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State Medicaid Reimbursement for Medications for Chronic Hepatitis C Infection from 2012 through 2015

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ABSTRACT

Background: New direct-acting antivirals (DAAs) can cure chronic hepatitis C virus (HCV) infection. High DAA prices combined with a large number of patients needing treatment may pose substantial economic burden on health systems. **Objectives:** To examine Medicaid reimbursement for medications for HCV infection before and after the availability of new DAAs overall and by state and to also assess the impact of Medicaid expansion on reimbursement for DAAs. **Methods:** We calculated Medicaid reimbursements for medications for HCV infection between 2012 and 2015 in all 50 states and the District of Columbia. Outcomes included inflation-adjusted Medicaid reimbursement for medications for HCV infection, market share of individual DAAs, percentages of Medicaid outpatient pharmacy reimbursement for DAAs, and Medicaid reimbursement per Medicaid enrollee with HCV infection. **Results:** Medicaid reimbursement for medications for HCV infection increased from $723 million in 2012 to $2.35 billion in 2015. We found variations in Medicaid reimbursement for DAAs between states in 2014 (up to 7.4 times HCV infection prevalence) that widened in 2015 (0.1–11.4 times HCV infection prevalence). Expansion states had significantly higher increases in reimbursement for DAAs per enrollee with HCV infection compared with non- or late-expansion states ($2178.60; 95% confidence interval $1558.90–$2798.40), controlling for pre-expansion reimbursement. **Conclusions:** Medicaid reimbursement for DAAs differs across states after controlling for HCV infection prevalence. A third of states contributed more than 5% to 15% of pharmacy reimbursements to DAAs. Medications for HCV infection are only one class of highly priced specialty drugs. Innovative policy strategies are needed for health systems to manage coverage for an increasing number of expensive specialty medications indicated for an increasing number of patients.

Keywords: DAAs, direct-acting antivirals, hepatitis C, Medicaid, sofosbuvir, specialty drugs.

Introduction

Innovative specialty medications constitute promising opportunities for treating life-threatening or disabling diseases. Specialty medications have at least one of the following characteristics: costly medication delivery, such as requirements for special handling (e.g., temperature control and protection from radiation); complex treatment administration (e.g., infusion and frequent dose adjustment); complex molecule composition (i.e., "biologics"); and high costs per patient (Medicare's definition is >$600/mo) [1]. Some specialty medications provide highly effective treatments for many of the nation's sickest and most vulnerable individuals, including those with chronic hepatitis C virus (HCV) infection.

Chronic HCV infection is a common blood-borne infection [2–4]. An estimated 80 to 150 million persons worldwide have chronic HCV infection [5,6], with about 3 to 4 million individuals in the United States [3,7]. Chronic HCV infection disproportionately affects poorer populations who tend to be enrolled in public insurance programs including the Medicaid programs [8]. If left untreated, chronic HCV infection can lead to cirrhosis, liver failure, and hepatocellular carcinoma [9,10]. The sustained virologic response for patients with genotype 1 (the most prevalent type in North America) treated with interferon-based regimens ranged from 40% to 50% in clinical trials, whereas patients with genotypes 2 and 3 had higher response rates (range 75%–85%). Nevertheless, response rates for interferon-based treatments are about 20% lower in real-world studies because of poor tolerability [11–13].

The recent availability of new direct-acting antivirals (DAAs) marked the beginning of a new era for treatment of HCV infection. In late 2013, the Food and Drug Administration (FDA) approved sofosbuvir, a DAA for the treatment of chronic HCV infection in combination with other drugs. Sofosbuvir is a pangenotypic nucleotide analogue NS5B polymerase inhibitor and

Conflicts of interest: The authors declare no financial interests or potential conflicts of interest.

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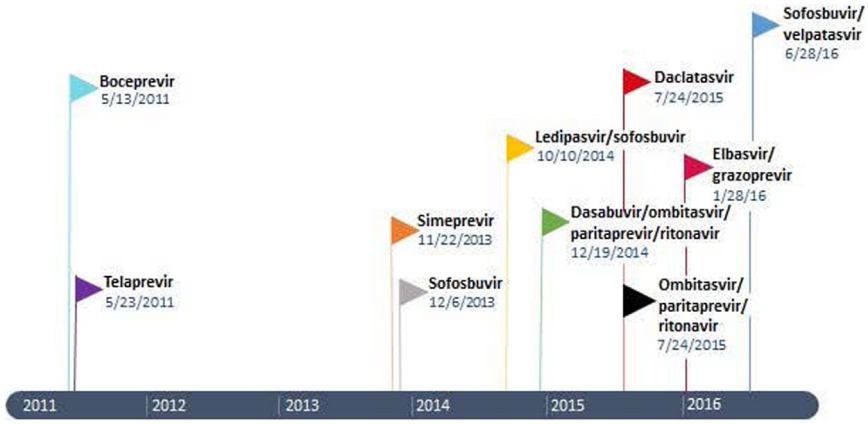

Fig. 1 – FDA approvals of DAAs for the treatment of chronic HCV infection. DAA, direct-acting antiviral; FDA, Food and Drug Administration; HCV, hepatitis C virus.

the first DAA indicated for use as part of an interferon-free regimen. Sofosbuvir-based interferon-free regimens showed response rates of approximately 90%, shortened treatment duration (12 weeks), and improved tolerability and safety compared with interferon-based therapy (although lower response rates are seen and longer treatment durations in combination with other medications are needed in persons with more advanced disease and certain HCV genotypes) [14]. After the approval of sofosbuvir, six other new treatments for HCV infection have become available (Fig. 1).

DAAs can greatly reduce HCV infection morbidity and mortality. The treatments are, however, highly priced. For example, the published wholesale acquisition cost of sofosbuvir is $1,000/d (equating to $84,000 [15] for a 12-week course), with additional costs of required concomitant treatments. A single combination tablet of sofosbuvir and ledipasvir (Harvoni) is available at a published price of $1,125 ($63,000, $94,500, and $189,000 for an 8-, 12-, and 24-week course, respectively) [16]. High prices and high demand (actual or anticipated) for the products have led payers to implement restrictions for reimbursement. Although Medicaid programs are entitled to a rebate of at least 23.1% of average manufacturer price [17,18], most state Medicaid programs have restricted reimbursement for DAAs to patients with advanced disease [19,20]. Subsidized access to these effective medications is particularly important for Medicaid beneficiaries, a socioeconomically disadvantaged population with a high prevalence of HCV infection. This study examined Medicaid reimbursement for medications for HCV infection before and after the availability of new DAAs overall and by state. We also assessed the impact of Medicaid expansion on reimbursement for DAAs.

Methods

Data

This study used data for covered outpatient drugs that are paid for by state Medicaid programs that have been reported by states since the start of the Drug Rebate Program in 1991 [21]. Total Medicaid reimbursements include dispensing fees but exclude manufacturer rebates or rebates from supplemental rebate agreements, which are confidential agreements between drug manufacturers and states that allow additional rebates beyond what is mandated by the Centers for Medicare & Medicaid Services (CMS). The data were obtained from the CMS. Data elements included the National Drug Code, product name, number of units reimbursed, number of prescriptions, and total amount reimbursed to pharmacies for medications for Medicaid members, by quarter for each state [6]. We examined all 50 states and the District of Columbia.

We selected medications for treatment of HCV infection in the First Databank [22] therapeutic category "Hepatitis C Treatment Agents" and identified relevant National Drug Codes. Traditional medications for HCV infection were interferon and ribavirin, and the first approved DAAs were telaprevir (Incivek) and boceprevir (Victrelis). At the time of the study, DAAs that were approved by the FDA after 2013 and could be used as part of an interferon-free regimen were daclatasvir dihydrochloride (Daklinza), ledipasvir/sofosbuvir (Harvoni), simprevir sodium (Olysio), sofosbuvir (Sovaldi), ombitasvir/paritaprevir/ritonavir (Technivie), and ombitasvir/paritaprevir/ritonavir/dasabuvir sodium (Viekira Pak) (Fig. 1). We used Drugs@FDA to identify FDA approval dates [23].

Study Period, Outcome Measures, and Analyses

The study period comprised the first quarter of 2012 through the third quarter of 2015 [21]. For each state, we calculated quarterly and yearly inflation-adjusted reimbursements made to pharmacies by Medicaid in 2015 US dollars for all medications for HCV infection (including DAAs) and for all outpatient drugs.

We estimated the market shares of individual DAAs in Medicaid (the percent share of Medicaid reimbursement for each individual DAA of total Medicaid reimbursement for all DAAs). To place the economic burden of DAAs in context, we estimated the percentage of total Medicaid reimbursement for all outpatient prescription drugs attributable to DAAs for each state and year (DAA reimbursement percentages). To account for state differences in HCV prevalence, we calculated two measures. First, we calculated the ratio of DAA reimbursement percentages and state-level HCV prevalence rates in 2010 [24]. Second, for each state and year, we estimated the number of Medicaid members with HCV infection on the basis of the annual number of Medicaid members [25,26] and the 2010 state HCV prevalence [24] and then calculated the Medicaid reimbursement ($) for DAAs per Medicaid enrollee with HCV infection.

Information on individual states' Medicaid expansion status in 2014 and 2015 was obtained from the Kaiser Family Foundation [27]. Six states (California, Connecticut, District of Columbia, Minnesota, New Jersey, and Washington) had expanded Medicaid to low-income adults through the Affordable Care Act option and/or Section 1115 waiver authority since 2010 [28]. We used a quasi-experimental difference-in-differences design to examine Medicaid reimbursement for DAAs per enrollee with HCV infection over time and between the expansion states and the

non- or late-expansion states. In our generalized estimating equations model [29,30], we adjusted for state-level poverty rate, unemployment rate, and penetration rate of Medicaid-managed care (i.e., percentage of Medicaid enrollees in comprehensive Medicaid-managed care plans). All costs were adjusted to 2015 US dollars using the consumer price index [31]. All analyses were carried out using the SAS software, version 9.3 (SAS Institute, Cary, NC) and STATA 14 (StataCorp, College Station, TX) [32].

Results

Between 2012 and 2015, reimbursement for DAAs increased in all state Medicaid programs. Medicaid reimbursement for all medications for HCV infection (interferon, ribavirin, and DAAs) increased from $723,065,136 in 2012 (with 60.5% attributable to DAAs) to $2,291,272,686 in 2014 and $2,353,036,231 in 2015 (with 94.4% and 99.3% attributable to DAAs, respectively) (Fig. 2). Rapid increases in reimbursement in 2014 corresponded to the uptake of sofosbuvir and ledipasvir/sofosbuvir in 2015. DAAs accounted for as high as 10% to 15% of 2015 reimbursement for all outpatient prescription drugs in Connecticut, District of Columbia, Massachusetts, Maryland, and New York (see Appendix Table 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.09.011).

Figure 3 presents the market share of individual DAAs of total Medicaid reimbursement for all DAAs over time. Between the first quarter of 2012 and the last quarter of 2013, telaprevir accounted for approximately 50% of the DAA market until sofosbuvir became available. Uptake of sofosbuvir was rapid and captured most of the market (almost 80%) in the first three quarters of 2014 until the availability of ledipasvir/sofosbuvir. In 2015, ledipasvir/sofosbuvir accounted for most of the market (about 75%).

In 2012 and 2013, only two DAAs (boceprevir and telaprevir) were available that required concomitant treatment with interferon. There was no variation between states in the percentage of Medicaid reimbursement for these treatments for HCV infection (Fig. 4; see also Appendix Table 1 in Supplemental Materials). State-level percentages of total Medicaid reimbursement for all outpatient prescription drugs attributable to DAAs increased from a median of 0.8% in 2012 and 0.5% in 2013 to 3.0% in 2014 and 3.8% in 2015. Marked variations in reimbursement between states existed in 2014 and increased in 2015 after adjusting for state-level HCV prevalence (Fig. 4). In 2014, percentage Medicaid reimbursement for DAAs ranged from less than 0.4 times the HCV prevalence in Alaska, Iowa, Rhode Island, Texas, and Wisconsin to more than 5 times in Minnesota, New York, Massachusetts, North Dakota, and Connecticut (see Appendix Table 1 in Supplemental Materials). In 2015, percentages Medicaid reimbursement for DAAs increased more than twofold in 13 states. Percentages Medicaid reimbursement for DAAs ranged from less than 0.2 times the HCV prevalence in Texas, Michigan, and Rhode Island to more than 7 times in Connecticut, Massachusetts, Maine, North Dakota, and New York. Analyses of Medicaid reimbursements for DAAs per Medicaid enrollee with HCV infection showed similar results (see Appendix Table 2 and Appendix Figure 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.09.011).

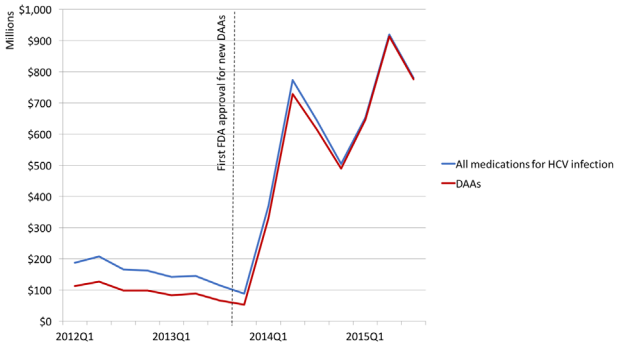

Fig. 2 – Medicaid reimbursement for medications for chronic HCV infection (inflation-adjusted US $), 2012–2015. HCV, hepatitis C virus.

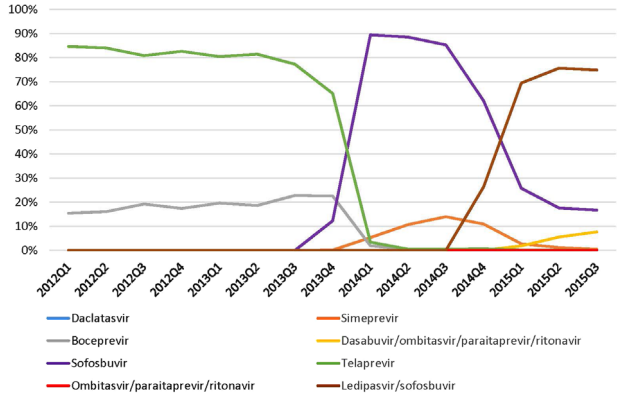

Fig. 3 – Market shares of individual DAAs in Medicaid, 2012–2015. DAA, direct-acting antiviral.

We found significant increases in Medicaid reimbursement for DAAs from the pre-Medicaid expansion period to the postexpansion period (Table 1). Increases were observed in expansion states, non- or late-expansion states, as well as "early adopters" that expanded Medicaid eligibility before 2012, suggesting that some increases are likely due to the advent of new DAAs. Expansion states had significantly higher increases in reimbursement for DAAs per enrollee with HCV infection than did non- or late-expansion states ($2178.60; 95% confidence interval $1558.90–$2798.40), controlling for pre-expansion reimbursement. Early adopter states also had significantly higher increases in reimbursement for DAAs per enrollee with HCV infection than did non- or late-expansion states ($1835.30; 95% confidence interval $1038.90–$2631.70).

Discussion

The high cost of specialty drugs, including DAAs for HCV infection, has generated much controversy in recent years [7,33]. Our longitudinal study shows that Medicaid reimbursement for medications for HCV infection increased sharply after the approval of sofosbuvir, the first DAA used without interferon, which represented a paradigm shift in the treatment of HCV infection. DAAs accounted for 99.3% of Medicaid pharmaceutical reimbursement for medications for HCV infection, or US $2.35 billion, in 2015. A substantial uptake of DAAs in the Medicaid population would be expected given that DAAs constitute new highly effective, well-tolerated treatments for a prevalent condition in this population. Nevertheless, DAAs for HCV infection can exert enormous budget pressure on health systems because they are highly priced therapies needed by a large number of patients. Public and private payers in the United States have tried to limit the budget impact of DAAs by restricting reimbursement to selected subgroups of patients. Restricting reimbursed access to a potentially curative, relatively well-tolerated, guideline-recommended [34] treatment of a potentially fatal chronic infectious disease, however, is controversial [8,35] and states have

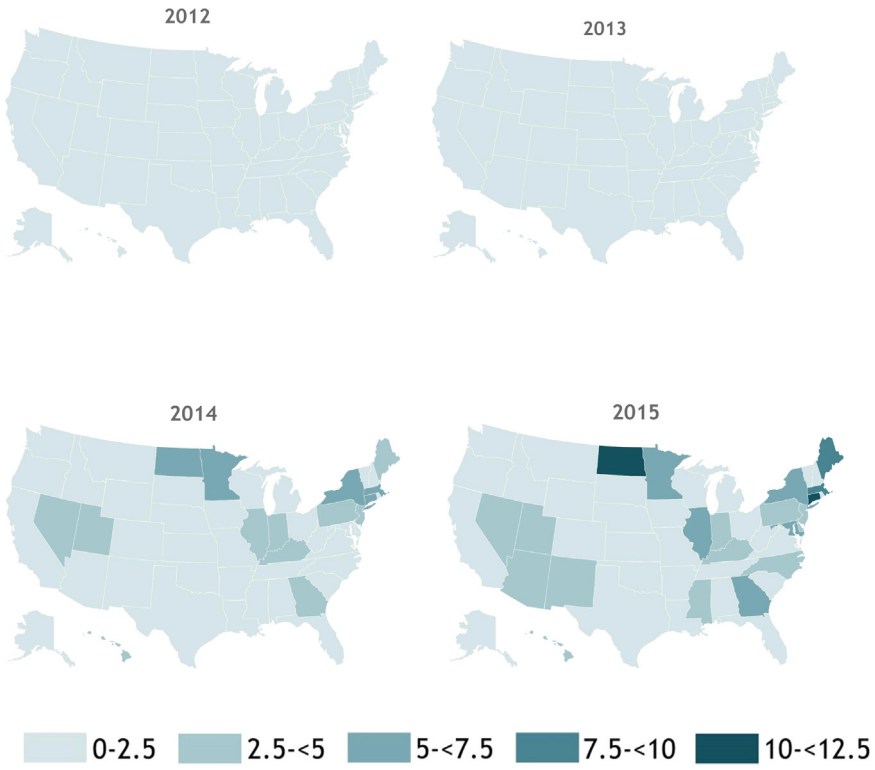

Fig. 4 – Ratio of percentage of Medicaid outpatient pharmaceutical reimbursement for DAAs and prevalence of chronic HCV infection, by year and state. DAA, direct-acting antiviral; HCV, hepatitis C virus.

been sued for not providing medically necessary treatments [36,37]. In November 2015, the CMS advised [38] state Medicaid programs that drugs may be excluded from coverage only if "the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes" [38]. As market competition increases with the approval of more DAAs, payers have increased negotiation power [39]. Clinical considerations, lawsuits, and presumably lower negotiated prices because more DAAs have come to market have led some state Medicaid programs [7] as well as other payers [40,41] to reimburse DAAs for all infected patients, regardless of severity of illness and comorbid conditions. Broad access to these drugs could eradicate a highly prevalent, infectious, and devastating disease but it could also strain the budgets of health systems, which need to reimburse a wide range of services and treatments for various medical conditions.

Our analyses found that DAAs accounted for as high as 10% to 15% of 2015 reimbursement for all prescription drugs in five

Table 1 – Estimated effects of expansions of Medicaid eligibility on Medicaid reimbursement for DAAs per Medicaid enrollee with chronic HCV infection (inflation-adjusted US $).

Expansion status	Pre-expansion period (2012, 2013)		Post-expansion period (2014, 2015)		Difference-in-differences	
	Adjusted mean ($)	95% CI	Adjusted mean ($)	95% CI	Estimate	95% CI
Non- or late-expansion states	204.15	−169.68 to 577.98	580.59	192.37 to 968.81	Reference	
Expansion states	442.01	1.36 to 882.66	2997.07	2405.99 to 3588.15	2178.63	1558.90 to 2798.35
Early adopter expansion states	800.84	22.47 to 1579.21	3012.61	2202.10 to 3823.12	1835.33	1038.93 to 2631.73

Note. Adjusted for state-level poverty rate, unemployment rate, penetration rate of Medicaid-managed care (i.e., percentage of Medicaid enrollees in comprehensive Medicaid-managed care plans). Early expansion states (before January 2014) were CA, CT, DC, MN, NJ, and WA. Non- or late-expansion states were those that did *not* expand during the study period: AK, AR, CO, IA, ID, LA, MI, MO, MT, OK, OR, RI, SC, SD, TN, TX, VA, VT, WI, WV, and WY.

Expansion states (effective from January 2014) were AL, AZ, DE, FL, GA, HI, IL, KS, KY, MA, MD, ME, MS, NC, ND, NE, NM, NV, NY, OH, and UT. NH, PA, and IN were not included in this analysis because their expansion started in the middle of 2014 or in 2015.

CI, confidence interval; DAA, direct-acting antiviral; HCV, hepatitis C virus.

states, with over 7.5% for DAAs in another five states. These findings raise important questions: Is it appropriate to devote as much as 15% of total reimbursement for all prescription drugs to one class of drugs? What impact does this spending have on spending for, and thus Medicaid beneficiaries' access to, medications for other diseases?

We also identified variations in Medicaid reimbursement for DAAs across states, after adjusting for state-level HCV prevalence. State Medicaid programs have implemented vastly different restrictions on reimbursements [19,20]. Eligibility criteria for reimbursement are complex with requirements related to (in various combinations) liver disease stage, HIV status, substance use disorder or alcohol dependence, periods of abstinence from drugs and/or alcohol use or abuse, and prescriber type. Variations in reimbursement restrictions together with difference in negotiated rebates might explain the large variability in DAA reimbursement percentages across states. This raises another important question: What approaches might be needed to reduce differences between states so that where a Medicaid patient lives does not dictate what treatment he or she receives?

We found significant increases in reimbursement for DAAs per enrollee with HCV infection in expansion states compared with non- or late-expansion states, controlling for pre-expansion reimbursement. Differences between early adopter states and non- or late-expansion states were similar. This contrasts with an earlier study that found no association between expansions and Medicaid reimbursement for prescription drugs overall in 2014 [34]. The difference in findings is not surprising given our focus on one drug class that required additional funding at a particular point in time that coincided with coverage expansion. Our finding suggests that the combination of Medicaid coverage expansion and the advent of new DAAs had enhanced access to DAAs.

DAAs for HCV infection are only one class of specialty drugs that pose important challenges to health systems because of their high economic burden. There is an increasing awareness of changes in prices of existing drugs, increases in the launch prices of new drugs, and increased cost shifting to patients, particularly for highly priced specialty drugs. In 2015 [42], specialty drugs accounted for 30.5% of spending on prescription drugs under Medicare, 36.5% in state Medicaid programs, and 33.3% among commercial health plans. There remains thus an urgent need for strategies that provide appropriate access to innovative, effective therapies while ensuring the sustainability of health systems. Budget impact of highly priced specialty drugs depends on more than their costs. DAAs have demonstrated real-world effectiveness, likely preventing future spending on treatment of sicker patients; their use is limited to short treatment courses rather than long-term as is the case for specialty drugs for inflammatory conditions; and availability of competitor products can decrease negotiated prices. Coverage decisions for other specialty medications are more challenging. For example, new cancer therapies often have uncertain, marginal, and/or short-term benefits; they are biologics usually without direct competitors; and state mandates for cancer treatment coverage limit payers' negotiation power. Rising costs of prescription drugs in general and specialty medicines in particular [43] are putting enormous pressure on budgets of public and private payers and families and remain a major concern for the American public [44]. Higher spending by payers will likely lead to higher premiums and/or deductibles, higher member cost sharing, or both—all of which threaten affordability of and equity in access to health care and may harm health [45].

Our study has several limitations. First, data provided by the CMS include both reimbursements for fee-for-service and managed care organization utilization but utilization may be underreported or reported incorrectly by states for managed care organizations as evidenced by a recent report by the Office of the Inspector General [46]; thus, our analysis might have underestimated reimbursement amounts. Second, data were missing for the following states and time periods: Alaska, all quarters of 2012 and quarter 3 of 2015; Alabama, quarter 3 of 2015; Florida, quarter 3 of 2015; North Dakota, quarter 3 of 2015; Oklahoma, all quarters of 2013; Tennessee, quarter 3 of 2015; Vermont, all quarters of 2015; and Washington, quarter 3 of 2015. We had data up to and include quarter 3 of 2015 for other states, thus underestimating 2015 reimbursement. Third, total Medicaid reimbursement reported in the CMS data does not account for manufacturer rebates or federal matching funds and the true net cost to the state is not reported by the CMS. Fourth, our analysis had adjusted for state-level prevalence of chronic HCV infection estimated for the state populations rather than specifically for the Medicaid populations. Finally, we used the only available chronic HCV infection prevalence rates that were estimated for 2010. Hepatitis testing (and thus known prevalence) may have changed with the availability of new medications for HCV infection since 2013, and growth in testing may differ across states, depending both on population demographic characteristics and on access to testing. Utilization and reimbursement data do not allow studying treatment outcomes, which remain an important topic for future work.

Conclusions

New DAAs can cure a potentially fatal, chronic infectious disease among vulnerable patients. Medicaid allocation to DAA reimbursement has increased considerably since the approval of sofosbuvir, the first DAA indicated for chronic HCV infection as part of an interferon-free regimen, and DAAs represented almost 8% or higher of total pharmaceutical reimbursement in 10 of 50 states in 2015. Medications for HCV infection are only one class of high-cost specialty drugs already on and coming to markets [47] that pose economic burden on health systems and society overall. Dialogue and innovative policy strategies are needed as health systems grapple with providing coverage for an increasing number of expensive specialty medications indicated for an increasing number of patients.

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Supplemental Materials

Supplemental data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.jval.2017.09.011.

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