QUICK TAKE

INNOVATIVE PAYMENT MODELS: AN ANALYSIS OF THE PROMISE AND PRACTICE OF NOVEL HCV MEDICATION PROCUREMENT STRATEGIES IN THE U.S.

HEPATITIS C VIRUS (HCV) INFECTIONS continue to be a public health threat in the United States. Several states have invested in innovative payment models to help eliminate cost and access barriers to HCV treatment for people on Medicaid and people in state-operated correctional systems. So far, Louisiana and Washington have implemented innovative payment models for treatment, and Michigan is currently taking steps to implement its model.

However, early analysis shows that they fall short of optimizing the potential benefits achievable when an innovative payment model is utilized. As more states such as Michigan implement HCV innovative payment models, it is important to carefully assess the varied applications of these types of models, progress to-date at increasing HCV treatment rates, and how the plans currently being implemented are impacting access to treatment.

EXISTING INNOVATIVE PAYMENT MODELS (IPMs)

IPMs are novel drug procurement strategies that secure large quantities of DAA medication to treat the people with HCV who receive state-covered health care through Medicaid or while incarcerated in state correctional facilities at minimal cost. Through IPMs, state health authorities negotiate agreements with pharmaceutical companies for an annual expenditure ceiling. Once this ceiling is met, each subsequent unit is offered at heavily discounted prices to maintain a nominal net cost throughout the contract period.

LOUISIANA "EXPENDITURE CAP" MODEL

Louisiana was the first state to implement an innovative payment model to acquire HCV medication. Louisiana's modified payment model set an annual maximum dollar amount (an annual expenditure cap) that the state would pay towards the purchase of DAAs from a contracted manufacturer. Under this expenditure cap agreement, the state purchases DAAs for its Medicaid program from the manufacturer at a negotiated price that utilizes only the federal drug rebates. Drugs for use within the state Department of Corrections would be purchased utilizing 340B rebates to discount the cost.

WASHINGTON'S VALUE-BASED MODEL

Washington's value-based model allows the state to utilize supplemental rebates to negotiate a low DAA price for the Medicaid program with a manufacturer. Value-based purchasing relies on drug effectiveness rather than volume, and allows the state to negotiate with the manufacturer on terms such as utilization period and outcomes-based benchmarks. Washington's

proposal sought to negotiate a guaranteed net per unit price (GNUP) for the state Medicaid program, the Department of Corrections, and all state entities that purchase DAAs directly, including the public employees benefits program, state hospitals, and workers covered by the state's worker's compensation system.

EMERGING IPM IMPLEMENTATION IN MICHIGAN

Building upon existing arrangements in Louisiana and Washington with expenditure caps, Michigan entered into an agreement with AbbVie to use Mavyret as the state's preferred HCV medication. Effective April 1, 2021, Michigan Medicaid removed all prior authorizations to prescribe Mavyret for HCV treatment, but prior authorization is required to prescribe a person a different DAA.

IPM PROGRESS TO DATE

Public health interventions of such significant scale should make their data publicly available, as public access to outcomes data can improve community investment and support, garner additional support from important stakeholders, and help hold the agency accountable. However, despite both plans being in Year 2 of implementation, there is a significant difference in the availability of publicly available data on the ongoing progress for Louisiana and Washington's IPM initiatives.

THE FUTURE OF IPMs AND HCV TREATMENT: LOOKING AHEAD

Existing models fall short of achieving true potential. In the absence of strong motivating fiscal incentives for both contracting parties to optimize care—which is the intent of true subscription models—the benefit these models lend to improving HCV treatment outcomes is substantially lessened.

Payment models can be a beneficial tool in a comprehensive elimination strategy. HCV elimination cannot occur unless existing cases are identified, treated, and cured. Greater access to DAAs will not yield the benefit of increasing the number of people cured if no resources exist to inform people of their risk of HCV and to get them screened and enrolled into Medicaid if they are eligible.

DIFFERENT TYPES AND IMPLEMENTATION OF IPMS

		MODIFIED SUBSCRIPTION MODELS		
		AUSTRALIA (AU)	LOUISIANA (LA)	WASHINGTON (WA)
MODEL TYPE	True Subscription Model	Widespread DAA Access Model	Expenditure Cap Model	Value Based Model
UP-FRONT PAYMENT	Yes . In such a model, health authorities would likely make lump-sum payments to cover HCV drugs and treat patients.	No. The Department of Health entered into Special Pricing Deeds of Agreement with DAA manufacturers to negotiate confidential discounted pricing arrangements for an unlimited supply of the medications.	No. In this modified "expenditure cap" model, LA set a maximum dollar amount equal to or less than what the state is currently spending to purchase DAAs from a contracted manufacturer.	No. WA has fixed a similar maximum dollar amount for the purchase of DAAs. WA engages in value-based purchasing, relying on drug effectiveness rather than volume purchased. There is no "Medicaid Best Price" requirement.
UNFETTERED ACCESS TO DRUGS	Yes. In such a model, the up-front lump-sum payment will act as a "flat fee" and provide unlimited access and supply to drugs during the contract period.	Likely, yes. The government committed over AU\$1billion to cover the cost for all DAA prescriptions needed during the contract period.	Maybe. The unlimited drug provision is triggered only if health authorities spend up to the expenditure cap. If the cap is met, subsequent DAA purchases are heavily rebated to a nominal net cost as low as pennies per unit.	Maybe. The unlimited drug provision is triggered only if health authorities spend up to the expenditure cap. If the cap is met, subsequent DAA purchases are heavily rebated to a nominal net cost as low as pennies per unit.
INCENTIVES FOR HEALTH AUTHORITIES AND MANUFACTURERS TO MAXIMIZE ACCESS TO HCV TREATMENT	Yes. More incentive because by making payments upfront, the health authority can set a predictable expenditure amount within its budgetary means. Manufacturers can negotiate a reliable revenue stream and means of distribution for its product that will widen its market share.	Unclear. Details of contract not publicly available. However, the intent of the agreement was to lower the price of HCV drugs. The government also committed more than AU\$1 billion to fund purchase of newly covered medication over 5 years.	Likely, no. Less incentive because there is no requirement for health authorities to meet the expenditure cap, which triggers the unlimited drug provision. This scheme also provides greater uncertainty of revenue returns to the manufacturer.	Likely, no. Less incentive because there is no requirement for health authorities to meet the expenditure cap, which triggers the unlimited drug provision. This scheme also provides greater uncertainty of revenue returns to the manufacturer.
ESTIMATED PATIENTS TO TREAT	N/A	130,089 people with HCV.	31,000 people with HCV enrolled in the LA Medicaid program or held in its prisons.	30,000 people with HCV enrolled in the WA Medicaid program or held in its prison.
PATIENTS TREATED	N/A	An estimated 82,280 between Mar. 2016 and Dec 2019.	8,187 people (as of May 10, 2021).	No data available.
AGENCIES INVOLVED AND COVERED UNDER IPM	N/A	National universal health care agency.	Medicaid and DOC	Medicaid, DOC, and all other state entities other than Medicaid that purchase DAAs directly, including the public employees benefits program and state hospitals.
OUTREACH COMPONENTS	N/A	N/A	Details not present in the contract.	Healthcare personnel training on treating HCV and the Awareness Bus (a mobile unit that travels especially to disproportionately impacted areas, providing HCV screening, counseling and care coordination)



SEPTEMEBER 2021

This Quick Take is a product of the Hepatitis Policy Project of the **O'Neill Institute for National and Global Health Law** and is supported by funding from and developed in partnership with *Gilead Sciences, Inc.* The Hepatitis Policy Project retains final editorial control over the content.