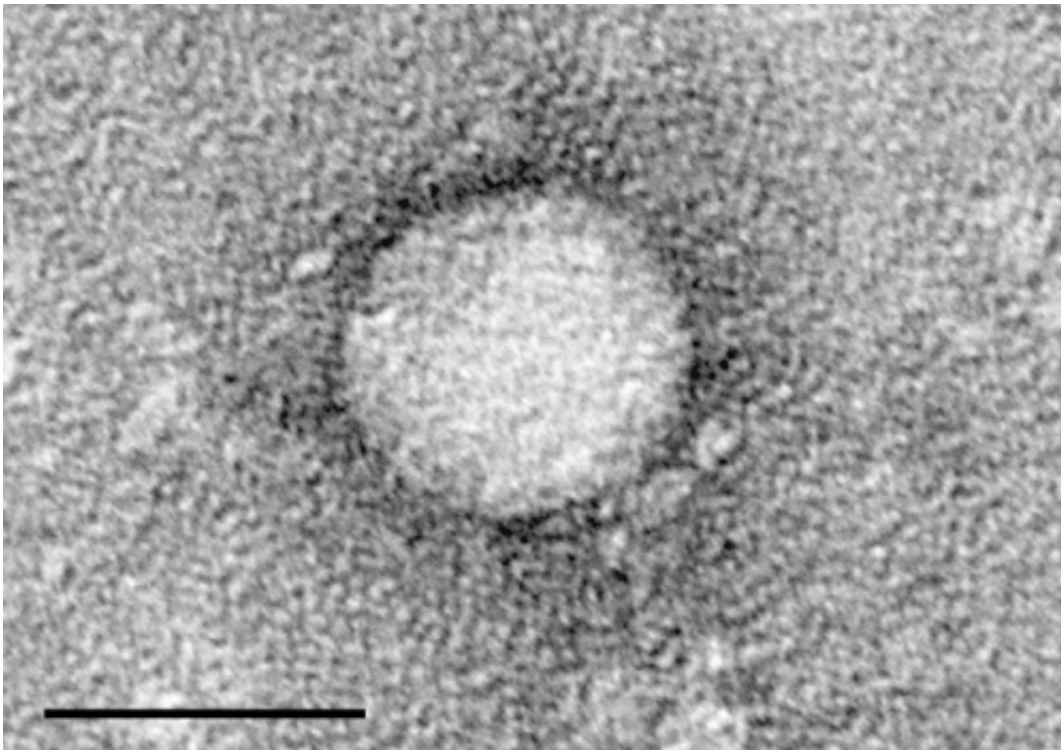


Insurance denials for new hepatitis C drugs remain high nationwide, study suggests

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Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

Highly effective drugs that can cure chronic hepatitis C infection in approximately 95 percent of patients first became available in the U.S. in 2014. But both public and private insurers continue to deny coverage for these costly drugs at high rates nationwide, despite efforts to remove

treatment restrictions, according to a new study published in *Open Forum Infectious Diseases*. The findings suggest that all chronic hepatitis C-infected patients' access to these medications, known as direct-acting antivirals, must be improved if the public health goal of eliminating hepatitis C infection is to be achieved.

For the [prospective cohort study](#), researchers used data from Diplomat Pharmacy Inc., which provides specialty pharmaceuticals, including direct-acting antiviral drugs for the treatment of [hepatitis C](#), to [patients](#) in 45 U.S. states. Their analysis included 9,025 patients who had prescriptions for these drugs submitted to the pharmacy between January 2016 and April 2017. The researchers calculated the incidence of absolute denials for coverage of these prescriptions by insurance type (Medicaid, Medicare, or a commercial insurer). If an insurer requested an alternative drug regimen because of formulary restrictions, these instances were not counted as denials in the analysis.

During the study period, about one-third (35.5 percent) of patients who were prescribed a direct-acting antiviral regimen for [chronic hepatitis C](#) were denied the treatment by their insurer, the study found. Denials were more common among patients with commercial insurance: 52.4 percent of these patients' prescriptions were denied compared to 34.5 percent among Medicaid beneficiaries and 14.7 percent among Medicare patients, respectively. The overall incidence of denials for the hepatitis C drugs across all insurance types also increased during the study period, from 27.7 percent in the first quarter to 43.8 percent in the last quarter.

"From a clinical standpoint, patients who are denied access to hepatitis C treatment are going to remain at risk for the development of liver complications like cirrhosis, hepatic decompensation, and liver cancer," said study senior author Vincent Lo Re III, MD, MSCE, an associate professor of Infectious Disease and Epidemiology in the Perelman School of Medicine at the University of Pennsylvania. "The denial of

this treatment can also lead to ongoing hepatitis C-associated liver and systemic inflammation, which could increase the risk of other extra-hepatic complications, like cardiovascular [disease](#), bone and joint disease, and kidney disease."

Current guidelines from the Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) recommend treatment with direct-acting antivirals for all patients with chronic hepatitis C [infection](#). In a 2017 report, the National Academies of Sciences, Engineering, and Medicine laid out a strategy to eliminate hepatitis B and C infections as public health problems by 2030 and called for eliminating access restrictions that are not medically indicated for direct-acting antiviral drugs for hepatitis C.

"Failure to treat and cure chronic hepatitis C infection also maintains a reservoir for transmission, which certainly can add to increasing incidence of the infection, especially given the growing opioid epidemic" said Dr. Lo Re, who also serves on the IDSA/AASLD Hepatitis C Guidance panel and was a member of the National Academies committee that developed last year's report. "If we want to achieve the goal of hepatitis C elimination, then access to hepatitis C therapy must be improved."

Fast Facts

- All-oral direct-acting antiviral therapies, highly effective but costly regimens that can cure chronic hepatitis C infection in most patients, first became available in the U.S. in 2014.
- From January 2016 and April 2017, about one-third of patients who were prescribed a direct-acting antiviral regimen for hepatitis C were denied the treatment by their insurer, based on an analysis of data from a national specialty pharmacy.
- Patients with chronic hepatitis C infection who are not treated

are at risk for developing liver complications, including cirrhosis, liver decompensation, and cancer. These patients may have increased risk for other extra-hepatic diseases as well.

Provided by Infectious Diseases Society of America

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