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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.

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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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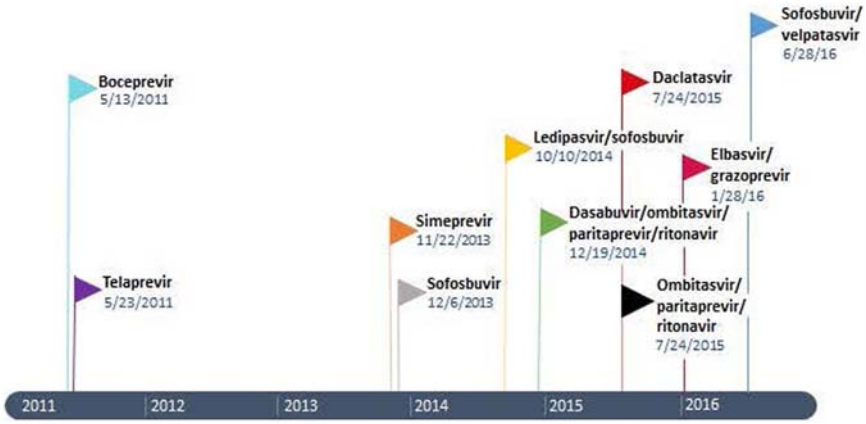

Fig. 1 – FDA approvals of DAAs for the treatment of chronic HCV infection. DAA, direct-acting antiviral; FDA, Food and Drug Administration; HCV, hepatitis C virus.

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

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