

Cost-effectiveness of Total State Coverage for Hepatitis C Medications

William V. Padula, PhD; Jonathan S. Levin, PhD; Joy Lee, MD, MPP; and Gerard F. Anderson, PhD

Direct-acting antivirals (DAAs) are associated with cure rates above 95% for hepatitis C virus (HCV).¹ However, the exorbitant costs of DAAs historically have made access prohibitive for many patients. Patients could rarely afford the total costs of these treatments when they entered the market at a price point above \$80,000, let alone the out-of-pocket co-pays associated with these drugs, which could exceed thousands of dollars per course of treatment.² Changes in the market and range of DAA offerings in the past several years have potentially made treatment of HCV more accessible, with a price range of \$20,000 to \$30,000 aside from co-pays, but this problem is not solved, especially for populations who are Medicaid eligible or uninsured.^{3,4}

Today, many state Medicaid programs cover DAAs for less than 30% of patients with HCV due to prohibitive pricing.⁵ The challenge for Medicaid regarding DAA coverage is primarily a budget issue.⁶ If all eligible Medicaid beneficiaries with HCV were covered simultaneously for a DAA, it would represent billions of dollars above most state Medicaid programs' total annual budgets.^{7,8} As a result, Medicaid programs are reluctant to spend money when costly consequences of HCV usually occur years later when patients are enrolled in Medicare.⁹

Thus, Medicare has significant financial incentives to partner with Medicaid today to treat the majority of HCV cases, thereby minimizing the impact of future HCV symptoms on the Medicare budget. Maryland's Total Cost of Care (TCOC) model represents a proposed policy designed to do just that, with the possibility of receiving a credit from Medicare to offset Medicaid investments in DAAs that could lead to Medicare savings. This financial model would address the mismatch between who spends money on health care and who benefits.

The cost-effectiveness of DAAs has been increasingly explored across a number of value-based purchasing scenarios.¹⁰⁻¹² Yet, the value of the Maryland TCOC proposal (ie, "total coverage") specifically remains unknown. We examined the cost-effectiveness and budget impact of Maryland state-sponsored total coverage for DAAs to all patients with HCV from a health care sector perspective and from the perspective of the state's Medicare budget. Both

ABSTRACT

OBJECTIVES: Most Medicaid beneficiaries with hepatitis C virus (HCV) are not treated with direct-acting agents because of budget constraints, but they experience costly complications after becoming Medicare eligible. Maryland's "total coverage" proposal could receive a credit from Medicare to offset Medicaid investments in treatments that could lead to Medicare savings. This study analyzes the cost-effectiveness and budget impact of total coverage for HCV treatments sponsored by state Medicare and Medicaid.

STUDY DESIGN: A Markov model simulated patients going through the care continuum of HCV. The model simulated 3 pathways: standard coverage with a 50% probability of screening for HCV and 20% probability of treatment; risk-stratified total coverage with assumed 80% probability of screening and 60% treatment rate; and total coverage with assumed 80% probability of screening and 100% treatment rate.

METHODS: The model calculated US\$ and quality-adjusted life-years (QALYs) to produce an incremental cost-effectiveness ratio evaluated at a willingness-to-pay threshold of \$100,000/QALY. The budget impact for the state of Maryland was calculated in terms of per member per year.

RESULTS: Total coverage and risk-stratified coverage saved \$158 per patient and \$178 per patient, respectively, compared with standard care at an increased effectiveness of 0.05 and 0.02 QALYs over 25 years. Total coverage and risk-stratified total coverage would save \$1.0 billion and \$1.1 billion, respectively, after 25 years.

CONCLUSIONS: Medicare-Medicaid partnerships to pay for all HCV treatments today represent good value and a low budget impact. States with trouble covering HCV treatments should consider using this model to plan coverage decisions.

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TAKEAWAY POINTS

Expanded coverage under a joint partnership by Medicare and Medicaid to treat all prevalent cases of hepatitis C virus (HCV) appears to be cost-effective by saving money and improving patient outcomes.

- ▶ This coverage policy could save \$1.4 billion over 25 years.
- ▶ This is the first economic evaluation that considers the effects of a joint Medicare-Medicaid partnership for coverage of HCV medications.
- ▶ In states where Medicaid does not have sufficient finances to cover all HCV treatments separately, there is justification for Medicare to supplement funds for treatment coverage in order to avoid dealing with disease symptoms as the population ages.

HCV rates in the Medicaid-eligible, uninsured, and elderly populations.

METHODS

We developed a semi-infectious disease model with Markov structure to evaluate the cost-effectiveness of DAA coverage plans for patients with HCV enrolled in the Maryland Medicaid program. We refer to this as “semi-infectious” because the model does not identify entire secondary transmission effects. The model had 3

comparator arms. The standard care option represented current state policies on screening and DAA coverage decisions for patients with HCV. The first alternative represented total coverage of DAAs for all patients with HCV in Maryland. The second alternative represented total coverage with prioritization for DAA access first given to patients with HCV who are at high risk for escalating chronic symptoms.

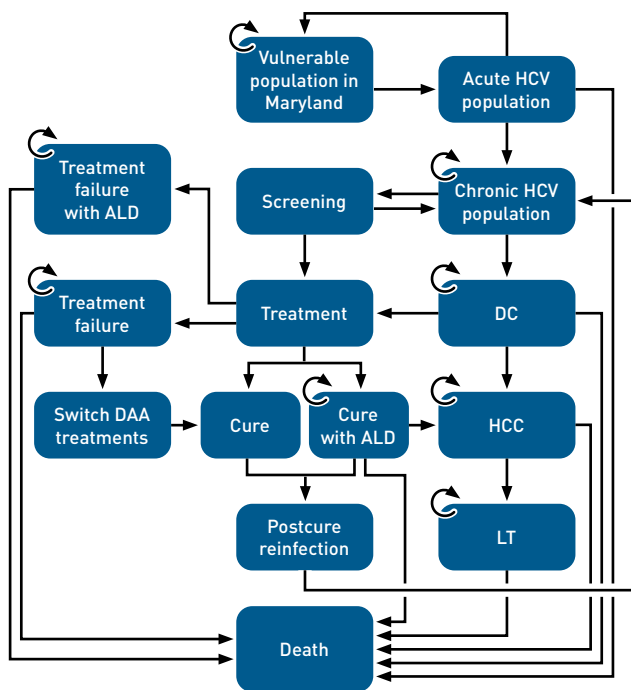
The model was designed to provide an incremental cost-effectiveness ratio (ICER) and budget impact to Maryland taxpayers, discounted at 3%. The Markov model examined common transitions between health states adjusted to current standards of care in Maryland, such as HCV diagnosis and treatment with coverage in 1-year cycles over a 25-year time horizon. This amount of time was necessary to measure the costs associated with the health complications due to HCV. The main outcome measures used in the ICER calculation were 2018 US\$ and effectiveness in terms of quality-adjusted life-years (QALYs). The ICER was calculated from a health care sector perspective according to methodological specifications set by the US Panel on Cost-effectiveness in Health and Medicine.¹³ Final results of the ICER were interpreted at a willingness-to-pay threshold of \$100,000/QALY.¹⁴

Model Design

The semi-infectious disease model assessed the cost-effectiveness of HCV outcomes based on increased treatment probabilities under the total coverage scenario, compared with 2 scenarios reflecting the current payer model with standard coverage for all beneficiaries or prioritized coverage for all high-risk beneficiaries (Figure 1). In the latter alternative, the 60% of patients with chronic HCV who had a liver fibrosis score of 2 or higher, as opposed to a fibrosis score of 0 or 1, received DAAs first, before lower-risk patients, in order to better manage budget impact.¹⁵

The standard coverage arm measured the current screening probability of 50% for chronic HCV and subsequent uptake probability of DAA treatment at 20%. Patients begin at either the “vulnerable population” (ie, susceptible to contracting HCV), “acute HCV,” or “chronic HCV” states depending on their health state, level of behavioral risk, and symptoms. Patients who either started at or progressed to chronic HCV were modeled as having higher rates of the escalating outcomes, although they had a lower probability of accruing DAA treatment costs.

FIGURE 1. Markov Model of the Health State Transitions for HCV Treatment^a



ALD, acute liver disease; DAA, direct-acting antiviral; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; LT, liver transplant.

^aThe model illustrates a clinically validated care pathway for diagnosis and approvals to obtain curative therapy for HCV. Patients start in either the “vulnerable population in Maryland,” “acute HCV,” or “chronic HCV” stages. As a Markov model, it is designed to incorporate reinfection rates for patients with high-risk behaviors, as well as to introduce new at-risk patients into the population during the 25-year time horizon from the Maryland health care sector perspective. The model reflects a common care pathway for patients with HCV in the state of Maryland.

perspectives incorporated the patient, payer, and provider costs for HCV treatment. The goal of this economic evaluation was to determine whether a policy like the TCOC holds good value and would sustain the Medicaid program budget in Maryland, as well as potentially other states that are facing an emergent concern of high

The model then included coverage for HCV diagnostic screening. Patients who were screened and verified to have HCV would then receive treatment with a course of DAAs. Once treated, most patients would either transition to a “cure” state or proceed to a cure state with the additional presentation of acute liver disease (ALD).

Some patients who received treatment would presumably fail one form of DAA and switch to another type of DAA to ultimately enter a cure state. The presence of ALD during treatment could also be an effect modifier on treatment failure, noted as “ALD treatment failure” in the model.

As appropriate with a semi-infectious disease model, some patients would enter a “postcure reinfection” state because their behavioral risk factors that led to the initial HCV infection could influence reinfection at a nontrivial probability. Those in the “acute HCV” state could also influence infection rates to the vulnerable population, as HCV cases left untreated lead to the spread of infection.

Patients who were diagnosed with chronic HCV but left untreated, as well as patients with HCV who have not been screened (and therefore are untreated), could display symptoms of HCV advancement, including decompensated cirrhosis¹⁶ and hepatocellular carcinoma (HCC). A small fraction of patients with HCC would ultimately face the prospects of a high-cost liver transplant. Patients in any of these chronic, symptomatic states, in addition to treatment failure, also faced the prospect of death.

Model Parameters

Costs of patients with HCV and ALD were extracted from studies using private insurance and Medicare claims. Based on reports by McAdam-Marx and colleagues as well as the sources used in Van Nuys and colleagues’ estimates of the incremental costs of chronic HCV, we subtracted their reported costs of antiviral medications and then calculated a weighted mean of \$5435 per patient.^{7,17-19} The costs of postcure advanced liver disease were drawn from research by Cheung et al.²⁰ We did not attribute costs for either being in the vulnerable population or death. Costs of DAA treatment were based on the wholesale acquisition price of glecaprevir/pibrentasvir (Mavyret; AbbVie): \$26,400 to \$39,600 for an 8- to 12-week treatment course (Table 1^{1,4,7,12,15,18-32}). This cost represents the latest DAA treatment available on the market at the lowest available cost that Medicaid would most likely approve.

TABLE 1. Model Parameters^{1,4,7,12,15,18-32}

Parameter	Expected value	Standard error for sensitivity analysis	Source(s)
Annual probabilities			
HCV infection	0.001309	0.003	23
Risk-stratified DAA coverage, chronic HCV fibrosis score 2+	0.6049	0.279	15
Spontaneous cure	0.2600	0.065	25
Progression from acute to chronic HCV	0.7400	0.065	25
Mortality, baseline	0.0084	0.002	26
Mortality with acute HCV	0.0160	0.004	27
Mortality with chronic HCV	0.0480	0.012	22
Mortality with DC	0.1470	0.037	24
Mortality with HCC	0.4270	0.107	24
Mortality with LT	0.1160	0.029	24
Historical screening for chronic HCV infection	0.4980	0.125	21
Total coverage screening for chronic HCV infection	0.8000	0.200	Assumed
Progression from chronic HCV to DC	0.0007	0.0002	28,29
Progression from chronic HCV to HCC	0.0002	0.00004	28,29
Progression from DC to HCC	0.0680	0.017	24
Progression from DC to LT	0.0230	0.006	24
Progression from HCC to LT	0.0400	0.010	24
Progression from cure + ALD to DC	0.0080	0.002	24
Progression from cure + ALD to HCC	0.0520	0.013	30
Treatment for universal coverage	1.0000	0.250	Assumed
Treatment for historical coverage	0.2000	0.050	Assumed
Success after first treatment	0.9600	0.145	1
Success after second treatment	1.0000	0.250	Assumed
Success for patients with DC or HCC	0.8160	0.204	31
Uptake for switching to second treatment	1.0000	0.250	Assumed
Reinfection of cured population	0.0095	0.007	32

(continued)

We measured the current screening probability of 50% for chronic HCV and subsequent uptake probability of DAA treatment at 20% in the standard-care arm.²¹ The model allows for those who were not screened in a given cycle to be screened in a subsequent cycle. Patients under total coverage had a screening probability of 80% to reflect the increase in awareness and coverage that would result from such an initiative. For those who are screened for chronic HCV, there was 100% uptake of DAA treatment; these values adjusted the assumptions from the state. In the high-risk model, only 60% of screened patients with chronic HCV were provided DAA treatment per year, according to findings of DAA coverage in the Medicaid population by Karmarkar.¹⁵

Health utilities measured in units of QALYs were extracted from existing economic models that used utilities in the past.^{12,22} These QALYs are typically extracted from EQ-5D index scores of US-based preference weights.³³

Upon completing the model, our results were checked for consistency with outcomes determined by Van Nuys and colleagues.⁷

TABLE 1. (Continued) Model Parameters^{1,4,7,12,15,18-32}

Parameter	Expected value	Standard error for sensitivity analysis	Source(s)
Annual costs (\$)			
Acute HCV	775.00	193.75	12
Chronic HCV	5435.00	847.78	7,18,19,31
Screening	533.00	133.00	12
First DAA treatment	26,400.00	6600.00	4
Treatment when in ALD	39,600.00	9900.00	4
Treatment failure	5435.00	847.78	7,18,19,31
Second DAA treatment	26,400.00	6600.00	4
HCV cure	131.18	32.80	22
DC	34,976.00	7403.00	22
HCC	35,940.00	9067.50	22
LT	102,520.00	30,406.00	22
Postcure reinfection	5435.00	847.78	7,18,19,31
Treatment failure in ALD stages	36,595.06	9148.77	22
Postcure compensated cirrhosis	24,215.38	6053.85	20
Annual QALYs			
Vulnerable population	0.99	0.025	Assumed
Acute HCV	0.930	0.050	12
Chronic HCV	0.860	0.075	22
Screened for HCV	0.860	0.075	22
Treated once for HCV	0.981	0.011	22
Failed HCV treatment	0.860	0.075	20
Treated twice for HCV	0.981	0.011	22
Cured of HCV	1.000	0.025	12
Postcure reinfection	0.860	0.075	20
DC	0.700	0.175	22
HCC	0.670	0.168	22
LT	0.780	0.195	22
Treatment failure in ALD stages	0.701	0.175	22
Postcure compensated cirrhosis	0.782	0.195	22

ALD, acute liver disease; DAA, direct-acting antiviral; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; LT, liver transplant; QALY, quality-adjusted life-year.

Budget Impact

Upon completion of the ICER calculation, a budget impact calculation was also conducted to estimate the per-member per-year costs of allocating Maryland taxpayer contributions to the Medicaid and Medicare budgets to implement total coverage. We assumed that 50% of patients with chronic HCV were enrolled in Medicare and 100% of patients in the ALD stages were Medicare eligible. This assumption was based on the fact that the 1945-1965 birth year cohort will all be Medicare eligible within the next 10 years.

Model Assumptions

The model started with a population of 6,050,000 individuals, of whom 50,000 currently had HCV, and half of whom had been born between 1945 and 1965. Those without HCV remain in the “vulnerable

population” stage. We also assume a constant 0.13% infection probability of the vulnerable population in Maryland, which is based on the infection rate in 2017 according to HepVu, and a 0.95% reinfection probability among patients with HCV during the postcure phase.²³ We also assumed that diagnosed patients who were untreated would undergo additional screenings before they would eventually initiate DAA treatment.

Under total coverage, we assumed 80% screening and 100% treatment probabilities. This assumption was made in order for the state to have an upper-bound estimate of the cost of this program. We assumed that untreated patients would experience continuous progression of outcomes in escalating stages, which included specific mortality probabilities.²⁴ We also assumed that patients with undiagnosed HCV who were experiencing these outcomes would become aware of their HCV status during these stages. The model assumed reinfection of some treated patients and newly infected patients from the existing cohort.

Under the total coverage alternative prioritizing high-risk patients, we assumed 80% screening and 60% treatment probabilities. The 60% treatment rate is based on Maryland Medicaid rates of coverage in high-risk cohorts—patients with chronic HCV with a fibrosis score of 2 (F2) and fibrosis scores of 3 and 4 (F3 and F4) have treatment rates of 85.4% and 97.5%, respectively.¹⁵ Relative to all patients with HCV in Maryland, F2 patients make up 40% of the population, and F3 and F4 patients make up 27% of the population.¹⁵ Under the assumption that the Medicaid program would first cover all patients with high-risk, chronic HCV with fibrosis scores of 2 or higher, this constitutes a risk pool of about 60% of screened patients.

This model did not account for the medical and social spillover effects of an HCV cure. Other assumptions were that the policy environment and current trends in health care policy remained the same.

Sensitivity Analysis

Sensitivity analyses were conducted to test uncertainty in the design of the economic model. We performed univariate 1-way and 2-way sensitivity analyses, as well as Bayesian multivariate probabilistic sensitivity analyses on all model parameters. The 1-way sensitivity analyses varied the parameters of screening and treatment probabilities. For the probabilistic sensitivity analysis, we tested uncertainty in all parameters simultaneously using 1000

TABLE 2. Incremental Cost-effectiveness Ratio (\$/QALY) Findings^a

Comparator	Cost (\$ per patient)	ΔCost ^b	QALYs (QALY per patient)	ΔQALYs ^b	\$/QALY
Standard coverage	686.72		16.33		
Total coverage (vs standard coverage)	528.90	-157.82	16.38	0.05	Dominates
Total coverage: risk-stratified HCV fibrosis 2+ (vs standard coverage)	508.65	-178.07	16.35	0.02	Dominates

HCV, hepatitis C virus; QALY, quality-adjusted life-year.

^aResults are over a 25-year period with a 3% discount per year.

^bΔ signifies change in costs and QALYs with respect to standard coverage.

Monte Carlo simulations.³⁴ Parameters without published distributions had assumed CIs of +/- 25% above and below the mean or median reported. Beta distributions were applied to probabilities and utilities that ranged in value from 0.0 to 1.0, and gamma distributions were applied to cost parameters that ranged from 0.0 to positive values greater than 1.0.

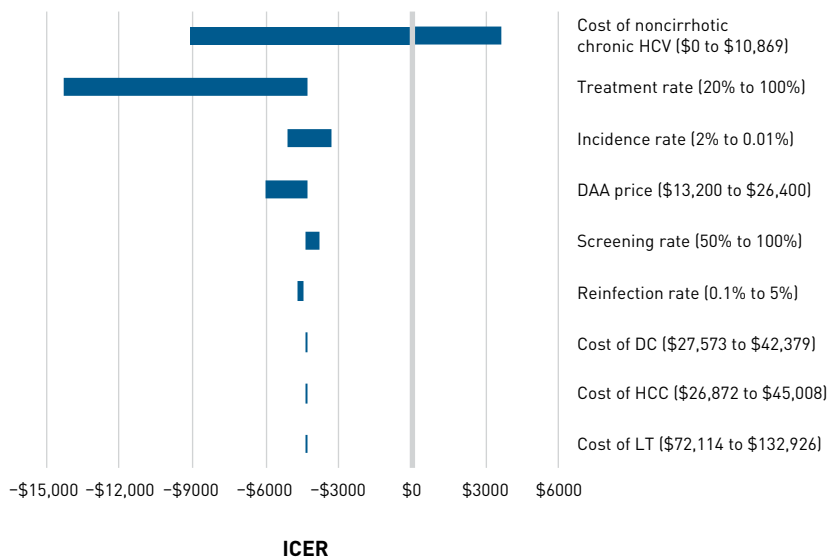
RESULTS

Total DAA coverage and risk-stratified total DAA coverage both dominated standard coverage as preferred payer models over the 25-year time horizon (Table 2). Total coverage saved \$158 per patient compared with standard care (\$529 vs \$687) at an increased effectiveness of 0.05 QALYs (16.33 vs 16.38 QALYs). Risk-stratified total DAA coverage saved \$178 per patient compared with standard care at an increased effectiveness of 0.02 QALYs. Both of these interventions represent clinically meaningful improvements in QALYs for a large patient population.

In a head-to-head comparison of total DAA coverage compared with risk-stratified DAA coverage, total DAA coverage is a cost-effective option at a slightly higher cost to deliver greater clinical benefit. The ICER for the added cost-effectiveness of total DAA coverage is \$675/QALY, which implies that facilitating access to DAAs for all patients holds good value.

At the health care sector level, total coverage would achieve break-even costs after 10 years and save \$1.0 billion after 25 years, and risk-stratified DAA coverage could save an additional \$1.1 billion. This timeline reflects estimates presented by Van Nuys and colleagues.⁷ However, if focusing on the budgetary impact of total coverage to Medicare, there was an incremental cost increase of \$7.55 per taxpayer per year. Thus, if this program were to be implemented, the additional \$635.9 million of public funds spent on DAA treatment would amount to less than \$10 per year across state taxpayers.

FIGURE 2. Tornado Diagram of the ICER (\$/QALY) Comparing Value of Total Coverage Policy With Standard Care^a

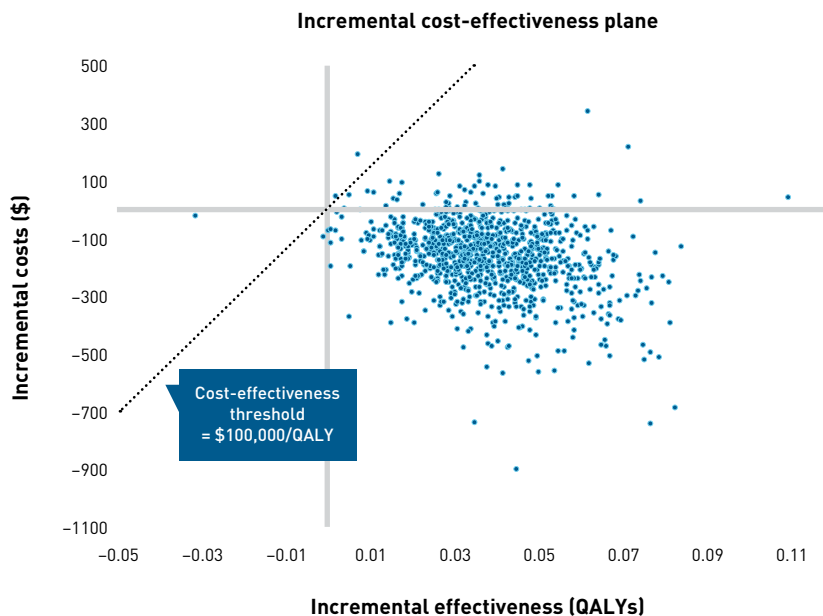


DAA, direct-acting antiviral; DC, decompensated cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; LT, liver transplant; QALY, quality-adjusted life-year.

^aThese are results from a univariate 1-way sensitivity analysis.

The cost-effectiveness results of total coverage compared with standard coverage did not vary based on the ranges tested in univariate 1-way or 2-way sensitivity analyses (Figure 2). From a state budgetary perspective, the model was most sensitive to the cost of noncirrhotic chronic HCV and treatment rate for total coverage. Increases in the cost of noncirrhotic chronic HCV and decreases in the total coverage treatment rate from our base estimates suggest that cost savings would occur to Medicare.

The probabilistic sensitivity analyses showed that total DAA coverage alternatives were cost-effective compared with standard coverage in 99.9% of simulations (Figure 3). The uncertainty around the utility values did not affect the results. In our calculation of the budget impact, 98% of simulations resulted in an overall incremental cost to Medicare within 25 years.

FIGURE 3. ICER (\$/QALY) Scatterplot Comparing Value of Total Coverage Policy With Standard Care^a

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

^aThese are results from a Bayesian multivariate probabilistic sensitivity analysis with 1000 Monte Carlo simulations.

DISCUSSION

Providing total coverage for DAA medications for all patients with HCV is systematically complex and may not be economically viable for state Medicaid programs that face some of the highest rates of HCV among payers. Joint Medicaid-Medicare coverage provides an efficient solution to treat all patients now to reduce harm caused by chronic infection in the United States. Recent price reductions for HCV treatments improve the outlook on affordability at the system level, as the \$26,400-plus price tag still makes it inaccessible to individual Medicaid enrollees. Furthermore, the long-term costs of untreated HCV typically borne by Medicare are offset under this concept. The Maryland TCOC model gives Medicare the option of crediting Medicaid for spending money today that it will save on health care costs in the future. This is an approach to resolve the mismatch between investing today and getting future returns.

Although total coverage offers good value to state-funded and federally funded payers, covering all DAAs may still represent an enormous investment that would be difficult to incorporate into many state budgets. Our alternative consideration for total coverage of all high-risk patients with fibrosis scores of 2 or higher would come at about a 3.7% lower budget impact.

Systems that adopt these models of payment will still need to build local capacity to screen and treat patients with HCV, even if the finances become available. This includes more provider screening and managed treatment over 8 to 12 weeks. However, the model

does not attempt to forecast price drops in HCV treatment further than the annual discount rate because most patients would likely be treated within the specific time horizon and exclusivity period of the DAA that was modeled, glecaprevir/pibrentasvir. New entrants at lower costs over the next 7-year period could improve the economic outlook.

Maryland may be one of the first states to pilot the concept of a total coverage solution for HCV treatment through joint Medicare-Medicaid payments. However, most of the 50 states are grappling with similar solutions. This model offers the prospect for states to simulate the local economics of whether or not to adopt a total coverage policy, with adjustments for rates of HCV incidence, prevalence, and a taxpayer base in order to determine the cost-effectiveness and budget impact. Other state public health agencies should explore the use of this model for the local needs and capacity building to treat HCV cases.

Limitations

The study has a number of limitations. First, the study assumes that some incident HCV cases will come from a vulnerable population who

developed an infection from normal risk; however, the vulnerable population could be stratified into higher-than-normal behavior risk strata that would better define the vulnerable population. There are not precise data to segment a high-risk population in the general public. Second, the study assumes a postcure probability of reinfection that is based on clinical assumptions but not well documented by data. Third, the total coverage model assumes screening and treatment probabilities of 80% and 100%, respectively, but despite total coverage, such probabilities may not reach expectations without local capacity building. Fourth, this model does not forecast future changes in the price of DAA treatments, which are likely to fall within a 25-year time horizon with future innovations, competition, and loss of exclusivity of existing DAAs.

Fifth, the model references reported rates of HCV for the state of Maryland from national statistics in HepVu. These data do not stratify HCV rates between adult or pediatric populations. Because the majority of incident cases affect adults, this rate represents a limitation of the study, as the rate would be higher for an adult-only population. Because we model a lower baseline rate for Maryland than the adult-only population, our expected findings are biased to "standard coverage," which makes the conclusions about the dominance of total DAA coverage more profound. Future research would benefit from subgroup analyses of DAA coverage value for cohorts stratified by age, in addition to race, sex, and ethnicity.

CONCLUSIONS

This is the first economic evaluation of DAA medications for HCV when considering joint efforts by Medicaid and Medicare to cover the cost of treatment for all current patients in Maryland. The model reflects potential value not only to the state of Maryland but also for many other states with below-average rates of DAA treatment in the United States. We recommend that all states explore the use of this economic model in planning potential coverage decisions jointly between state Medicaid and Medicare programming. Cost sharing between the 2 programs will have the added effect of improving the lives of patients diagnosed with HCV and minimizing the probabilities of future infection. ■

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William V. Padula, PhD, and Jonathan S. Levin, PhD, contributed equally to this manuscript as co-first authors.

Author Affiliations: Department of Pharmaceutical & Health Economics, School of Pharmacy (WVP), and Leonard D. Schaeffer Center for Health Policy & Economics (WVP), University of Southern California, Los Angeles, CA; Department of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health (JSL, JL, GFA), Baltimore, MD; now with RAND Corporation (JSL), Arlington, VA; now with Cambridge Health Alliance (JL), Cambridge, MA.

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Authorship Information: Concept and design (WVP, JSL, JL, GFA); acquisition of data (WVP, JL, GFA); analysis and interpretation of data (WVP, JSL, JL, GFA); drafting of the manuscript (WVP, JSL, JL, GFA); critical revision of the manuscript for important intellectual content (WVP, JSL, JL, GFA); statistical analysis (WVP, JSL, JL); provision of patients or study materials (WVP, JL); obtaining funding (WVP, GFA); administrative, technical, or logistic support (WVP, JL, GFA); and supervision (WVP, GFA).

Address Correspondence to: William V. Padula, PhD, Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California, 635 Downey Way (VPD), Los Angeles, CA 90089. Email: padula@healthpolicy.usc.edu.

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