

Nearly Half of Hepatitis C Patients on Medicaid Denied Coverage for Life-Saving Drugs, Penn Researchers Report

First Data to Report on Denial and Delay Rates for Hepatitis C Antiviral Agents

SAN FRANCISCO — Nearly 50 percent of Medicaid patients infected with chronic hepatitis C whose doctors had prescribed newer, life-saving antiviral drugs were denied coverage to the therapies because they weren't considered “a medical necessity” or because the patients tested positive for alcohol/drugs, among other reasons, according to new Penn Medicine research. The data was revealed through a prospective analysis of prescriptions submitted to a specialty pharmacy that services patients in Pennsylvania, New Jersey, Delaware and Maryland.

[Vincent Lo Re III, MD, MSCE](#), an assistant professor of Medicine and Epidemiology in the division of Infectious Diseases at the Perelman School of Medicine at the University of Pennsylvania and the Center for Clinical Biostatistics and Epidemiology, will report the findings at the American Association for the Study of Liver Diseases (AASLD) 2015 Liver Meeting (**Abstract #LB-5**).

This is the first data of its kind to report delay and denial rates in a cohort of Medicaid, Medicare and privately insured patients for the class of hepatitis C drugs known as direct-acting antiviral agents, potent therapies with very successful cure rates and an expensive price tag. Costs to treat one patient for a 12-week course can be up to \$90,000.

“It’s the high costs of these agents to treat—and in most cases, cure—these infections and barriers to coverage that have resulted in denials and delays for the therapies,” Lo Re said. “It has created a serious health disparity. Patients on Medicaid are more likely to be suffering from these infections, yet they are much more likely to be denied coverage for the drugs.”

The issue was examined in two *Annals of Internal Medicine* studies published in July 2015, which found that restrictions for the drugs vary widely across states' Medicaid programs. One study said many of the restrictions violate federal law. Last week, the U.S. Centers for Medicare and Medicaid Services sent a letter to Medicaid state directors noting just that. The data presented by Lo Re’s team provide direct evidence of the magnitude of the denial rates by insurance.

To determine the number and determinants of denials, the team analyzed prescriptions from 2,342 patients between November 1, 2014 and April 20, 2015 submitted to Burman’s Specialty Pharmacy branches throughout the four states. Among those patients, 517 were covered by Medicaid; 800 by Medicare; and 1,025 by commercial insurers.

A total of 377 (16 percent) received an absolute denial, the researchers report. In the Medicaid group, 46 percent received a denial, while 5 percent who had Medicare received a denial, and 10 percent who had private insurance did.

The most common reasons for denial by Medicaid were “insufficient information to assess medical need” (48 percent), “lack of medical necessity” (31 percent), and positive alcohol /drug screen (4 percent).

The team also found that those who did receive therapy through Medicaid had to wait ten days longer to have prescriptions filled compared to privately insured and Medicare patients.

At least three million Americans suffer from hepatitis C, with baby boomers representing a large proportion of those infected. Many in the infected population are also on Medicaid. Hepatitis infections can lead to chronic hepatitis, which can become cirrhosis, liver failure and liver cancer. Hepatitis C is also the most common cause for liver transplantation in the U.S.

Medicaid programs should seek to increase access to these new drugs for patients prescribed the drugs, the authors said.

“The implications of these denials remain unknown, but there may be adverse downstream outcomes for both patients and providers,” Lo Re said. “Patients who need treatment, but are unable to gain access, may see their liver disease progress, putting them at a high risk for cirrhosis and liver cancer, and may develop extra-hepatic complications, such as bone, kidney, and cardiovascular diseases. What’s more, it’s crucial to treat chronic hepatitis C patients so that rates of transmission are significantly reduced and the spread of the disease is limited—and less people have to be treated.”

Co-authors on the abstract, Charitha Gowda, Paul N. Urick, Josh Halladay, Amanda Binkley, Dena M. Carbonari, Kathryn Battista, Cassandra Peleckis, Jody Gilmore, Jason A. Roy, K. Rajender Reddy, and Jay R. Kostman.