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High-Cost HCV Drugs in Medicaid: Final Report

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Contents

Introduction

Although prescription drugs account for less than six percent of Medicaid expenditures in 2015,[1] federal and state policymakers have long been concerned with the rate of growth for this category of service.[2] Medicaid drug spending increased by less than five percent per year between 2008 and 2013,[1] primarily because many new multiple source (generic) products entered the market as substitutes for popular single source (brand-name) drugs. However, spending surged nearly 25 percent from 2013 to 2014, and another 14 percent in 2015.[1] A significant factor in this resurgence is the introduction of new, high cost drugs for various conditions.[3] Many of these new products are called "specialty" drugs, although there is no broadly accepted definition of what is a specialty product.

Some of the most visible examples of the new wave of high cost drugs, and certainly among the most important for Medicaid programs, are much-publicized treatments for hepatitis C. These drugs offer the promise of a "cure" for many patients, in terms of sustained viral response, but have list prices that many argue are unaffordable and unsustainable. Data from the Centers for Medicare & Medicaid Services (CMS) indicate that Medicaid programs nationwide spent more than $2.8 billion in 2015 on the two most popular hepatitis C treatments at the time, Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir), almost five percent of total drug spending ($57 billion; neither amount includes federal or state rebates).[4,5]

The first phase of this project documented trends in the use and spending for hepatitis C drug treatments, new and old, across all states. This final report focuses on how state Medicaid programs reacted to the introduction of new hepatitis C drugs. Most of the findings come from series of semi-structured interviews conducted with pharmacy and medical directors and other top Medicaid officials in 11 states from September to December 2016. We also interviewed representatives from the national Medicaid managed care plan associations to get their perspective on state and plan policies. The discussions covered three main topics:

1. How states developed coverage and prior authorization policies for the new hepatitis C drugs, starting with Sovaldi in 2013, and how those policies changed as more drugs entered the market and the economic, social, and political landscape evolved.
2. How states addressed the effects of the new hepatitis C drugs on Medicaid budgets and the finances of managed care plans serving Medicaid enrollees.
3. How their experiences with the new hepatitis C treatments affected state Medicaid officials' and managed care plan representatives' thinking about policies for other high-cost drugs.

The intent of the interviews was to gain insights into whether, how, and why state and managed care policies have changed. We also intended to capture insights into how Medicaid agencies and managed care plans are responding to the evolving landscape of high-cost drugs more generally. By comparing and contrasting responses across states, we assessed the extent to which their experiences managing the impact of high-cost drugs suggest realistic options for federal policy.

Background

A Brief Epidemiology of Hepatitis C

Hepatitis C is a liver infection caused by the blood-borne hepatitis C virus (HCV), with seven distinct genotypes.[6,7] Transmission occurs mostly by percutaneous exposure, such as unsafe injection practices, needle-stick injury, or inadequate infection control. Infection may be acute or chronic. Acute infections are not life-threatening and often clear in less than a year without treatment. However, most people who are infected (55% to 85%) develop chronic HCV infections, and 15% to 30% of these people develop liver cirrhosis within 20 years.[8]

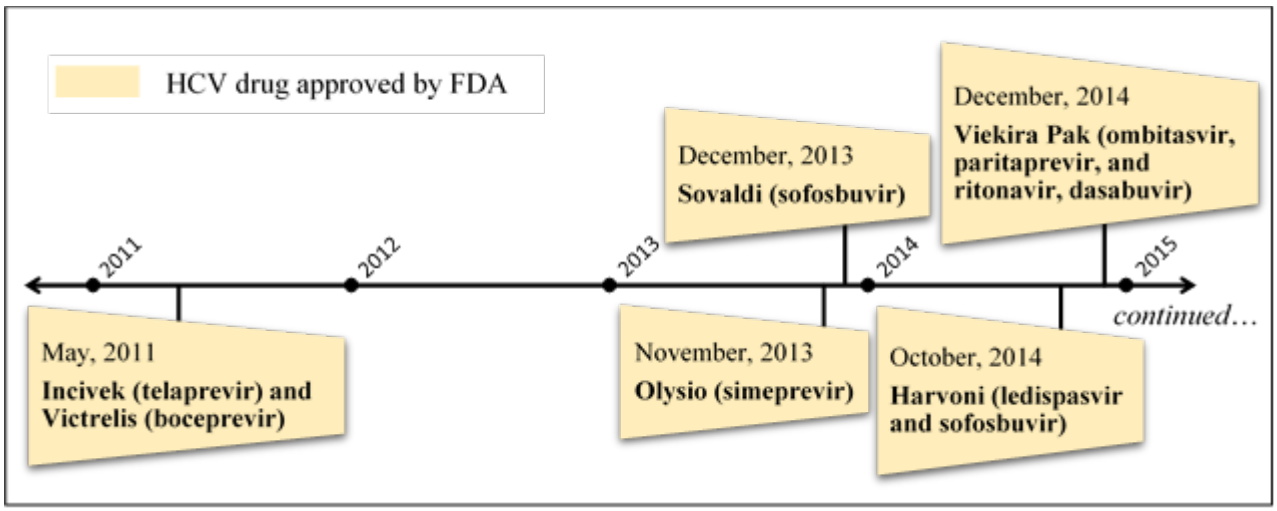
An estimated 3.5 million US residents live with HCV.[9] The prevalence of chronic HCV infection in the US (i.e., the number of people living with the infection) dropped between 1988 and 2010, in part due to lower transmission rates but also because of increasing mortality, which is an important impetus for the search for more effective treatments.[10,11] However, incidence of new HCV infections trended upward in the last 3-5 years, albeit at rates far below those of the 1980's, when roughly 230,000 persons were newly infected each year.[12] The Centers for Disease Control and Prevention (CDC) estimates that 30,500 persons were newly infected in 2014.[13] A rising incidence of acute HCV infection in younger populations is associated with injectable heroin use.[14]

Drug Treatment Options for Hepatitis C

Until recently, the standard treatment for chronic HCV infection was pegylated interferon plus ribavirin, a nearly year-long regimen of weekly injections and multiple pills per day, which had relatively low success rates and significant side effects.[15] This unappealing combination led many patients to forgo treatment.[16]

In 2011, the FDA approved two new HCV drugs, Merck's Victrelis (boceprevir) and Vertex's Incivek (telaprevir) (Figure 1). Both offered modest improvements in outcomes, but the regimens were complex and had significant side effects, including anemia.[15] They were discontinued in 2014 because newer drugs offered better outcomes and fewer side effects. However, the relatively high list prices for Victrelis and Incivek were factors that contributed to

Figure 1. Timeline of Notable HCV Events



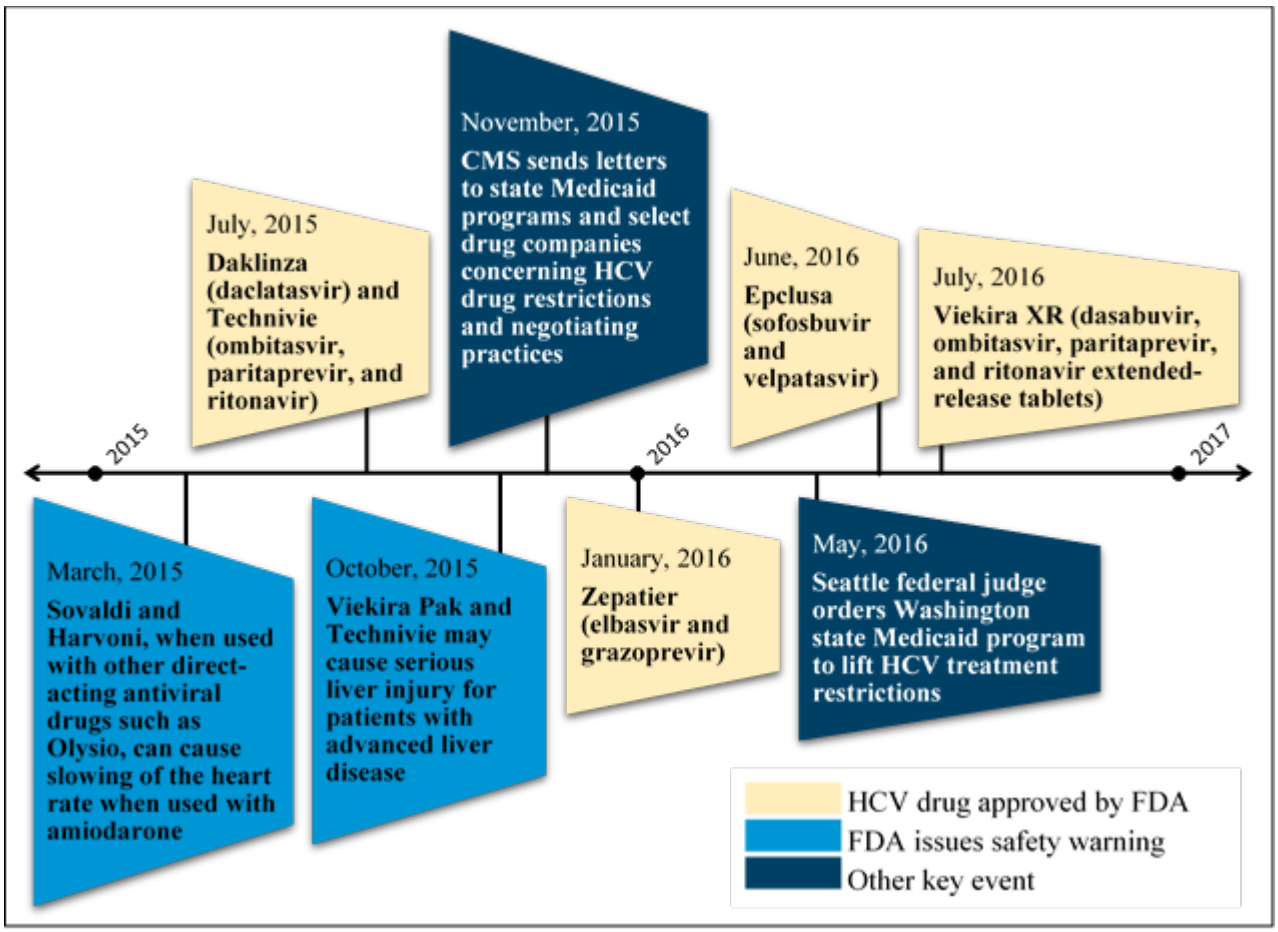
the even higher initial list prices for the next wave of treatments.[17]

Janssen's Olysio (simeprevir) and Gilead Science's Sovaldi (sofosbuvir) received approval in 2013 for use with pegylated interferon and ribavirin to treat HCV genotype 1, the most common genotype in the US (Figure 1). Sovaldi was more popular due to better clinical trial results, but was also more expensive: Sovaldi's initial list price was $28,000 per bottle of 28 tablets, or $84,000 for a standard 12-week regimen.[18] Olysio was priced at about $66,000 for a 12-week regimen.

In late 2014, the FDA approved use of Sovaldi and Olysio together for genotype 1, which eliminated the need for pegylated interferon (and its unpleasant side effects). Although very expensive, this combination is one of several regimens for genotype 1 recommended by the American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA).[19] Sovaldi is also indicated as a component of combination therapies for genotypes 2, 3, and 4.[20]

The next major entrant to the market was Harvoni (sofosbuvir/ledipasvir), also from Gilead, which was approved to treat HCV genotype 1 in October 2014 (Figure 1). It was initially priced at $94,500 for a standard regimen.[21] Subsequent approvals expanded indications to patients with genotypes 4, 5,

Figure 1 (continued). Timeline of Notable HCV Events



and 6; HIV coinfection; genotype 1 with decompensated cirrhosis; and liver transplant recipients. This one-pill-per-day combination drug eliminated the need for interferon, and is an AASLD/ISDA recommended treatment. It quickly replaced Sovaldi as the most popular HCV therapy.

Harvoni was followed by Abbvie's Viekira Pak (ombitasvir-paritaprevir-ritonavir tablets; dasabuvir tablets), approved by the FDA in December 2014 to treat genotype 1 patients, including those with compensated cirrhosis (Figure 1). The list price is $83,319 for a 12-week regimen. Viekira Pak demonstrated similar efficacy to Harvoni in clinical trials, but requires patients to take multiple pills in the morning and one in the evening. This complex regimen is a disadvantage relative to Harvoni's once-daily dose. However, it made the HCV market competitive, leading to significant discounts from manufacturers to major insurers and pharmacy benefit managers (PBMs).[22]

The most recent HCV drugs, all approved between July 2015 and July 2016, include Bristol-Myers Squibb's Daklinza, Merck's Zepatier, Gilead's Epclusa, and two Abbvie products, Technivie and Viekira XR (Figure 1). These drugs expanded options for patients with all of the HCV genotypes, HIV co-infection, decompensated cirrhosis, or following liver transplant. Technivie is one component from Viekira Pak, and Viekira XR is an extended-release co-formulation of all of Viekira Pak's active ingredients.

Prices for the new drugs are generally high. The list price for Daklinza (daclatasvir) is $63,000 for a 12-week regimen, but is only approved for use with Sovaldi, making it a very expensive combination. Epclusa (sofosbuvir-velpatasvir) may be used for 12 weeks with or without ribavirin, depending on whether the patient has compensated or decompensated cirrhosis. The list price for 12 weeks is $74,760. Technivie is approved for use with ribavirin to treat genotype 4 patients without cirrhosis. The list price is $76,653 for a 12-week regimen. Viekira XR was approved in July 2016 for genotype 1 patients, including those with compensated cirrhosis (Figure 1). Its list price is the same as Viekira Pak, $83,319 for 12 weeks.

The lowest list price in this group is Zepatier (elbasvir-grazoprevir), a once-daily tablet currently approved for genotypes 1 and 4. It typically requires a 12-week regimen. The list price for that duration is $54,600. While the list price is relatively low, it is in line with the estimated discounted prices paid by major purchases for the AbbVie and Gilead products.[23] Due to the confidentiality of rebates, the net prices to Medicaid, or any other third party payer, are unknown.

The Strained Relationship between Hepatitis C and Medicaid

Medicaid serves a high proportion of patients with HCV.[24] Spurred by the costs of Sovaldi, and with an eye toward other potentially high cost products in research and development pipelines, state Medicaid directors sent a letter to congressional leaders in October 2014 asking for a federal solution to drug costs.[25] Public outcry over Sovaldi's launch price also led the Senate Finance Committee (SFC) to investigate Gilead's pricing for Sovaldi and Harvoni, and the results of those pricing decisions on access. Despite these high-profile efforts, no federal solution has been implemented.

Absent concerted federal action, state Medicaid programs implemented a range of

policies to try to manage the budgetary challenges posed by new HCV treatments.[24] The SFC investigation showed that at least 27 state Medicaid programs required prior authorization for Sovaldi as of May-September 2014, with most limiting access to people with the highest levels of disease severity (measured by METAVIR fibrosis scores).[17] Delays in establishing criteria for access to Sovaldi in Texas resulted in few Medicaid beneficiaries being able to get the drug in 2014.[26] A study by researchers at Brigham and Women's Hospital (BWH) in Boston found significant variation in the use of Sovaldi across state Medicaid programs in 2014, with rates of use ranging from 2% of all prescriptions for HCV drugs in Texas to 44% in Hawaii.[27]

As part of the SFC inquiry, the Center for Evidence-based Policy at the Oregon Health & Science University (OHSU) compiled a summary of state policies for Harvoni and Viekira Pak as of late April/early May 2015, including placement on preferred drug lists (PDLs) and clinical coverage criteria. Harvoni was listed as a preferred agent in 12 states, Viekira Pak was preferred in 13 states, and 18 states had no stated preference between them.[28] Clinical criteria varied according to disease severity, substance use (historical or current), and other factors such as evidence of early viral response for continued treatment.[28] Some states limited the number of lifetime treatments.

Representatives of state Medicaid programs and Medicaid managed care plans have argued in the past that the coverage restrictions are necessary, or at least were necessary in the first year or two, to balance demands for access with budgetary circumstances. In their 2014 letter to Congress, Medicaid directors argued that, "it is not practical to expect Medicaid programs to finance the upfront costs of Sovaldi and other breakthrough hepatitis C treatments, at the expense of providing other needed services, on the promise of seeing savings 10, 20, or 30 years later."[29] States must balance their budgets on one- or two-year cycles, and many beneficiaries who received treatment will likely cycle to other payers or onto Medicare, or become uninsured, before long-term savings accrue. Similarly, the CEO of an association representing several private insurers that run Medicaid managed care plans argued that, "prior authorization efforts are the best clinical effort to make sure that those that need [HCV treatment] most get it first."[30] Some officials also expressed concern that clinical trials were small and did not include subjects similar to Medicaid patients most likely have HCV, including the poor, minorities and people with substance use disorders (SUD).[26]

In a letter to states dated November 5, 2015, CMS reiterated the general federal rules that apply prescription drug coverage in state Medicaid programs. Federal officials made two primary points in the letter: (1) states cannot unreasonably restrict access to the new HCV drugs or any medically necessary drugs, and (2) states need to make sure that policies are consistent between managed care plans and states' fee-for-service (FFS) programs.[31]

States face pressure from consumers and advocates to lift restrictions on access to the new HCV treatments. For example, news reports noted that pressure from advocates was one factor that influenced New York Medicaid to eliminate its fibrosis score requirement in May 2016.[32] Similarly, an advisory panel in Pennsylvania pushed for broader access to HCV drugs.[33]

State also face legal pressure. Several class action lawsuits have been filed challenging states' policies for HCV drugs. Lawsuits in Colorado, Indiana, and Washington argue that restrictions in these states violate federal law because they deny patients access to medically necessary treatments.[34] The U.S. District Court for the Western District of Washington issued a preliminary injunction order in May 2016, requiring Washington Medicaid to treat HCV patients in Medicaid without regard to fibrosis score. The state agreed to continue this policy for at least three years under the terms of a settlement reached in late 2016.[35] In response to a demand letter sent to state officials in March 2016, Delaware Medicaid made HCV medications available to all recipients for whom treatment is medically necessary.[36] The Indiana case, *Jackson v. Secretary of the Indiana Family and Social Services Administration* is still pending in the U.S. District Court for the Southern District of Indiana. The lawsuit in Colorado was filed in September 2016, after the state reduced its fibrosis score, but not far enough to satisfy the plaintiffs in the case.[37]

Methods

Data

Drug Utilization Data

We obtained data for covered HCV drugs paid for by state Medicaid programs through the publicly-available Medicaid State Drug Utilization data.[38] We tracked use of, and spending for, HCV drugs in each state from 2011 until the most recent available period. For most states, the most recent data at the time of analysis were for the 3rd quarter of 2015 (Q3 2015).

To identify drugs associated with HCV, we relied on a May 4, 2015 memo from South Carolina Pharmacy Director Bryan Amick to Medicaid Managed Care Plans in his state.[39] This memo, which detailed medications for HCV treatment that would be carved out of the South Carolina Medicaid Managed Care Organization pharmacy benefit, included a list of all HCV drugs available at the time, and their NDC numbers. We also searched for specific HCV drug names in the dataset to ensure we did not miss any NDCs that may not have been included in the memo.

Prior Authorization Policies

To select states for interviews, we used existing research to identify HCV prior authorization criteria for Sovaldi (2014), Harvoni (2015), and Viekira Pak (2015) in state Medicaid programs (Table 1). For Sovaldi, prior authorization criteria were compiled from 46 states.[40] Harvoni/Viekira Pak criteria were available for 33 states.[28]

Table 1. Prior Authorization Criteria Considered for State Selection

Sovaldi (2014)	**Harvoni/Viekira Pak (2015)**
Disease severity (minimum fibrosis score)	Disease severity (minimum fibrosis score)
Specialist consultation or prescription	Specialist consultation or prescription
Abstinence from alcohol, alcohol abuse, drug use, or injection drug use	Abstinence from substance use (3, 6, or 12 months)
	Once-in-a-lifetime limit
	Test for viral response to therapy
	Patient informed consent
	Vaccination for hepatitis A and B

Prior to conducting state interviews, we tried to locate current prior authorization criteria guidelines and PDLs, online, for each of the eleven states. Policies were easier to find in some states than others, but we generally found them within a reasonable period. It was sometimes a challenge to determine if the materials presented online represented the most up-to-date policies; most materials were labeled with effective dates, but not all.

Other Covariates

We included state 2014 population size[41] and number of adult Medicaid beneficiaries. State-level estimates of the number of adult Medicaid beneficiaries were published by the Kaiser Family Foundation through 2013; such figures have not been made available for 2014 and 2015. We estimated the number of adult beneficiaries for these years by applying the change in total number of Medicaid beneficiaries from mid-2013 to December of 2014 and 2015, which are available in Monthly Eligibility Reports from CMS,[42] to the Kaiser Family Foundation's estimates of adult Medicaid enrollment as of 2013.[43]

To estimate the burden of HCV in each state, we used CDC's WONDER system to obtain 2014 state mortality rates (per 100,000 population) from acute or chronic HCV.[44] Additionally, from the National Notifiable Diseases Surveillance System, we obtained the 2014 rate of reported acute HCV cases per 100,000 population.[45] There are no reliable state-level estimates of the prevalence of chronic HCV, which would better reflect the population potentially needing treatment.

Analysis

Descriptive Analyses

We examined HCV drug utilization and spending trends for all 50 states and the District of Columbia from 2011 through 2015 quarter 3. We grouped the many variations and names for the same HCV drug. Drugs which had various brand and generic names included: interferon (infergen, roferon,intron, pegintron), ribavirin (copegus, rebetol, ribapak, ribasphere,ribatab, moderiba), and Viekira (Viekira Pak). Some HCV drugs, namely rebetron, Technivie, and Daklinza, were rarely reported by states; these drugs were dropped to focus on the drugs most commonly used across all states.

Key Informant Interviews

Based on the results of our data analyses, we collaborated with MACPAC staff to select states to focus on in the second, qualitative phase of the project. We selected states reflecting a range of policy contexts and approaches to managing the fiscal and access implications of new HCV medications. Contextual features considered included geographic region, whether or not the state adopted Medicaid expansion under the Affordable Care Act, and the level of managed care in a state. Prior authorization criteria considered included minimum METAVIR fibrosis score, limiting prescribing to specialists, and substance use guidelines.

We invited 17 states to participate, and 11 agreed. To identify respondents within states, Medicaid directors in participating states were asked to identify experts in their department, e.g. the pharmacy or medical director, who could best describe their state's approach to managing access to HCV medication. In some states, multiple experts

were interviewed jointly, leading to a total of 32 participants across the 11 state interviews.

We also interviewed representatives from the two national membership associations for Medicaid managed care plans, the Association for Community Affiliated Plans and Medicaid Health Plans of America the to gain their perspectives.

Interviews were conducted from September through December 2016. Interviews lasted approximately 60 minutes and were conducted by the Principal Investigator and trained research staff. Detailed notes were taken and summarized by the team. To enhance validity, we conducted member checking (verifying results with respondents) by sending summaries of the calls to participating states and inviting feedback.[46] To develop overall themes, the team met to compare impressions throughout data collection and tabulated key points from summaries.

Findings

Most States Used Standard Processes to Establish Prior Authorization Criteria for HCV Drugs

All respondents noted that, regardless of other features of state policy, prior authorization was necessary. Every state in our sample used the information collected through the prior authorization process to manage utilization, and to gather baseline patient characteristics for the purposes of monitoring outcomes and projecting future demand for treatment.

Most states reported that they used the same core steps that they follow for any new drug to develop policies for treatment of HCV with the new medications. These steps included review of the evidence from scientific literature; prescribing information from manufacturers' label/package inserts; cost effectiveness studies from the Institute for Clinical and Economic Review (ICER) and similar entities; and practice guidelines from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA). Consistent with federal requirements, decisions about preferred drug list (PDL) placement and prior authorization criteria were made by or in consultation with expert panels, typically pharmacy and therapeutics (P&T) committees or drug utilization review (DUR) boards. These panels always include pharmacists and physicians, and may include other experts and/or patients.

Several states noted the Oregon Health and Sciences University's Drug Effectiveness Review Project (DERP) and/or the state's PBM contractor as reliable sources of information for their reviews of new medications, including the HCV drugs. A few states noted that they routinely worked with a school of pharmacy in the public university system. Other groups consulted by one or more states include the U.S. Department of Veterans' Affairs (VA), state departments of corrections or public health, and public hospitals.

While the basic steps and parties involved were standard, respondents were nearly universal in noting that the experience with HCV drugs was definitely not business as usual. The high costs of these drugs and the relatively large patient population with HCV made balancing access and cost factors very challenging. Some state officials admitted that the high prices caught them off guard, adding to the urgency to establish policies to manage utilization.

Respondents from nearly all states commented that the frequency of new drug approvals, updates to existing indications, and rapidly-evolving evidence base required many more reviews of HCV treatments in a short period than is typical. Officials from several states also noted that there was more scrutiny on their coverage decisions for the HCV drugs from lawmakers, the federal government, and the public.

Seven of the 11 interview states deliver services through managed care plans, in addition to FFS programs. These states took a variety of approaches to establishing prior authorization and other coverage criteria for HCV drugs for managed care. A few states carve out HCV and other drugs from the package of managed care services and cover them on a FFS basis. Most of the remaining states allow managed care plans to set their own criteria, but plans must closely align their policies with the FFS program. Some

states require all plans to use the same PDL and prior authorization criteria as FFS, at least for HCV drugs. Efforts to minimize or eliminate variation in HCV drug policies preceded the CMS letter in some states, and is a result of it in others. Managed care plan representatives voiced a strong preference for states to allow them to retain control of their own formularies, but states are pushing for greater uniformity.

A small number of states said that the process they used to set criteria for HCV drugs was much different than the usual process. For example, in one state with a predominately managed care delivery system, the plans (or their PBMs) ordinarily establish their own formularies/PDLs, prior authorization criteria, and other policies. For Sovaldi and other HCV drugs, the state instead convened a workgroup that included state officials and representatives of the managed care plans. This workgroup developed a single policy that applies statewide across all plans and FFS.

States Expect Downstream Benefits, But Struggle with Upfront Costs

The state officials and Medicaid managed care representatives we spoke with almost universally lauded the new HCV drugs as breakthroughs in treatment. They noted that the treatment duration and side effect profiles for the new drugs were dramatically better than earlier therapies, making it easier for patients to tolerate and adhere to the regimen. Respondents also believed that the greater efficacy of the new drugs and the high likelihood of a "cure" – defined as sustained virologic response (SVR) – could provide significant benefits over the long run, particularly in terms of better patient outcomes.

While respondents were collectively optimistic about the potential for the new HCV drugs from a clinical perspective, there was far less consensus around the optimal policies to balance beneficiary access with the up-front costs. The heterogeneity in state policies reflects the flexibility they have to establish policies based on the needs and demands of their populations; finances; health care resources (e.g., specialists); and political environments.

A small number of states that we examined placed relatively few limitations on access to the new HCV drugs, right from the start with Sovaldi. Officials in these states indicated that the new drugs were worth the initial investment, due to their efficacy and high cure rates, and should be broadly available. They commented that treating HCV, even at early stages, likely prevents other costs later. For example, officials in one state are actively working to enhance access to screening and services for high risk patients, through primary care providers and emergency departments.

On the other hand, a small number of states place more strict limitations on access. The most restrictive states in our sample require most patients to have a fibrosis score of F3 or higher, with some exceptions for patients at higher risk of rapid progression, such as those with HIV co-infection. Although officials in these states noted that they would like to be able to expand coverage of the new drugs to all patients with HCV, they felt constrained by state budget limitations.

Most states fall between these approaches, although their specific responses differ. Respondents from several states in our sample believed that HCV treatment can significantly reduce both potential future

costs and transmission of HCV. However, they said the costs of the drugs are a major barrier. As a result, policies in these states reflect attempts to balance access and state budgets. For example, one Medicaid agency using an F2 disease severity requirement is partnering with the state's public health agency and drug manufacturers to promote appropriate screening, awareness, and prevention programs. The Medicaid agency identified pockets of HCV patients across the state and targeted those areas for educational outreach. Officials from another state remarked that they wanted to treat as many patients as possible, but they felt it was appropriate to establish the F2 disease severity standard to prioritize the patients who need treatment most urgently.

Officials in nearly all of the states with a minimum fibrosis score requirement referenced AASLD/IDSA guidelines as supporting this position. Past versions of the guidelines suggest how to prioritize treatment by the highest need if resources (experienced providers, finances, etc.) are limited.[47] More recent versions of the guidelines, starting with those issued in July 2016, do not contain prioritization guidance and recommend treatment 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.

Respondents in several states commented that providers and patients also make decisions that affect utilization and costs. Even in states with low or no fibrosis score requirements and shorter prior authorization forms/processes, physicians may "self-triage" by treating the neediest patients first. With the high degree of public scrutiny of the prices of HCV drugs, respondents suggested that physicians are more likely to know the (approximate) costs of these medications. In addition, a few respondents pointed out that the new HCV drugs are powerful medicines and, while side effects are better than past treatments, eligible patients may not always want to take them.

States are Expanding Coverage for HCV Treatments

Nearly all of the states we interviewed have expanded coverage for HCV drugs to more Medicaid beneficiaries since 2014. Several states reduced the minimum fibrosis score required for treatment (generally to F2 from F3 or F4), or eliminated this requirement altogether. Some states required managed care plans with stricter limitations to match the less restrictive FFS standards, before and after the CMS letter from November 2015. Officials in nearly every state expressed a desire to eventually eliminate restrictions based on disease severity/fibrosis scores.

Affordability is Paramount

The primary concern that state officials and managed care plans raised about the new HCV drugs is affordability. Respondents in all states agreed that the budget impact from the new HCV medications is substantial, and no state could afford to treat every infected beneficiary in a short period of time. As in the case of prior authorization, states used a range of approaches to try to manage the overall costs of HCV drugs.

States used different contracting strategies with drug manufacturers. One of the larger states in our sample contracted very quickly with Gilead for supplemental rebates on Sovaldi, even before AbbVie brought its competing drugs to market. The ability of larger states to generate sales volume for manufacturers is an inherent advantage over

smaller states, when there is little or no competition between treatment alternatives. More commonly, states spoke about how AbbVie's Viekira Pak launch in December 2014 led to significant discounts to states, via supplemental rebates, from both Gilead and AbbVie. The additional competition from other manufacturers in 2015 and 2016 further increased available discounts.

Even with the combination of mandatory federal and state supplemental rebates reducing net prices by 40-60% off wholesale acquisition cost (WAC) or "list" prices, officials lamented the high cost of HCV treatments. Officials from most states noted that treating the relatively large numbers of patients with HCV would require major outlays, even at discounted – but still high – prices. A few respondents commented that the practice of lowering net costs through rebates and prior authorization does not address the issue of high initial prices set by manufacturers.

Some of the states in our sample participate in multi-state pools that negotiate supplemental rebates, which respondents generally believe gives them more leverage with manufacturers, and thus larger discounts, than would be possible on their own. Officials from other states in our sample dismissed pooling as unnecessary because they could get sufficient rebates on their own.

States Use Many Approaches to Help Managed Care Plans Pay for HCV Drugs

States faced another significant challenge arising from the high up-front costs of HCV medications: helping Medicaid managed care plans shoulder the burden. Managed care representatives said that affordability was a critical issue immediately following Sovaldi's launch, when plans first learned of the drug's high price, and continues to be important today. States used a variety of approaches to help plans cover the costs of HCV medications, but they fall into roughly three categories: (1) supplemental or "kick" payments; (2) risk sharing; and (3) carve out – that is, direct state management and payment for HCV medications.

One state in our sample began providing supplemental payments to plans for HCV drugs in mid-2014, based on actuarial estimates. These payments continue to the present, although they have been adjusted over time to reflect changes in utilization and reductions in net prices after rebates. There is no plan to end the supplemental payment program and incorporate the expected costs into the baseline for managed care plans, according to state officials.

Two states used a combination of the approaches described above. Both started with one-time special rate adjustments to plans. Moving forward, one of these states added the expected costs of HCV drug treatment to the base rate paid to plans. The state added a risk corridor program, where the state will cover 100% of costs in excess of actuarial estimates for plans that experience higher-than-expected costs and recover funds from plans with lower-than-expected HCV drug costs. The tradeoff for plans is that they must follow a single state PDL for these drugs. The other state shifted to a combination of a risk sharing plan and a supplemental payment pool, designed to incentivize plans to implement effective care management strategies to improve patient adherence and track viral response.

A few states in our sample incorporated the expected costs of HCV drugs into managed

care capitation rates. In one of these states, the legislature refused to support the initial request for supplemental funds specifically to cover HCV drugs, but it approved this funding in a later period and it is part of the baseline budget moving forward. Another state made a rate adjustment after the new HCV drugs came to market, and added this funding to the standard capitation rates (with some adjustments) in subsequent periods.

Two states in our sample carve out HCV drugs from managed care. One of these states carves out nearly all drugs. Officials from the other state said that they chose to carve out HCV drugs because they did not have sufficient experience with these drugs to understand potential utilization patterns and establish a capitation rate. The state reviews carve out decisions on a regular basis, and may choose to move these drugs back into the package of managed care services and establish a capitation rate in the future. One respondent noted that patient advocacy groups in the state generally prefer the carve-out approach for HCV drugs, but did not say why.

Patient Management and Monitoring by the State is Perceived as Beneficial

Several states from our sample are actively managing patients receiving HCV treatment. For example, some states monitor changes in viral load by requiring test results to be submitted during treatment (typically at 4 weeks, sometimes also at 8 weeks). Officials indicated that these programs were based on clinical guidelines, and put in place for quality assurance and to encourage patients to adhere to treatment regimens.

Respondents from about half of our states commented that determining parameters for retreatment requests was a challenge. Officials in some states reported that they keep track of patients who have completed treatment, in part to observe downstream effects on outcomes, and to watch for retreatment. They noted that very few patients have sought retreatment to date, although this observation is not surprising given the relatively high success of the new drugs in clinical trials and the short period for which these drugs have been available.

Officials in other states expressed concern about compliance and adherence. to treatment. They noted that some patients fail to take their medications consistently or lose their prescriptions, which they suggested might be indicative that patients do not always understand the benefits or costs. In one state that does not currently allow retreatment, officials are working to determine if a system should be put in place to enable reviews of retreatment requests by a clinical pharmacist. Officials noted that some patients have more justifiable reasons than others as to why they discontinued use of medications.

One official from a Medicaid expansion state noted that more than half of the beneficiaries treated to date were in the expansion group, for which the state currently receives 100% federal financial participation. This enhanced match means that the cost to the state budget is much smaller than the total expenditures for HCV drugs might suggest. The official noted that this was valuable information, both for projecting future state financing needs and for mitigating lawmakers' concerns about HCV drug expenditures. However, this was the only state in our sample that knew the breakdown in use between the expansion group and standard beneficiaries.

CMS Letter to States Had Greater Impact on Managed Care Policies

The portion of the CMS letter dealing with access had limited effect on the FFS policies in our sample states. Several states had already adjusted coverage policies for HCV drugs earlier in 2015 in ways that expanded access for patients. Changes included lower disease severity requirements (e.g., moving from fibrosis scores of F3 or greater to F2 or greater) or eliminating the fibrosis score standard entirely, and lessening or dropping requirements related to substance use. These changes reflected other factors, such as reductions in net drug costs to states as competition among drug makers led to larger discounts; active or threatened litigation; and state officials' interest in providing treatment to as many people as possible with available resources.

Several states made no changes to their policies as a result of the letter. Officials from multiple states using fibrosis score requirements of F2 or lower believed that their state's policies were not targeted by CMS. However, a couple of states noted that the letter was one factor in subsequent decisions to change their disease severity requirement or other policies. These states primarily shifted to a fibrosis score standard of F2, down from F3 or higher.

The most salient effects of the CMS letter were on policies for managed care plans. In the letter, CMS noted that the conditions for coverage of the new HCV drugs appeared to be more restrictive in managed care than in FFS programs, and often differed between various managed care plans within a state.[31] Many state officials remarked that the letter led to reviews of plans' policies, regular meetings between managed care pharmacy directors and Medicaid agency staff, and policy changes. One state official noted that the experience with HCV drugs highlighted the importance of aligning policies for all specialty drugs across their managed care plans and FFS program.

Medicaid managed care representatives confirmed that the letter contributed to a flurry of activity aimed at eliminating disparities in coverage of HCV medications. However, they raised concerns about losing the ability to develop their own treatment criteria and formularies, commenting that the system of care management begins to break down when pieces are taken away and coordination is lost.

States also consider feedback from other stakeholders in gauging whether access to the new HCV drugs, or any other Medicaid service, is sufficient. Respondents in many states noted that stakeholders including professional associations, patient-rights groups, and hepatitis C organizations, are vocal when they see gaps in access. For the most part, respondents indicated that access to HCV treatment was not a major concern in their state, measured by the volume of external feedback. However, it was also clear from our discussions that states have been, and continue to be, actively engaged with stakeholders to develop and review their policies, and try to be responsive to feedback. The strongest public pressure seems to be in states that continue to use fibrosis score standards or F3 or greater.

Specialist Involvement is Broadly Viewed as Appropriate, Not Harmful for Access

Most states in our sample require that a specialist either prescribe or consult when patients receive treatment using the new HCV medications. Officials from these states viewed specialist involvement as

appropriate and desirable, particularly in states that also apply a disease severity standard. The general notion is that patients meeting the standards for treatment – for example, who have more advanced fibrosis or comorbidities such as HIV – should be under the care of a specialist at that point. Some respondents also felt that the smaller community of HCV specialists facilitated greater engagement with the state.

Even in states that do not require specialists to prescribe or consult when patients receive HCV treatments, respondents indicated that most treatment is done by specialists. This observation suggests that primary care practitioners may not be comfortable prescribing these powerful agents, instead referring patients to specialists who are more aware of how HCV drugs should be used. Officials from one state in our analysis noted that primary care providers without specific training in HCV treatment were referring patients with hepatitis to specialists long before the new drugs came to market.

Although requirements to use specialists raise concerns about access, the respondents in our states usually said that access to specialists has not been a significant problem, even in rural areas. Officials in some of the smallest and most rural states from our study noted that specialty physicians have been willing to work with rural providers. Some noted that there are systems in place to facilitate collaborations and enable consultation when patients cannot reach specialists, such as telehealth, coordinated care, and multi-disciplinary committees where a specialist may not directly provide care, but helps to develop treatment plans for individual patients.

Where access is a concern, states have been working with providers to encourage more collaboration with specialists. Officials in several states – large and small – also noted that primary care providers can get approval to prescribe HCV drugs if they have extra training or experience involving hepatitis C treatments. We also heard of programs using specially-trained pharmacists and pharmacy technicians to engage with patients and encourage them to adhere to the full course of treatment. The Indian Health Service (IHS) program has pharmacists who are specially trained in HCV management, so patients in this program are allowed to have HCV medications prescribed and managed by a pharmacist.

Views on Substance Use Disorder Criteria are Mixed

Respondents in several states noted that AASLD/IDSA guidelines now encourage treatment of patients with a substance use disorder (SUD), past or active. One state official also remarked that their discussions with representatives of the VA suggested that rates of adherence and successful treatment among patients with SUD were "quite good" with proper clinical support. These factors influence decisions to curtail substance use restrictions on access to treatment, although many states continue to consider substance use in prior authorization protocols.

Although critics of SUD criteria worry that these policies harm access,[24] some of the state officials we spoke with suggested that there can be advantages to having such policies in place. For example, if a patient has an SUD or has had one in the past, capturing this information on a prior authorization request form enables the state to look to see what measures have been or

are being taken to help the patient. Officials in one state noted that their criteria do not require abstinence or drug testing, but rather enrollment in an SUD treatment program. The intent is to engage in a comprehensive plan to "cure" the HCV infection and treat the SUD, which they hope will reduce the risk of reinfection.

Lessons Learned that States May Apply to Other High Cost Drugs

We asked the state officials and managed care plan representatives how their experience with the HCV products informed how they think about/plan for other high-cost drugs. Some states described how the experience with HCV drugs highlighted a need to improve their efforts to monitor drug pipelines – and other health care developments – to better predict future budget challenges. Lack of reliable information about the prevalence of HCV in Medicaid, or even in the state population more broadly, was noted as a problem by officials in several states.

One state discussed a plan to use a monitoring process to enable them to anticipate new drug introductions, utilization, and costs, enabling them to request base adjustments from the legislature in advance rather than separate funding requests each time a new, high cost and/or high use drug enters the market. The state is working with its PBM to develop custom reports to aid in this endeavor.

Officials from one state also noted that engaging physicians in the discussion about high cost drugs is helpful, allowing physicians to determine the drug's appropriate place in clinical practice.

Respondents from a few states talked about changes to their supplemental rebate processes. In one state, officials recognized a need to be more proactive and pursue supplemental rebates for new drugs – and high cost drugs already on the market in some classes – even where there might be only limited (or no) competition. Officials in another state noted that they chose to join a multi-state pool to negotiate discounts, rather than continue to try to manage negotiations on their own.

We also asked respondents about policy options their states are exploring for high-cost drugs going forward. One state enacted a policy that will automatically apply prior authorization to new outpatient pharmacy drugs, enabling the state to determine how the drug fits into therapy and what prior authorization criteria to apply (if any), in the long run. Another respondent comments that they were looking into step therapy approaches in some drug classes.

To help plans shoulder the costs of high cost drugs in managed care, a few state officials talked about developing or expanding risk sharing agreements. However, most state officials seemed to think that the approach their state used to help plans – whether it was supplemental payments, risk sharing, or carve out – was still the best choice for their particular circumstances. Managed care representatives expressed concern that there may be movement toward standardized coverage criteria and formularies established by states in the aftermath of the CMS letter. They noted that these approaches do not necessarily result in use of the lowest cost alternative plans.

Despite the growing movement among public and private insurers and other third-party payers to develop pay-for-performance and value-based payment, respondents

typically did not bring up these approaches without prompting from our research team. While respondents in several states noted that their Medicaid programs were exploring value-based designs, pay-for-performance, and outcomes-based payment options, these efforts largely seem to be in early developmental stages. Moreover, it is not clear that HCV treatments or other high cost drugs will be a particular area of focus within these efforts.

Several states are participating in the SMART-D initiative, a program through OHSU that is intended to assist state Medicaid programs in using alternative purchasing models (APMs) for high-cost drugs, and in concurrently balancing budget challenges alongside patient access to safe, effective treatments. One goal of SMART-D is to give states the tools necessary to implement value and/or risk-based drug purchasing pools, which respondents believe helps them plan for future high-cost drugs.

Some respondents noted that the tendency to look at utilization and costs in silos must be overcome. They suggested that taking a holistic approach to an individual's medical and behavior health concerns, as well as lifestyle and societal factors, is a better way to address the root cause(s) of disease states. One official remarked that comprehensive, coordinated, well-managed care will be a major strategy for limiting the need for high cost drugs.

Tools that May Help States Better Manage High Cost Drugs

One respondent remarked that "Hep C was easy" because the new treatments were a major step forward in terms of effectiveness. Therefore, it was not a question of coverage, just cost. The bigger problem, said the respondent, is when drugs are incremental additions or have questionable outcomes, where it is harder to weigh the costs and benefits. Respondents in multiple states remarked that Medicaid and other insurers are essentially paying for confirmatory trials for a growing number of high cost/specialty drugs that gain accelerated approval based on relatively small trials. They expressed concern that states do not necessarily have sufficient comparative efficacy or clinical outcomes data to help them determine the appropriate policies to manage these drugs. Officials suggested that potential solutions might include public funding for trials; requiring manufacturers to conduct post-marketing safety and effectiveness studies; or more support for research or economic analyses by independent experts and academics could help determine whether drugs with questionable efficacy will be successful for Medicaid populations.

When we asked respondents across all states what additional tools or information would be useful to help them address the challenge of high cost drugs, a common suggestion was access to more high-quality cost effectiveness reports, comparative studies, and evidence reviews. While states often have data analysts on staff or could request analyses from a contractor, such as their PBM, some officials we spoke with noted that these sources provided useful but limited information. If it were possible to retrieve data more quickly and have more staff in place to analyze the data, officials believed they would be able to make better and more informed decisions.

Officials in one state noted that might be able to avoid unnecessary costs associated with retreatment for HCV if they were able to obtain data analytics faster. Better

forecasting – or advanced notice – of launch prices for new drugs would also help, because prices generally are not known until the manufacturer officially releases them (usually about the same time as the drug receives FDA approval).

Discussion

The goal of this project was to gain insights into how states set their Medicaid policies affecting access to HCV treatments, and how the strategies of agency leaders with regard to these and other high-cost drugs continue to evolve. The state officials we spoke with came from states reflecting a broad range of HCV-related drug policies, managed care penetration, geographies, and social and political circumstances.

We cannot comment on whether the six invited states that chose not to participate differ in significant ways from the 11 responding states. We know that active and threatened litigation was a factor in some states' decisions not to participate, but it is not clear that policies in these states as a whole were more or less restrictive than policies in our participating states.

Most states reported that they used the same core steps that they follow for any new drug to develop policies for treatment of HCV with the new medications. However, nearly all respondents noted that the HCV drugs were not business-as-usual, given the high costs; greater scrutiny from legislators, the federal government, and/or advocates; and the frequency with which market changes required re-reviews and updates.

While state officials and managed care representatives were optimistic about the potential of HCV drugs to "cure" patients and even save lives, they were clearly frustrated by the upfront costs and the resulting need to manage access to keep expenditures in check. Yet many of our respondents suggested that their state's prior authorization requirements also encourage appropriate utilization, engagement with expert practitioners, and better management of patients both during and after treatment.

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) released a report in late 2016 that evaluated HCV treatment access through the end of October 2016.[48] Their report focused on fibrosis score criteria, substance use requirements, and limitations on the types of providers who could prescribe treatment, and compared findings with another CHLPI analysis from 2014.[24] They found that states were more transparent about their policies in 2016 compared to 2014, typically posting information online in relatively easy-to-find locations. They reported that several states had eased fibrosis score criteria – with a few dropping it entirely – and smaller numbers reduced limitations based on substance use or prescriber type. These findings align with our observations.

There was no consensus in our sample of states on best practices for managing costs for the current HCV drugs or other high cost products. The lack of emphasis on value-based, pay-for-performance, and outcomes-based payment approaches specifically for high cost drugs (and pharmacy generally) may reflect challenges inherent in the structure of the Medicaid drug benefit and other policies. It is difficult for states to exclude coverage for a drug altogether when the manufacturer has an active federal rebate agreement. Limitations on beneficiary cost sharing in Medicaid make it difficult to

mimic the value-based prescription benefits that have been successful in private health plans, which frequently rely on significant differences in cost sharing to influence patient and provider decisions.[49,50] It is also not clear whether the "Best Price" provision in the federal Medicaid rebate program could be triggered if a manufacturer gave a larger discount – or full refund – to a state to offset drug costs for patients where the drug failed to produce the agreed-upon outcome.

The desire for better data and analytics is one place where federal help could prove valuable. States' in-house data analysts are frequently generalists who support requests from across the state Medicaid agency, and may therefore lack the time or specific expertise needed to produce the in-depth analyses that would be helpful when assessing the state's patient population, medication access, and treatment success. Similarly, PBMs can run analytics focused on pharmaceutical use and costs, but the state agency may not have the resources (staff or financial) to combine pharmacy, medical, and other claims data to increase understanding of the patient population.

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