

Half of hepatitis C patients with private insurance denied life-saving drugs

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The number of insurance denials for life-saving hepatitis C drugs among patients with both private and public insurers remains high across the United States, researchers from the Perelman School of Medicine at the University of Pennsylvania reported in a new study published in the journal *Open Forum Infectious Diseases*. Private insurers had the highest denial rates, with 52.4 percent of patients denied coverage, while Medicaid denied 34.5 percent of patients and Medicare denied 14.7 percent.

The data was revealed through a prospective analysis of over 9,000 prescriptions submitted to a national specialty pharmacy between January 2016 and April 2017.

Direct-acting antiviral drugs (DAAs) - once-a-day pills that first became available in the United States in 2014—are highly effective, with a 95 percent cure rate and few side effects for [patients](#) with chronic [hepatitis C](#), but expensive. Because they can cost between \$40,000 and \$100,000, both private and public insurers have restricted access to the medications, approving the drugs only for patients with evidence of advanced liver fibrosis and/or abstinence from alcohol or illicit [drug](#) use, for example.

More recently, some of those restrictions had been relaxed because of vocal stakeholders and leaders, class action lawsuits, and greater drug price competition that experts believed would help increase the overall approvals by insurers. However, analysis of the data suggests otherwise.

"Despite the availability of these newer drugs and changes in restrictions in some areas, insurers continue to deny coverage at alarmingly high rates, particularly in the private sector," said study senior author Vincent Lo Re III, MD, MSCE, an associate professor of Infectious Disease and Epidemiology. "It warrants continued attention from a public health standpoint to have more transparency about the criteria for reimbursement of these drugs and fewer restrictions, particularly in private insurance and certainly to continue the push in public insurance, if we want to improve hepatitis C drug access across all states."

The reason for the higher than expected denial rate is unclear, the authors said, but may be due to the varying restrictions on reimbursements that exist among the states. It's likely there were more attempts to treat patients who have less advanced liver fibrosis, have not met sobriety restrictions, or have not had consultation with a specialist, they wrote.

The team analyzed prescriptions from 9,025 patients between January 2016 and April 2017 submitted to Diplomat Pharmacy Inc. throughout 45 states. Among those patients, 4,702 were covered by Medicaid; 1,821 by Medicare; and 2,502 by commercial insurance. In all, 3,200 (35.5 percent) were denied treatment.

The denial rates appear to be increasing, as well. The overall incidence of denials across all insurance types increased during the study period from 27.7 percent in the first quarter to 43.8 percent in the final quarter. In addition, a Penn study from 2015 found that just five percent who had Medicare received a denial, while 10 percent who had private insurance did.

That same study also found that 46 percent of Medicaid patients were denied coverage, compared to the current study's 35.7 percent. A statement from the Centers for Disease Control and Prevention in 2015

indicating that restrictions violated federal law prompted class action suits and legal action against Medicaid, which likely contributed to the public insurer easing its criteria across some states and improved approval rates, the authors said. Still, Medicaid denials increased over the study period.

"From a clinical standpoint, patients with chronic hepatitis C who are denied therapy can have continued progression of their liver fibrosis and remain at risk for the development of liver complications, like cirrhosis, hepatic decompensation, and liver cancer," Lo Re said. "In addition, chronic hepatitis C promotes not only liver inflammation, but systematic inflammation, which can lead to adverse consequences on organ systems outside of the [liver](#), such as bone, cardiovascular, and kidney disease. Further, untreated patients can continue to transmit infection to others."

A recent report from the National Academies of Science, Engineering, and Medicine determined that at least 260,000 chronic hepatitis-infected patients must be treated yearly to achieve elimination of the virus in the United States by 2030. To reach that goal, they recommended that public and [private insurers](#) remove restrictions to the hepatitis C drugs that are not medically indicated and offer treatment to all [chronic hepatitis C](#)-infected patients. Those recommendations are also consistent with guidelines from the American Association for the Study of Liver Diseases and Infectious Diseases Society of America.

"Eliminating hepatitis C in the U.S. is a feasible goal," Lo Re said, "but that's going to be hard to achieve if payers are not reimbursing for the treatment."

Provided by Perelman School of Medicine at the University of Pennsylvania

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