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Gilead's \$1,000 Pill Is Hard for States to Swallow; Hepatitis C drug Sovaldi strains programs for the poor; Texas didn't pay for it last year

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## Abstract

Catherine Moizeau, a Davis, Calif.-based primary-care physician, said Medicaid insurers denied hepatitis C treatment to about 30 of her Medicaid patients last year, including some who are "on the edge" of decompensated cirrhosis, the point at which most patients die unless they receive a liver transplant.

## Full Text

A pricey pill made by Gilead Sciences Inc. caused Medicaid spending on hepatitis C treatments to soar last year, even as most states restricted access to the drug, leaving many low-income patients untreated.

State Medicaid programs spent \$1.33 billion on hepatitis C therapies through the third quarter of last year, or nearly as much as the states spent in the previous three years combined, a Wall Street Journal analysis of federal data shows.

The growth was primarily driven by Gilead's Sovaldi, a highly effective therapy that has a wholesale cost of \$84,000 per person over the course of treatment, or \$1,000 per pill. The price has sparked an outcry from insurers, members of Congress and others worried about the cost of treating an estimated three million Americans with hepatitis C, which can lead to cirrhosis or cancer of the liver.

The data show patient access to Sovaldi varied widely state by state, reflecting different coverage of the drug and also long-standing disparities in how states deliver health benefits to the poor. Many states limited Sovaldi's availability to the very sickest patients, primarily those with severe liver scarring.

These barriers to treatment have sparked local disputes about coverage, with officials pleading budgetary constraints and doctors complaining that economic considerations are trumping medical judgment. The soaring costs and tension are likely to continue as other expensive drugs reach the market.

"Now we have a wonder drug for hepatitis C; in fact, we have several, but as soon as the drugs appeared they've been snatched from our grasp," Brian R. Edlin, associate professor of medicine at Weill Cornell Medical College, said. "We could literally end the hepatitis C epidemic if we put these tools to use."

In total, states spent \$1.08 billion on Sovaldi in the first nine months of 2014, representing 82% of all hepatitis C drug spending, according to the Journal's analysis of the data, which provide the most comprehensive picture yet of Sovaldi's financial impact on Medicaid programs. The second-largest expenditure, at \$136.3 million, was for Olysio, a pill made by Johnson & Johnson that was often used in combination with Sovaldi.

States are entitled to get a portion of their money back through legally mandated rebates of at least 23.1%. Rebates are expected to be higher this year after the launch of a competing hepatitis C drug made by AbbVie Inc. The data analyzed by the Journal doesn't include rebates.

Sovaldi was Medicaid's third-largest drug expenditure after Abilify, an antipsychotic medication that cost \$1.73 billion, and a generic version of the cholesterol-lowering treatment Lipitor, which totaled \$1.12 billion in spending.

Texas, which has the nation's third-largest Medicaid population after California and New York, spent nothing on Sovaldi in the first nine months of the year, according to the data, making it the only state in the U.S. to not pay for the drug. Although federal data for the full year isn't yet available, a state spokeswoman confirmed Texas didn't pay for the drug in the fourth quarter, either. A Texas state spokeswoman said "price was the biggest issue" affecting coverage of Sovaldi in 2014. Beginning this month, Texas has made AbbVie's drug Viekira Pak available to patients with advanced disease, the spokeswoman said.

Gilead has provided free hepatitis C drugs to several hundred Texas Medicaid patients and more than 10,000 people with all insurance types across the U.S., Cara Miller, a Gilead spokeswoman, said. "Most states have covered Sovaldi with varying degrees of access and many are in the process of" reviewing their policies after the launch of newer drugs, she said.

New York, known for offering relatively generous Medicaid coverage, was the biggest spender on Sovaldi during the first nine months of 2014, at just over \$297 million, or 7.6% of the state's total drug spending. New York spent \$47.50 on Sovaldi per Medicaid enrollee. California, the most populous state in the U.S., spent \$86.94 million on the drug, or \$7.29 per enrollee.

California uses private and nonprofit insurers to administer Medicaid benefits to most enrollees. Doctors in California say some insurers are denying hepatitis C drugs even to patients with advanced disease.

Catherine Moizeau, a Davis, Calif.-based primary-care physician, said Medicaid insurers denied hepatitis C treatment to about 30 of her Medicaid patients last year, including some who are "on the edge" of decompensated cirrhosis, the point at which most patients die unless they receive a liver transplant. Under California's statewide policy, such patients should be eligible for treatment.

Randall Murphy, a Medicaid recipient with late-stage liver disease, said his insurer rejected his applications for Gilead's Sovaldi at least twice after Dr. Moizeau first prescribed it last summer. This fall, she prescribed for Mr. Murphy a new Gilead drug, Harvoni, which was also denied by California Health & Wellness, a subsidiary of Centene Corp. In a February denial letter, the insurer said Dr. Moizeau hadn't provided enough information about Mr. Murphy's condition and test results.

In early April, Mr. Murphy was approved to receive Harvoni.

"They're picking and choosing who gets to live and who gets to die and they're not even being honest about it," Mr. Murphy, of Coloma, Calif., said in an interview prior to receiving the treatment.

Centene Corp. declined to comment on Mr. Murphy specifically, citing privacy rules. "We consistently ensure members, who meet the state's evidence-based guidelines submitted by their providers, have access to hepatitis C medication regardless of cost," a spokeswoman said in an email.

The state has received reports about "inappropriate denials," but has found "the majority of the denials were appropriately made," said Anthony Cava, a spokesman for the California Department of Health Care Services, which oversees the state's Medicaid program.

Mr. Cava said the drug's cost didn't play a role in the state's policy.

Medicaid spending on hepatitis C is likely to keep climbing. Competition between Gilead and AbbVie has allowed states to negotiate discounts totaling 40% or greater for the drugs, which should help states widen coverage.

Still, most states aren't planning to open access to all medically eligible patients, and will continue to limit access to those with advanced liver damage, Matt Salo, executive director of the National Association of Medicaid Directors, said.

"Total costs will go up," Mr. Salo said. "While we're fortunate that the price per pill has come down from \$1,000, it's still too high to provide complete access for the millions of infected patients in this country."

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