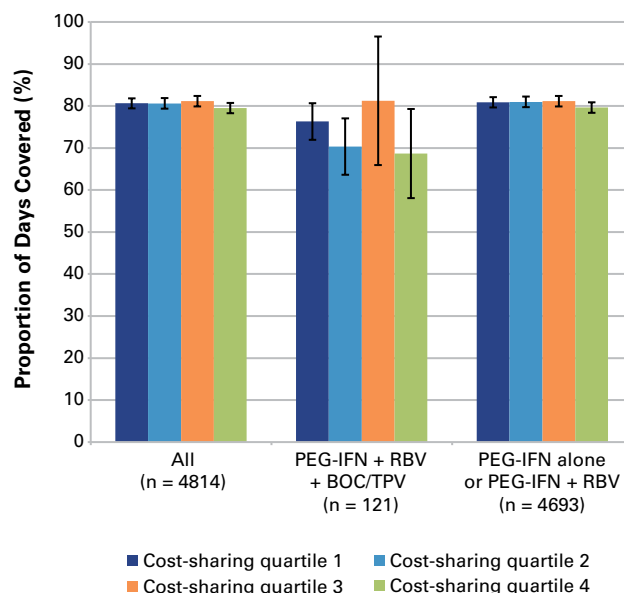
The point of insurance is to protect risk-averse consumers from bearing the full risk of large negative outcomes. Most individuals would prefer to pay a \$1000 premium for homeowner’s insurance than live in the perpetual shadow of a 1% chance of a \$100,000 loss. Even though the expected cost of both these arrangements is identical, risk-averse consumers would strictly prefer to buy actuarially fair insurance than to live with the risk of a sudden, large financial loss. The same logic applies to health insurance: consumers would rather pay an actuarially fair premium to cover services that they may or may not eventually use than to bear the risk of a large, but uncertain, negative outcome.

This is true even in the case of high cost-sharing arrangements. Suppose annual healthcare costs for a severely ill patient are \$100,000 and that 1 of 10 premium-paying beneficiaries is severely ill in a given time period. Now, compare a cost-sharing arrangement that requires those who become severely ill to pay \$10,000 of their healthcare costs out of pocket with one that increases premiums by \$1000 for all beneficiaries. Both of these arrangements generate the same amount of total revenue to the insurer; however, most consumers would rather pay \$1000 in premiums to avoid the 10% risk of suddenly losing \$10,000 with the onset of a severe illness. To this point, prior research shows that consumers would rather pay \$260 per month in additional premiums in order to avoid an expected cost of \$100 per month in cost sharing on high-cost drugs.³

This is not to say that cost sharing is never a useful tool or that premiums are always a preferable substitute for them, but the economic goal of cost sharing is to discourage inappropriate use of therapies that are not legitimately needed—this is not the issue with novel HCV therapies. New DAAs are highly appropriate and effective,⁴ curing HCV in more than 90% of patients.^{5,7} Other research in this special issue on HCV argues that even early stage patients with high functional status can benefit substantially over the long-term from DAA treatment.⁸

Cost sharing appears even less efficient when one considers that treatment makes long term financial sense for society: the treatment of HCV today will lead to lower medical expenditures for covered individuals in later years. Combined with the health and longevity gains from treatment, this is likely to lead to a return on investment within 8 years.⁸ Curing more patients with HCV in the present also prevents more cases of infection in the future, and the reduced rate of transmission will accelerate the return on investment even further. Further, there is no good economic reason to discourage patients with HCV

■ **Figure. Adherence (proportion of days covered) by Plan Cost-Sharing Quartile^{a,b,c}**



BOC/TPV indicates boceprevir or telaprevir; HCV, hepatitis C virus; PDC, proportion of days covered; PEG-IFN, pegylated interferon; RBV, ribavirin. ^aData used are from a large employer-insured claims database. ^bSample was restricted to patients aged 18 to 64 years, diagnosed with chronic HCV infection between 2004 and March 2013. Study sample included 4814 observations in total from 1867 individual patients. ^cAnalysis was conducted at patient time-period level of observation, where time periods are 12-week intervals from first claim for HCV drug. Columns illustrate the average PDC per patient per 12-week period. Black lines represent the 95% CIs of average PDC.

from using novel agents and every reason to protect them against financial risk.

Finally, high cost sharing for HCV is not only inefficient, it is also inequitable. The imposition of high out-of-pocket costs on highly effective drugs can have disastrous effects on patients’ financial well-being. These effects are seen clearly in other clinical areas: for example, patients with cancer in Washington state have more than double the risk of filing for bankruptcy compared with individuals without cancer.⁹ Furthermore, cancer’s financial burden is particularly high for low-income households, with over a quarter of personal bankruptcies among low-income households filed as a result of patients’ out-of-pocket medical expenses.¹⁰ The question of equity becomes particularly acute in the case of American patients with HCV, nearly one-third of whom live below the poverty line.¹¹ Shifting costs onto the least financially secure members of society is tantamount to a regressive tax, with high potential penalties—in terms of illness and HCV transmission—for those unable to pay.

Conclusions

HCV treatment is expensive, but it is also extraordinarily effective. Although investing in it will impose real costs on society, those costs are justified by even larger downstream benefits. Insurers are struggling to find ways to afford the costs of treatment, but high cost-sharing arrangements that impose large out-of-pocket expenses on very sick individuals are sub-optimal solutions. Instead, modestly higher premiums for all beneficiaries can achieve the same financial goals for the insurer, without excessively burdening the sickest and least advantaged members of society.

Author Affiliations: Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California (DNL), Los Angeles, CA; Precision Health Economics (MTL, JV-O), Los Angeles, CA.

Source of Funding: None.

Author Disclosures: Dr Vanderpuye-Orgle and Mr Linthicum are employed by Precision Health Economics (PHE), a healthcare consultancy to life science firms. Dr Lakdawalla is the chief strategy officer and owns equity in PHE.

Authorship Information: Concept and design (DNL, MTL, JV-O); acquisition of data (JV-O); analysis and interpretation of data (DNL, MTL, JV-O); drafting of the manuscript (DNL, MTL, JV-O); critical revision of the manuscript for important intellectual content (DNL, MTL, JV-O); statistical analysis (JV-O); and supervision (DNL).

Address correspondence to: Darius N. Lakdawalla, PhD, USC Schaeffer Center, 635 Downey Way, Verna & Peter Dauterive Hall (VPD), Ste 210, Los Angeles, CA 90089-3333. E-mail: dlakdawa@healthpolicy.usc.edu.

REFERENCES

1. Goldman DP, Joyce GF, Escarce JJ, et al. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA*. 2004;291(19):2344-2350.
2. Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61-69.
3. Romley JA, Sanchez Y, Penrod JR, Goldman DP. Survey results show that adults are willing to pay higher insurance premiums for generous coverage of specialty drugs. *Health Aff (Millwood)*. 2012;31(4):683-690. doi: 10.1377/hlthaff.2011.1301.
4. Bhattacharya J. A way out of the dismal arithmetic of hepatitis C treatment. *Am J Manag Care*. 2016;22(5 Spec Issue No. 6):SP183-SP184.
5. Afdhal N, Reddy KR, Nelson DR, et al; ION-2 Investigators. Ledipasvir and sofosbuvir for previously treated HCV genotype 1 infection. *N Engl J Med*. 2014;370(16):1483-1493. doi: 10.1056/NEJMoa1316366.
6. Afdhal N, Zeuzem S, Kwo P, et al; ION-1 Investigators. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. *N Engl J Med*. 2014;370(20):1889-1898. doi: 10.1056/NEJMoa1402454.
7. Kowdley KV, Gordon SC, Reddy KR, et al; ION-3 Investigators. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. *N Engl J Med*. 2014;370(20):1879-1888. doi: 10.1056/NEJMoa1402355.
8. Moreno G, Mulligan K, Huber C, et al. Costs and spillover effects of private insurers' coverage of hepatitis C treatment. *Am J Manag Care*. 2016;22(5 Spec Issue No. 6):SP236-SP244.
9. Ramsey S, Blough D, Kirchoff A, et al. Washington state cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Aff (Millwood)*. 2013;32(6):1143-1152. doi: 10.1377/hlthaff.2012.1263.
10. Gross T, Notowidigdo MJ. Health insurance and the consumer bankruptcy decision: evidence from expansions of Medicaid. *J Public Econ*. 2011;95(7-8):767-778.
11. Denniston MM, Jiles RB, Drobeniuc J, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. *Ann Intern Med*. 2014;160(5):293-300. doi: 10.7326/M13-1133. ■

www.ajmc.com Full text and PDF