

Hepatitis C drug can cure, if patients can get it

By **Meredith Cohn**
The Baltimore Sun

JULY 18, 2015

Awonder drug came on the market two years ago that cures hepatitis C, a potentially deadly liver disease afflicting millions of Americans, killing 15,000 a year.

The problem is, many patients could not afford it. A standard course of Sovaldi cost \$84,000, or \$1,000 a day. And many insurers would not approve it for any but the sickest of patients.

"Here we had this disease we couldn't cure, and this drug is developed and it's almost like a miracle," said Dr. Paul J. Thuluvath, a gastroenterologist and liver specialist at Mercy Medical Center in Baltimore, who has treated hepatitis for 25 years. "I was so upset it was so expensive."

Thuluvath and others say barriers put up by private insurance companies and state Medicaid programs aimed at controlling costs have made it hard for patients to get the drug, with many left to worsen as they sought charity or appealed their cases.

Three million people in the United States have hepatitis C, but the number could spike as more baby boomers adhere to new medical guidelines to get tested for the infection that leads to liver damage, cancer and even more costly transplants.

Many people contracted hepatitis C through transfusions and transplants before the blood supply was screened in the 1990s. Infection is now more common from tainted needles, or less commonly from sex.

The drug's cost highlights a growing debate that could intensify as breakthrough therapies for high cholesterol, heart failure and other ailments are approved.

Drug makers defend the costs as necessary to bring radical new medications to market. And insurers defend treating the sickest patients first because of the price and because damage usually takes time.

An estimated 100,000 people in Maryland are infected with hepatitis C, but there is no tally for the number of people treated. Thuluvath said insurers have approved prescriptions for more than 440 people, or most of his sickest patients, since October, when Harvoni, a second-generation hepatitis C drug costing \$94,000, was approved.

Thuluvath, a professor at the University of Maryland School of Medicine and author of a forthcoming hepatitis guide, has two staff members working full time on insurance appeals. About 30 percent to 40 percent of the prescription requests initially are rejected, even for some patients in later stages of the disease.

"We spend so much time appealing," he said. "But my experience has been better than expected, and better than my peers around the country."

Pharmacies affiliated with Johns Hopkins Hospital have filled thousands of prescriptions for the drugs, also filing appeals in many cases, officials said.

The state Medicaid program paid for the drugs for 534 hepatitis C patients in 2014, and expects to cover more this year, said Dr. Mona Gahunia, chief medical officer for the Maryland Department of Health and Mental Hygiene.

"Our priority is to make sure people who need them the most can get them without a lot of hurdles," she said.

One of those people is Michael Roesen, a Frederick man nearing the end of his Harvoni treatment. Each month for six months, the small staff at the Frederick County Hepatitis Clinic where he goes has had to plead with his Medicaid managed-care organization to refill the prescription.

Constance Callahan, the clinic's executive director, called it baffling, considering Roesen's high viral load and liver damage — and his immediate response to the drugs. His infection was nearly undetectable after 10 days on the drug.

His infection had festered because a previous insurer would not cover the drugs, he said. Another would not even issue a policy because a blood test revealed he had hepatitis.

A volunteer patient advocate at the clinic files most of the appeals, using her personal cellphone minutes to call and wait on hold with insurers. The extra work is a burden on the small nonprofit that operates on grants, donations and discounted rent at Frederick Memorial Hospital. It can afford only one full-time employee.

Roesen, who believes he was infected by a tattoo needle in 1999, was grateful for the clinics' efforts and the state insurance. He had beaten unrelated cancer, but years of the hepatitis infection were debilitating. The fatigue made his work in warehouses and installing drywall tough.

"I have a new attitude about life," Roesen said during a recent checkup. "I feel great."

Public and private insurers follow guidelines that require, for example, that patients wait until they have advanced disease or see specialists. Even then, high deductibles can put drugs out of reach, doctors and advocates say.

United Healthcare and Kaiser Permanente of the Mid-Atlantic States say their coverage decisions are consistent with clinical guidelines.

However, Kaiser Mid-Atlantic President Kim Horn said the high drug cost is not sustainable and that the company is trying to "influence the national discussion on affordable pricing."

According to the Express Scripts Drug Trend Report, "specialty" drugs for chronic and difficult conditions accounted for just 1 percent of U.S. prescriptions but 31.8 percent of drug spending in 2014.

Dr. Peter Beilenson, CEO of Evergreen Health Co-op, said his company has few restrictions on covering the drug because curing the infection staves off more expensive treatments, including transplants, which cost hundreds of thousand of dollars.

"But it's gross profit" for drug companies, he said. "If you look at other countries, like France and Germany, the company sells them for half the price when U.S. taxpayers were involved in developing the drugs."

A spokeswoman for the drugs' maker, Gilead Sciences, said there are programs for the uninsured and underinsured and tiered pricing for less wealthy countries. So far, 310,000 people worldwide have gotten the drugs, including 210,000 in the United States.

"Unlike treatment for other chronic diseases, Sovaldi and Harvoni offer a cure at a price that significantly reduces hepatitis C treatment costs and delivers significant savings to the health care system over the long term," said Cara Miller, the Gilead spokeswoman.

Drug prices do reflect costs from research, much of which fails, said George T. Haley, a marketing professor at the University of New Haven. He said it also reflects the lack of bargaining power by the largest U.S. health programs, Medicare and Medicaid.

Further, Gilead did not develop the drug, rather it bought Sovaldi's maker, which had initially priced it at \$36,000, less than half what Gilead charges.

An analysis by the nonprofit Institute for Clinical & Economic Review determined that, based on its costs and benefits, the price of Sovaldi should be \$36,000 to \$42,000.

The company has begun offering rebates now that there is another competitor and more on the horizon, said Dr. Steven Pearson, the institute's president. But he said access nationwide remains a "pretty mixed picture."

High costs make more sense when the drugs benefit only a few, Pearson said. The hepatitis drugs and others for common ailments in the pipeline should spark serious debate about costs.

Sue Simon, president of the Hepatitis C Association, was diagnosed with advanced hep C in 1991 after a doctor discovered that her liver was enlarged during a routine exam. She believes it stemmed from a blood transfusion after a car accident.

While she credits Gilead with helping offset the costs for some and private groups for helping others, she said the costs remain too high for many.

Simon, who quit her job as a teacher to head the national advocacy group based in New Jersey, got a Sovaldi competitor, called Viekira Pak, through a clinical trial by AbbVie Inc. She was cured in six weeks, though her liver damage must be monitored because patients can develop cancer.

"I'd tried every treatment and nothing worked. The side effects were worse than the disease," she said. "Fatigue and muscle and joint pain, headaches, fever. I was anemic and getting really sick.

"But," she added, "the point is these new drugs are curing people."

meredith.cohn@baltsun.com

Copyright © 2015, The Baltimore Sun