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Improving Access to High-Value, High-Cost Medicines: The Use of Subscription Models to Treat Hepatitis C using Direct Acting Antivirals in the United States

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Abstract

State payers may face financial incentives to restrict use of high-cost medications. Yet, restrictions on access to high-value medications may have deleterious effects on population health. Direct acting antivirals (DAAs), available since 2013, can cure chronic infection with Hepatitis C virus (HCV). With prices upwards of $90,000 for a treatment course, states struggled to ensure access to DAAs for Medicaid beneficiaries and the incarcerated, populations with a disproportionate share of HCV. Advance purchase commitments (APCs), wherein a payer commits to purchase a certain quantity of medications at lower prices, offer payers incentives to increase access to high-value medications and companies guaranteed revenue. Here, we discuss the use of subscription models, a type of APC, to support increased access to high-value DAAs to treat HCV. We start by providing some background information about HCV, its treatment, and state financing of prescription medications. We review the implementation of HCV subscription models in two states, Louisiana and Washington, and early evidence of their impact. We discuss challenges in evaluations of state-sponsored subscription models, and conclude with implications of subscription models targeting DAAs and other high-value, high-cost medicines.

Keywords

Prescription drugs; advanced purchased commitments; subscription models; states; affordability; equity; access

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The pharmaceutical industry has successfully developed numerous medications with the potential to treat or prevent conditions that once were responsible for high morbidity, mortality and associated economic loss. For example, the Hepatitis C virus (HCV), the most common bloodborne infection in the United States (U.S.), can now be effectively cured in more than 90% of patients or chronically managed with direct-acting antiviral (DAA) medications (American Association for the Study of Infectious Diseases and Infectious Diseases Society of America 2021). Many of these diseases disproportionately impact marginalized populations (Perlman and Jordan 2018). Consequently, these DAAs and other groundbreaking medications have the potential to substantially improve individual and population-level health, reduce the economic burden of disease, and improve equity (Liao and Fischer 2017).

High-value medications are commonly launched into the U.S. market with high unit prices. For example, Sovaldi was approved for sale and launched by Gilead Sciences in late 2013 as the first DAA that effectively cures HCV. Infamously, Sovaldi was priced at $1,000 per pill and $84,000 for an 8-week course of treatment.

Moreover, oftentimes high-value medications may increase overall spending by payers, if the population treated is large enough. For example, the launch of Sovaldi was responsible for a 24.6% increase in overall expenditures for Medicaid prescription drug spending in 2014 and the highest expenditures for any covered prescription drug across all payers that year (Schumock et al. 2015) (Medicaid and CHIP Payment and Access Commission 2018). Gilead Sciences and other pharmaceutical companies subsequently launched other DAAs into the U.S. market (Table 1). Between 2014 and 2018, the U.S. spent approximately $59 billion dollars on DAA-based HCV treatment alone (Shakeri et al. 2020).

The high unit prices of high-value medications can undermine societal goals of widespread use and improved population health. While independent economic experts determined that the prices for a complete course of Sovaldi and others DAAs are cost effective according to standard benchmarks (Chhatwal et al. 2015) (Institute for Clinical and Economic Review 2015), the collective costs of paying per prescription unit sold across all eligible HCV-positive people are significant. In 2014, the estimated costs to treat the entire U.S. population eligible for treatment (3.7 million people with HCV) with Sovaldi were $310 billion (Schumock et al. 2015). For comparison, total national spending on all prescription medications in 2014 was $360.7 billion. Moreover, a majority of DAA expenditures were expected to fall to public payers. For example, in 2014, Medicare was responsible for more than 70% of the $6.4 billion in U.S. expenditures on DAAs (Ornstein 2015).

Among payers that may need to balance their budgets or are otherwise cash-strapped, these expenses can force difficult choices between spending on medical care and the support of other social needs. For example, the state of Louisiana calculated that providing Sovaldi to all enrollees in the state's Medicaid program who would benefit from the medication would exceed the states' annual budget for K-12 education. Such cost pressures may also have consequences. Many states decided to restrict access to DAAs based on clinical, personal, and behavioral characteristics of treatment eligible patients (National Academies of Sciences, Engineering, and Medicine 2017) (Breskin et al. 2019).

Consequently, the challenge for payers, policymakers, and pharmaceutical companies is how best to ensure widespread access to high-value medications to all those who may benefit. There are alternative approaches to increase access to highly effective medicines. In this article, we examine subscription models, one approach used by two states in the U.S. to increase access to the DAAs to treat HCV, as a paradigmatic example of how to publicly finance high-value medications to improve individual and population health.

Additional Background on HCV and the DAAs

An estimated 2.5 million people are infected with HCV in the U.S., but the true number infected is likely much higher due to a dearth of testing and the infection's long asymptomatic period (Vermehren et al. 2018). Many are unaware of their infection status because HCV produces little to no clinical symptoms initially, however more than 50% of those with acute HCV will go on to develop chronic infection (Ryerson et al. 2020). Over years to decades, chronic HCV frequently causes comorbidities including cirrhosis, end-stage liver disease, and hepatocellular carcinoma which may lead to liver transplantation or death (National Academies of Sciences, Engineering, and Medicine 2017). Chronic HCV infection results in nearly 19,000 U.S. deaths annually, which exceeds the combined deaths from 60 other common infectious diseases including HIV (National Academies of Sciences, Engineering, and Medicine 2017). While historically the prevalence of HCV was highest among the baby boomer generation, the opioid epidemic has spurred rising rates of acute HCV among young adults, who now constitute the majority of new infections (Rosenberg et al. 2018). Injection drug use is a risk-factor for blood-borne infections, like HCV and HIV, primarily due to the sharing of contaminated injection equipment, and rates of injection drug use have increased concomitantly with the rise of the opioid epidemic (Zibbell et al. 2018). Thus, HCV now represents a multi-generational public health problem.

DAAs revolutionized HCV treatment when they were introduced to the market. Historically, the standard treatment for HCV entailed long-term management with a variety of medications (e.g., interferon) for those who progressed to a later stage of disease. Use of these older medications frequently resulted in unpleasant side effects, and few patients receiving treatment achieved a sustained virologic response (Carter, Connelly, and Struble 2017). Older medications suffered from significant treatment non-adherence and rendered eradication of HCV in at-risk populations highly challenging (National Academies of Sciences, Engineering, and Medicine 2017). With the advent of highly effective, well tolerated DAAs, physician groups and public health organizations recommended universal screening for HCV and treatment for all those eligible (Schillie et al. 2020) (Waters and Broder 2018).

However, DAAs are high cost with prices ranging from $54,000-$95,000 per treatment course (Shakeri et al. 2020). High expenditures anticipated with widespread DAA use resulted in scrutiny from policymakers, the media, and ultimately, a U.S. Congressional investigation into the price-setting of DAAs by pharmaceutical companies (US Senate Finance Committee 2015). The U.S. Senate Finance Committee found that Gilead, the pharmaceutical company responsible for Sovaldi and Harvoni (Table 1), may not have appreciated the impact that the prices of these medications would have on patient access. To

improve affordability, pharmaceutical companies offered DAAs at discounts to U.S. payers. For example, Gilead offered an average discount of 46% off list price for its two DAAs (Sovaldi and Harvoni) initially, and this discount increased to more than 60% in the years following launch (Institute for Clinical and Economic Review 2015). While the number of DAAs available that treat HCV has increased in recent years (Table 1), the costs of these medications have remained high. Thus, nationwide access to HCV screening, diagnosis, and treatment has been challenged by poor patient access, high treatment costs, and insufficient health system capacity (Kapadia et al. 2019).

Background on State Covered and Financed HCV Treatment

Ensuring widespread access to DAAs have been particularly problematic among populations insured by state Medicaid programs and criminal justice systems, which face limited budgets and a disproportionate share of beneficiaries with HCV (Gifford et al. 2020). State Medicaid programs provide coverage to more than 80 million people, many of which have considerable health needs. While prescription drug coverage is not mandated by federal law, all state Medicaid programs provide this benefit. State Medicaid programs have faced rising spending on prescription drug over the last decade and use different strategies to provide this benefit while attempting to contain costs, but generally finance prescription drug coverage through two mechanisms. A state may choose to pay pharmacies directly for dispensed prescription drugs per unit under fee-for-service (FFS) payment arrangements. Alternatively, states can contract with private managed care plans to provide prescription drug benefits and pay a capitated rate to the Medicaid managed care (MMC) organization (Gifford et al. 2020) inclusive of all expected prescription drug spending. In turn, MMC organizations typically pay pharmacies for dispensed prescriptions directly and do not receive additional state reimbursements. The majority of states use the MMC arrangement.

There are two existing policies that ensure that the per unit prices paid by states for prescription drugs are affordable. First, all states participate in the Medicaid Drug Rebate Program (MDRP) (Medicaid and CHIP Payment and Access Commission 2018). The MDRP requires that pharmaceutical companies offer a statutory rebate to state Medicaid programs after drugs are dispensed (Medicaid and CHIP Payment and Access Commission 2018). In turn, state Medicaid programs must cover all approved drugs from pharmaceutical companies participating in the MDRP. Statutory rebates are currently set as the lower of the drug's average manufacturer price minus 23% or the Medicaid best price (Medicaid and CHIP Payment and Access Commission 2018). States can and do negotiate supplemental rebates with pharmaceutical companies, which can further reduce the per unit price of prescription medications. However, pharmaceutical companies typically only agree to provide supplemental rebates under certain conditions, such as to secure preferential status for their drug when there are competing branded medications within a therapeutic class (Medicaid and CHIP Payment and Access Commission 2018) (Hwang, Kesselheim, and Sarpatwari 2017).

Another policy initiative to increase access to prescription drugs for vulnerable populations is the 340B program. The 340B program requires pharmaceutical companies who participate in the MDRP to sell prescription drugs to selected 'safety net' health care organizations

at significantly reduced acquisition costs. The patients eligible for treatment with these discounted drugs are those receiving regular treatment at 340B participating clinics and hospitals serving the needs of the uninsured, rural communities, and underserved populations (Williamson and Horvath 2019) (National Conference of State Legislatures 2021). By statute, 340B discounts for prescription drugs are set based on Medicaid statutory rebates and may even be lower than the net prices state Medicaid programs pay for the same drug. States have explored partnerships with 340B safety net providers to provide access to selected high value, high cost medications among their uninsured and incarcerated populations (Williamson and Horvath 2019).

Nevertheless, rising spending on prescription drugs have prompted state Medicaid programs to explore other avenues to constrain use. Utilization management strategies are frequently employed to limit access to high cost prescription medications (US Senate Finance Committee 2015) (Gifford et al. 2020). For instance, the majority of state Medicaid programs have imposed criteria requiring severe liver damage and substance sobriety to limit access to the DAAs (Ooka, Connolly, and Lim 2017; Bruen, Brantley, and Thompson 2017). States have also used preferred drug lists (PDL) as a tool to negotiation larger supplemental rebates from pharmaceutical companies and lower their costs of providing HCV treatment (Gifford et al. 2020).

Advanced Purchase Commitments (APCs) and HCV-Targeted Subscription Models

One alternative approach to improve access to high value, high cost medications for all treatment-eligible individuals is to use advanced purchase commitments (APCs). APCs entail a voluntary partnership between a payer and a pharmaceutical company, where the payer commits to a minimum quantity purchased at a specified price and another price when use exceeds a predetermined threshold (Towse and Kettler 2005). APCs have been used to ensure widespread and equitable access to high value, high cost medications that treat pneumococcal disease, malaria, tuberculosis, and other diseases primarily afflicting low-income and middle-income countries (Kremer, Levin, and Snyder 2020) (Berndt et al. 2007) (Mueller-Langer 2013). In the past two years, the U.S. government has entered into APCs for COVID-19 vaccines and therapeutics (Frank, Dach, and Lurie 2021), and the U.S. has a history of using APCs for other vaccines and medications to prevent or treat other infectious diseases. APCs are attractive to pharmaceutical companies because they guarantee revenue once a product is brought to market and can be structured to guarantee revenue even if the therapeutic class experiences subsequent entry and competition. The downside of APCs to pharmaceutical companies is the erosion of pharmaceutical companies' ability to charge high prices to non-participating payers.

One type of APC that is currently used to improve HCV treatment access in the U.S. has been dubbed a 'subscription' model in the popular press. Subscription models are usually limited to a specific payer (e.g., Medicaid) or patient type (e.g., incarcerated persons) and operate using existing payment structures (e.g., payment per use) augmented with additional discounts and rebates to limit spending above a certain threshold. Subscription models

enable reductions in the use of utilization management techniques to support the goal of greater medication access and improved individual and population health.

The states of Louisiana and Washington implemented subscription models for HCV treatment. Others have followed the example of these states in their use of subscription models to address HCV and other diseases, but public details are scarce on these arrangements (Liu, Mulcahy, and Rose 2020).

Louisiana pioneered the use of subscription models for HCV treatment in the U.S., expanding access for the state's Medicaid insured and incarcerated populations in July 2019 (U.S. Department of Health and Human Services 2020). The state contracted with Gilead Science's subsidiary Asegua Therapeutics for access to the authorized generic versions of two of their DAAs, Epclusa and Harvoni, with an expected end date of June 2024 (Louisiana Department of Health 2019b). Louisiana agreed to preferentially contract with Asegua Therapeutics and in exchange the company agreed to supply their DAAs at a unit cost until an annual cap was reached that was approximately the state spend on DAAs in the prior year. After the cap is reached, Asegua agreed to provide unlimited drugs to the state's Medicaid program at no cost through supplemental rebates for five years. Louisiana's subscription model is expected to treat an additional 31,000 incarcerated persons during the contract period (Beckman et al. 2016), leveraging the availability of 340B drug discounts with partner clinics responsible for screening and treatment. In this way, Louisiana negotiated unlimited access for incarcerated persons at a set price using state dollars existing outside the state Medicaid budget.

Prior to implementing the subscription model, Louisiana made several changes to the delivery of its Medicaid prescription drug benefit, including expanding Medicaid to low-income adults under the ACA in 2016 and adopting a uniform PDL in 2019 (Magellan RX Management 2019) (Morley, Stuard, and Dickson 2020) (Kaiser Family Foundation 2020). Louisiana also removed prior authorization requirements for subscription DAAs (U.S. Department of Health and Human Services 2020).

Washington state also implemented a subscription model targeted to HCV treatment in July 2019 (Washington State Health Care Authority 2019). It did so after implementing other changes to their Medicaid prescription drug benefit in prior years, including expanding Medicaid to low-income adults in 2014 and removing most clinical restrictions to access HCV medications in late 2016 (Center for Health Law and Policy Innovation 2017). The state contracted with Abbvie for access to their DAA, Mavyret, using two separate five-year arrangements: one for the state Medicaid population and another for the state's non-Medicaid insured population (Washington State Health Care Authority 2019). The non-Medicaid insured population contract includes state employees, incarcerated persons, and patients of certain hospitals in the state. Under both the Medicaid and non-Medicaid contract, Mavyret is the only preferred DAA for HCV treatment on the plans' respective PDLs. Under the Washington state Medicaid contract, Mavyret is provided at a discounted price through supplemental rebates up to an annual utilization threshold (Washington State Health Care Authority 2019). After the threshold is met, the cost of additional prescriptions is nominal for the state's Medicaid program. The annual utilization threshold can be re-

negotiated, and was during the COVID-19 pandemic. The non-Medicaid contract includes discounts that require Abbvie to provide Mavyret at the ‘best guaranteed net unit price’.

The Early Impact of Subscription Models on HCV Treatment in Louisiana and Washington

The effects of Louisiana and Washington’s subscription payment models are still being evaluated, but initial research examining their impact on access to HCV treatment suggests promise. Data published by Louisiana’s Department of Health (Louisiana Department of Health 2021) reports that more than 9,000 people insured by the state have initiated HCV treatment since their subscription model was implemented. In comparison, they report that fewer than 300 individuals insured by the state’s Medicaid program in 2016. Auty et al. (2021) used a synthetic control approach and state-level, publicly available Medicaid prescription claims data to conduct an early evaluation both states’ subscription models. Louisiana’s HCV subscription model was associated with a 534.5% increase in Medicaid-covered DAAs dispensed in the year after implementation compared to the previous year. Auty et al. (2021) also found that Washington did not experience a significant change in Medicaid-covered DAAs dispensed in the year after implementation compared to the previous year.

There are several potential reasons for divergent results between the two states in their first year after implementing HCV targeted subscription models. First, both Louisiana and Washington engaged in significant public awareness campaigns with the implementation of subscription models, although the specifics differed (Washington State Department of Health 2019; Louisiana Department of Health 2019; U.S. Department of Health and Human Services 2020). Louisiana’s public health strategy was developed with significant and diverse buy-in; the pharmaceutical company, physicians, hospitals, Medicaid managed care companies and parish (county) health systems throughout the state were involved early in implementation plans to meet the needs of local residents. The Louisiana Department of Health leadership toured the state and implemented extensive training on criteria and protocols for HCV treatment for primary care practitioners. Moreover, Louisiana’s model specifically targeted the incarcerated population, which had previously been unable to access HCV treatment.

Unlike Louisiana, many of Washington’s awareness initiatives occurred contemporaneously with its implementation of the subscription model in July 2019. Guided by high rates of injection drug use and rising rates of HCV among this population, a core component of Washington’s strategy was co-location of substance use treatment and HCV screening (Washington State Health Care Authority 2019). Abbvie also committed to help identify HCV-positive individuals through community outreach using an HCV awareness bus that travelled to HCV hotspots across the state. Both initiatives were halted following the pandemic’s onset; they were partially resumed in 2021 (Sullivan, Fliss, and Evaskus 2020). Moreover, HCV screening and related services for Medicaid enrollees generally were disrupted due to delays or cancellations of non-urgent care during the pandemic. Thus, delays in the state’s efforts to increase HCV screening and disruptions in care related to the

pandemic likely impacted use of the DAAs in the year following the state's implementation of their subscription model.

Lastly, there appears to have been significant pent-up demand for HCV treatment in Louisiana. Before the implementation of the subscription model, Louisiana's Medicaid program required HCV-positive individuals to maintain sobriety and have severe liver damage to access DAA medications, while Washington removed these restrictions several years prior to the implementation of their subscription model. Prior research has demonstrated that removal of these restrictions significantly improves utilization of DAAs, which may decrease demand for these medications in future years (Liao and Fischer 2017; Kapadia et al. 2018).

Challenges to Identify and Overcome in Estimating the Effects of Subscription Models

Formal economic evaluations of the impact of both states' subscription models on a wide array of clinical and economic outcomes are currently underway. However, stakeholders may have to wait for years for empirical evidence of their impact. In this section, we detail what is known about epidemiological outcomes of interest, specifically whether more individuals have been treated with the implementation of these models. We then discuss challenges faced in evaluating subscription payment models in Louisiana and Washington, and using these estimates to compare the potential impact of these models over potential alternatives.

First, as of writing, national and state specific HCV diagnosis and treatment statistics annually collated and publicly reported by the Centers for Disease Control are only available through 2018 and therefore cannot be used to assess the impact of subscription models.

Second, state policy changes are often initiated in reaction to poor outcomes and/or high costs, and the implementation of such policies may be dictated by the unique realities of each state. Thus, a considerable concern is that policies that may naively appear effective are in fact a product of endogenous policy selection and implementation. In Louisiana, there was active championing of the HCV subscription model by its then Secretary of Health, the state's Governor, and one of the state's U.S. Senators (Gee 2019) (Johnson 2017), Senator Bill Cassidy, who is also a physician specializing in liver disease. The pharmaceutical company partnering with the state, Gilead Sciences, was also well versed in similar models globally and already had an active presence in the state supporting existing HCV/HIV screening and treatment efforts. The result of significant multi-stakeholder buy-in may ultimately contribute to the success of the subscription model, but also makes the experience of the Louisiana HCV subscription potentially less generalizable to other contexts.

Third, randomized controlled trials (RCT) are often viewed as a gold standard for causal inference, but are practically difficult to implement (Alsan and Finkelstein 2021) (National Conference of State Legislatures 2017). This has led to a rise in the use of quasi-experimental research methods to draw causal conclusions from observational data (Basu, Meghani, and Siddiqi 2017) (Stuart and Rubin 2008). The planned evaluation of

the Louisiana HCV subscription model will employ the use of difference in differences and instrumental variables exploiting differential program rollout by selected providers throughout the state to identify a plausibly causal estimate.

There are still potential problems that could challenge state policy evaluations. State Medicaid claims and administrative data have considerable data lags, are expensive and administratively burdensome for researchers to obtain, and there is considerable variation in data quality across states (Leonard et al. 2017; Crystal et al. 2007; Hennessy et al. 2007). Moreover, data on health service use among incarcerated persons can be difficult to obtain, hindering efforts to improve the health of this population (Binswanger et al. 2019). Data on health service need and use is typically managed by a state sub-agency separate from the state Medicaid data and entails separate and additional permissions. Finally, the risk of politically inconvenient results from independent evaluators may also incentivize states to restrict data access, reduce the types of questions that may be evaluated, or prevent findings from being widely communicated.

Future Directions for Research and Policy

States are often at the forefront of strategies to improve access to care, health outcomes and affordability. The use of subscription models in Louisiana and Washington, among other states, are exciting developments and are paving the way for other efforts by stakeholders to improve access and affordability to high-value medications (Conti, Dusetzina, and Sachs 2020).

Given the early success of the subscription model in Louisiana even in the midst of the COVID-19 pandemic, payers, pharmaceutical companies and policymakers might consider its use to improve access to DAAs and other high-value medications. According to recent estimates, less than 50% of those aware of their current HCV infection status receive treatment (Stasi, Silvestri, and Voller 2020). Possible additional candidates for subscription models include pre-exposure prophylaxis (PrEP) for HIV (Centers for Disease Control and Prevention 2021) and medications for opioid use disorder (U.S. Department of Health and Human Services 2018), as both medication classes have already been judged to be highly cost-effective and target diseases that disproportionately burden the uninsured, incarcerated persons, and those who experience other structural barriers to high-value medical care. There is also evidence that these medications are currently being rationed by payers due to high expected expenditures (Greenwald, Waters, and Cayer 2020). Stakeholders should seek to reduce barriers to systematic evaluations of these and other models by researchers and communicate results to improve knowledge of best practices. Subscription payment models have the potential to radically improve access to high-value medications for vulnerable patients and ultimately improve population health.

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Table 1

Direct Acting Antivirals Approved for the Treatment of Hepatitis C in the U.S.

FDA Approval Date	Pharmaceutical Company	Brand or Generic	Brand Name	Active Ingredients
December, 2013	Gilead Sciences, Inc.	Brand	Sovaldi	Sofosbuvir
October, 2014	Gilead Sciences, Inc.	Brand	Harvoni	Ledipasvir/sofosbuvir
June, 2016	Gilead Sciences, Inc.	Brand	Epclusa	Sofosbuvir/velpatasvir
July. 2017	Gilead Sciences, Inc.	Brand	Vosevi	Sofosbuvir/velpatasvir/voxilaprevir
January, 2019	Asegua Therapeutics	Authorized generic	N/A	Sofosbuvir/velpatasvir
January, 2019	Asegua Therapeutics	Authorized generic	N/A	Ledipasvir/sofosbuvir
December, 2014	AbbVie Inc.	Brand	Viekira Pak	Ombitasvir/paritaprevir/ritonavir/dasabuvir
July. 2015	AbbVie Inc.	Brand	Technivie	Ombitasvir/paritaprevir/ritonavir
July, 2016	AbbVie Inc.	Brand	Viekira XR	Dasabuvir/ombitasvir/paritaprevir/ritonavir
August, 2017	AbbVie Inc.	Brand	Mavyret	Glecaprevir/pibrentasvir
January, 2016	Merck	Brand	Zepatier	Elbasvir/grazoprevir