

Accessing the Cure: Helping Patients With Hepatitis C Overcome Barriers to Care

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Hepatitis C virus (HCV) is an illustrative example of the dilemma faced by patients in the American healthcare landscape: HCV is a chronic, progressive disease for which a cure exists, but at such high prices that cost-sharing innovations create significant barriers to care, treatment, and a cure. Previous HCV treatments were ineffective and had a wide range of severe side effects, so much so, that patients and their providers chose to wait for newer and more effective options. Yet, once these options became available, cost-sharing mechanisms such as plan premiums, deductibles, co-payments, and coinsurance created barriers to treatment, producing a large pool of patients infected with HCV who were willing but unable to access a cure. In response, advocacy organizations like the National Viral Hepatitis Roundtable (NVHR) and Project Inform have developed innovative strategies to improve access to HCV care and treatment.

Overview of HCV

HCV is the most common blood-borne pathogen in the United States, with 3.2 to 5 million individuals currently infected. If left untreated, up to 30% of those with HCV will develop cirrhosis—scarring that damages the liver, causing it to not function properly—in 20 to 30 years. Among patients with cirrhosis, there is a 1% to 5% annual risk of developing liver cancer, and a 3% to 6% annual risk of hepatic decompensation—disease progression requiring a liver transplant. Once an individual is diagnosed with a decompensated liver, their risk of death in the next year runs 15% to 20%.^{1,2} However, early treatment and cure of HCV can virtually eliminate all of these long-term complications.

State of HCV Treatment

Prior to 2013, HCV treatment was long (24-48 weeks), carried a host of severe side effects that were intolerable for many, and relatively ineffective (sustained virologic response

ABSTRACT

Hepatitis C virus (HCV) is an illustrative example of the dilemma faced by patients in the American healthcare landscape: HCV is a chronic, progressive disease for which a cure exists, but at such high prices that cost-sharing innovations create significant barriers to care, treatment, and cure. Previous HCV treatments were ineffective and had a wide range of severe side effects, so much so, that both patients and their providers chose to wait for newer and more effective options. Yet, once these options became available, cost-sharing mechanisms, such as plan premiums, deductibles, co-payments, and coinsurance, created barriers to treatment, producing a large pool of patients infected with HCV who are willing but unable to access a cure. In response, advocacy organizations like the National Viral Hepatitis Roundtable and Project Inform have developed innovative strategies to improve access to HCV care and treatment.

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[SVR], the equivalent of virologic cure, with rates ranging from 45%-80%). Consequently, many patients and their providers chose to wait for better options. In 2013, the pegylated-interferon free direct-acting antiviral (DAA) era began. With these new medications, and several more in the years since, the HCV treatment landscape has changed dramatically: the new regimens are shorter (average 12 weeks), have fewer side effects, and cure 90% to 100% of patients depending on genotype, severity of disease, treatment experience, and other factors.

The Benefits of Curing HCV

In their guidance for managing and treating HCV, the American Association for the Study of Liver Diseases and Infectious Diseases Society of America state: “Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.”³ The goal of treatment is to cure the patient.

Once a cure is achieved, most patients experience improved liver functioning, and many experience a reversal of fibrosis (mild scarring) over time. Even patients with cirrhosis (severe scarring) experience improved liver function and a reduction in the risk of developing end-stage liver complications. There is also evidence that cirrhosis can be reversed once SVR is achieved. This reduction in fibrosis and return to normal liver function comes with a host of other benefits, including the fact that cured patients live longer. Additional benefits of cure can be found in the [Figure](#).⁴

In addition to the clinical benefits, treating HCV is cost-effective. In a review of both the clinical and financial value of HCV treatments, the California Technology Assessment Forum found that although treating all patients regardless of liver disease severity is expensive, it meets the benchmark for cost-effectiveness in terms of the benefits gained.⁵ Waiting for more advanced liver disease to treat HCV significantly increases cost, and the cost per cure is lower for both treatment-naïve and non-cirrhotic patients, providing further evidence for the effectiveness of early HCV treatment.^{6,7} Additionally, curing HCV lowers healthcare costs—now and in the future—for all patients, including those with end-stage liver disease. Studies show that patients who are treated and cured of HCV have significantly lower medical expenses than those who are not, with savings increasing as the severity of HCV-related liver disease increases.⁸ When combined, the cost-effectiveness of treatment and long-term savings associated with curing HCV further cement the rationale for treating all patients with HCV.

■ Figure. Benefits of HCV Cure⁴

- Normalization of liver function enzymes
- Platelet increase in patients with thrombocytopenia
- Reduced risk of developing cirrhosis
- Reversion of fibrosis and, in some cases, cirrhosis
- Disappearance of varices (dilated blood vessels in the esophagus)
- Reduced risk of progression to liver cancer
- Reduced risk of decompensated liver disease
- Reduced risk of progression to liver failure and liver transplant
- Eliminates risk of transmission to drug-using or sexual partners
- Eliminates risk of mother-to-child transmission
- Improves quality of life
- Reduction of psychological distress (eg, anxiety, depression)
- Eliminates hepatitis C-related stigma
- Lessens healthcare utilization and costs
- Return to the workforce and/or improves productivity

HCV indicates hepatitis C virus.
Source: Marinho et al (2014).

Impact of Cost Sharing on Patient Access

In spite of the clinical benefits and cost-effectiveness of new DAAs, patient access has been limited. With the confluence of high-cost drugs, a millions-large potential patient pool, and pent-up demand for highly tolerable curative treatments, payers turned to heavy-handed utilization management strategies. The resulting spate of treatment denials prompted numerous lawsuits against commercial plans,^{9,10} Medicaid plans,¹¹ and correctional systems.¹²⁻¹⁴ In response to such a landscape and patient advocates’ concerns, CMS sent guidance in late 2015 to state Medicaid directors regarding the circumstances under which Medicaid law permits utilization management, clarifying that management strategies based on cost containment violate federal law.¹⁵ Although blanket treatment denials have hit Medicaid beneficiaries particularly hard, issues of cost sharing for commercial health insurance and Medicare beneficiaries are another important piece of this troubling puzzle. According to according to its Chief Development Operations Officer, Alan Richardson, from January through September 2015, of patients seeking treatment access assistance through the Patient Advocate Foundation’s Hepatitis C CareLine, 39% had commercial insurance and 25% were Medicare beneficiaries.

The latest innovations in HCV drug development fit neatly into the often cost-prohibitive benefit structures that health insurance plans have increasingly adopted. Commercial health insurers have numerous cost-sharing mechanisms at their disposal, including plan premiums, deductibles, co-payments, and coinsurance. Recent data show that insurers and, subsequently, employers, have steadily shifted the cost of healthcare to beneficiaries.¹⁶ Further, prescription drug plans have gradually instituted tiered formularies, initially beginning with just 2 tiers—1 for generics and 1 for brand-name medications—to the majority of plans now having 4 or 5 tiers, with the highest tier (ie, with the greatest cost sharing) reserved for so-called “specialty” or high-cost medications.¹⁷

Although the Affordable Care Act (ACA) implemented out-of-pocket (OOP) expense limits (not applicable to premiums) for nongrandfathered plans offered through the marketplace—up to \$6850 for an individual and \$13,700 for families in 2016¹⁸—these up-front costs can be prohibitive for those with chronic conditions requiring high-cost medications, such as for HCV. Due to the fractured and complex nature of healthcare coverage in the United States, with myriad cost-sharing variations, there is significant variability across payers and plans. However, 2015 data from the Kaiser Family Foundation ([eAppendix 1](#) [eAppendices available at www.ajmc.com]) show the significant burden of cost sharing.¹⁹ Fewer than half of all households described as nonelderly or nonpoor possess financial resources greater than mid-range OOP limits for their private insurance. This plummets to 18% when considering those at 100% to 250% of the federal poverty level.¹⁹ One can imagine a similar, if not grimmer, scenario among Medicare beneficiaries, approximately half of whom earned less than \$23,500 in 2013. Many will find themselves additionally encumbered by premiums for supplemental coverage.²⁰

Prescription drug formulary tiering is another mechanism by which patients encounter burdensome cost sharing. New DAAs for HCV are often classified as “specialty” drugs and placed on the highest cost-sharing tier. A 2015 Avalere Health study demonstrated that over a quarter of Silver-level marketplace plans placed HCV medications on specialty tiers.²¹ A similar picture emerged from a late 2015 examination of Florida’s Silver-level plans by The AIDS Institute, which also illustrated another trend—particularly among high/specialty drug tiers—toward cost sharing via coinsurance rather than co-payment.²²

Coinsurance—charging patients a percentage of a medication’s cost rather than a fixed co-payment—can result in significant costs to the patient, especially those with high deductibles and/or who require high-cost medi-

cation. In 2013, of employer-sponsored commercial prescription drug coverage plans with specialty tiers (23%), nearly half imposed coinsurance, with rates for specialty drugs averaging 30%, but reaching as high as 50%.²³ Nearly 100% of both Part D plan and Medicare Advantage drug plan beneficiaries have plans with a specialty tier, with nearly half of Part D plans and 81% of Medicare Advantage plans charging the maximum allowable 33% coinsurance rate. The same report cited that costs for one of the DAA agents could exceed \$5000 for a beneficiary in the first month alone. The Kaiser Family Foundation figure found in [eAppendix 2](#) offers a snapshot of this troubling trend in Medicare Part D Drug Plans.²⁴

Although cost-sharing strategies have a sensible place in healthcare financing, the placement of HCV curative therapies exclusively on specialty tiers and the trend toward coinsurance is highly problematic for patients, especially those of modest means, given the lack of generic alternatives. DAA treatments for HCV are the standard of care²⁵; there is no other equally safe and effective, yet less expensive, option for patients to try first. This puts patients with HCV in the quandary of either paying the cost—potentially sacrificing other necessities or incurring debt—or giving up on curing their chronic, potentially fatal illness.²⁶

Further, increased cost sharing negatively impacts treatment adherence. A 2012 literature review found that 85% of studies examined demonstrated that increases in cost sharing led to decreases in adherence.²⁷ In the case of HCV, poor adherence can lead to preventable drug resistance. Adherence—and subsequent cure—is vital for patients with HCV due to the often-overlooked multi-systemic nature of the virus, as well as its associated comorbidities, many of which exacerbate the progression and/or manifestation of HCV. Several such conditions also require prescription medication, at additional cost, particularly those that are also chronic (eg, diabetes, HIV, depression). Moreover, cure as prevention, that is, curing those at potential risk of transmitting the virus thus preventing further transmission, is critical to a public health elimination strategy, as HCV is infectious and incidence is rising in certain populations.²⁸

Solutions

In response to burdensome cost sharing for HCV patients, Project Inform and the NVHR are pursuing independent and collaborative strategies at the individual, state policy, and federal policy levels. At the micro level, Project Inform co-hosts (in collaboration with several other community-based organizations) HELP-4-HEP, a peer-managed, toll-free telephone helpline for those affected by HCV. Through HELP-4-HEP, patients can receive (among other

information and resources) assistance locating co-pay and other financial assistance for treatment, assistance navigating appeals processes, and referrals to local support groups to help ease the emotional hardship of living with a chronic, life-threatening virus, and the challenges that come with the related financial burdens.²⁹

In California, Project Inform publishes an annual Covered California plan choice guide³⁰ and a formulary analysis,³¹ addressing HIV, hepatitis B, and HCV medications. The plan choice guide provides information and resources for consumers to choose the most appropriate marketplace plan to meet their needs, while the formulary analysis helps consumers easily see what HCV drugs are on each plans' formularies, find what tier the medications are on, and identify some of the utilization controls placed on the medications.

Project Inform, in collaboration with other health advocates, also participated in a Covered California Specialty Drug Task Force. Consequently, Covered California adopted changes to help consumers to better understand and manage their prescription drug costs. Among other changes in the 2016 plan year, all marketplace plans will now provide out-of-pocket cost estimates for specific drugs; and for tier-4 drugs, will charge no more than \$250 per month for a single 30-day drug supply for Silver, Gold, and Platinum plans, and no more than \$500 per 30-day supply for Bronze plans.³²

Additionally, Project Inform and other partners worked to pass Assembly Bill (AB) 339, which limits cost sharing on specialty drugs, consistent with rules adopted by Covered California, but applied to private plans operating outside the exchange. In addition, AB 339 ensures coverage for drugs with no therapeutic equivalent across all plans, and the states that place most or all drugs to treat a condition on the highest cost formulary tiers may be considered discriminatory; additionally, plans shall not reduce the benefit for those with chronic conditions.³³

These state-level policy changes not only improve Californians' access to medications by limiting cost sharing, but also serve as useful examples for advocates in other states. To that end, NVHR provides open forums for partners like Project Inform to share this, and other strategies, with advocates around the country through webinars, monthly policy calls, and resource tools posted on the NVHR website.

At the federal level, NVHR continues to advocate, both independently and in coalition, with HHS on this issue, specifically for guidance and enforcement mechanisms as they relate to discriminatory benefit design under Section 1557 of the ACA, which addresses nondiscrimination protections for those with chronic conditions, among others.³⁴ Regardless of the intentions behind the cost-sharing strategies outlined above, their effect is for patients with more

costly, chronic conditions like HCV to self-select out of plans, and greatly reduces the plan options available. Plans designed in a way that actively dissuades patients from selecting them undermines both the intent and the spirit of the ACA. As such, it is critical that HHS provide explicit guidance, examples, oversight, and enforcement mechanisms to ensure equitable access to coverage and reasonable cost sharing for those living with chronic conditions.

Conclusions

For individuals living with HCV, the immense hope created by a cure has been stifled due to the current crisis in treatment access, and highly burdensome cost sharing in commercial health insurance and Medicare plans represent significant barriers. The potential effects on patients are immense physically, psychologically, and financially. Project Inform and NVHR are proud partners in addressing the issues presented by cost sharing across health insurance payers, and employ strategies at multiple levels of intervention to achieve the greatest impact and broadest support for our communities. From individual assistance and sharing best practices, to state- and federal-level policy advocacy, Project Inform and NVHR are dedicated to removing such obstacles to achieve universal treatment access for everyone living with HCV.

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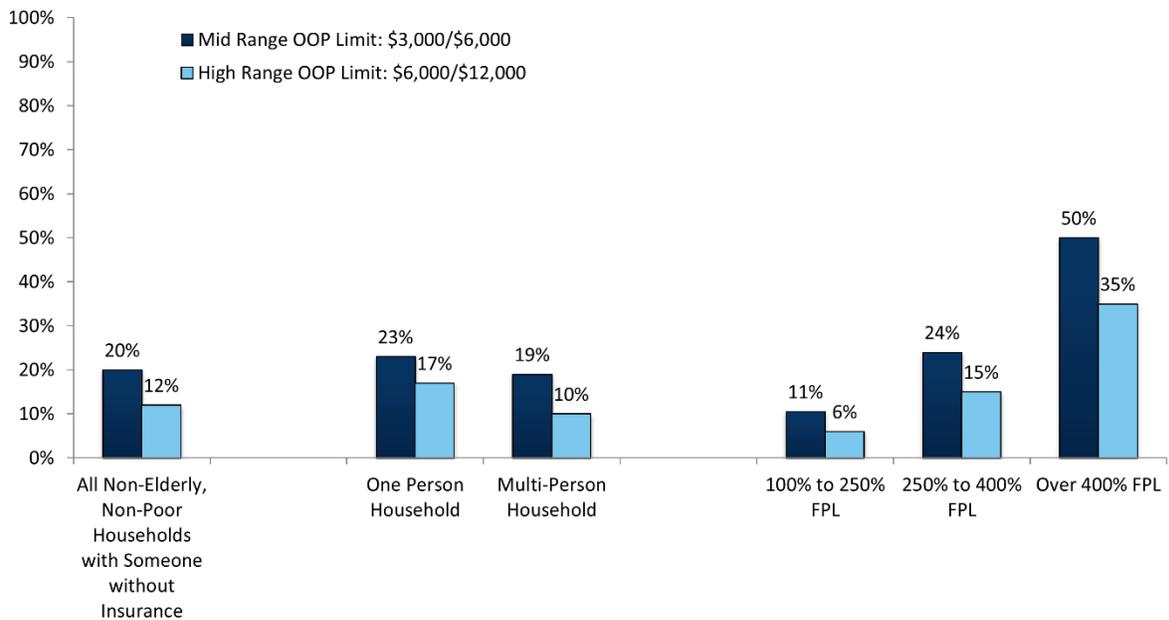
eAppendix 1

Taken from the Kaiser Family Foundation issue brief, “Consumer Assets and Patient Cost Sharing,” their figure illustrates the household’s ability to pay out-of-pocket health costs.

Figure 9

Percent of Households with Liquid Financial Assets Greater than Specified Out-Of-Pocket Limits

Among All Non-Elderly, Non-Poor Households with Someone without Insurance



NOTES: FPL refers to the 2013 Federal Poverty Level.

SOURCE: Kaiser Family Foundation analysis of 2013 Survey of Consumer Finance (SCF) data.



FPL indicates federal poverty level; OOP, out-of-pocket.

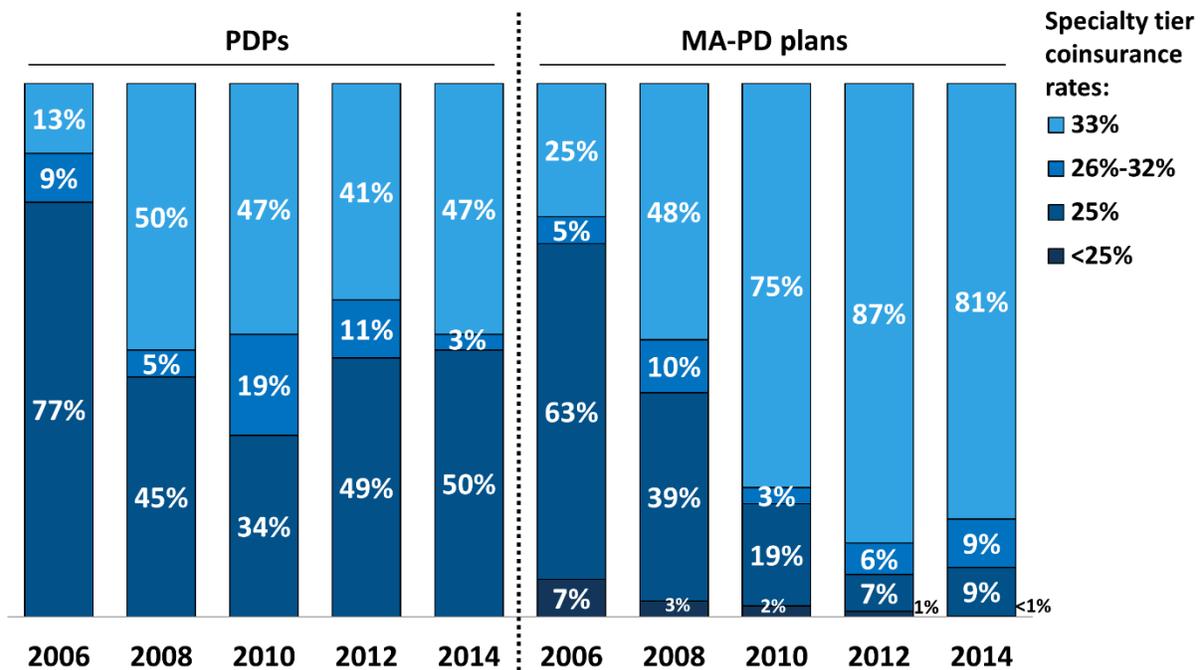
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eAppendix 2

Taken from the Kaiser Family Foundation report, “Medicare Part D in Its Ninth Year: The 2014 Marketplace and Key Trends, 2006-2014,” their figure illustrates specialty drug tier coinsurance rates for Medicare Part D.

Exhibit 3.4

Share of Enrollment in Medicare Part D Plans with Specialty Tiers, by Coinsurance Rate, 2010-2014



NOTE: PDP is prescription drug plan. MA-PD is Medicare Advantage Drug Plan. Estimates weighted by enrollment in each year. Analysis of MA-PD plans excludes Special Needs Plans. Excludes plans with flat copayments for specialty tiers. SOURCE: Georgetown/NORC analysis of data from CMS for the Kaiser Family Foundation.



MA indicates Medicare Advantage; PDP, prescription drug plan.

Figure used as is from source: Hoadley J, Summer L, Hargrave E, Cubanski J, Newman T.

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