National study finds life-threatening barriers in access to breakthrough drugs

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Various pills. Credit: Wikipedia

Most states violate federal Medicaid law because they deny coverage for sofosbuvir, a new and highly effective treatment to cure hepatitis C, according to Lynn E. Taylor, M.D., director of The Miriam Hospital's HIV/Viral Hepatitis Coinfection Program. Taylor's team of researchers examined Medicaid policies for hepatitis C virus treatment using sofosbuvir, more commonly known as Solvadi, and found that most should change policy to improve access to the treatment. The study and its findings were published online in advance of the August issue of the *Annals of Internal Medicine*.

Hepatitis C virus affects over three million Americans. Worldwide, an estimated 120 to 150 million people have chronic hepatitis C. Left untreated, the infection can lead to cirrhosis, liver failure, and liver cancer. Sofosbuvir is a highly effective pharmaceutical used in combination with other medications to cure the disease.

Taylor's research team, which included the Harvard Law School Center for Health Law and Policy Innovation, Treatment Action Group, Kirby Institute of Australia, and Brown University, found that most Medicaid coverage restrictions for sofosbuvir violate federal Medicaid law, which requires states to cover drugs consistent with their U.S. Food and Drug Administration (FDA) labels.

"Federal Medicaid law requires coverage, yet reimbursement criteria for Medicaid programs effectively deny access," said Taylor, lead author of the study. "The denial of treatment by most states violates the spirit of the law. In our analysis, we found that most states with known sofosbuvir Medicaid reimbursement requirements impose undue restrictions on eligible recipients."

The most common restrictions fall into three categories: 1) The level of fibrosis (i.e., scarring of the liver); 2) substance use and abstinence from alcohol/drug use together with toxicology screening; and 3) provider limitations, which limit the physicians allowed to prescribe sofosbuvir.

"Ultimately, we found that access restrictions are not based on scientific evidence, current treatment guidelines, or clinical data," said co-author Robert Greenwald, J.D., director of Harvard Law School's Center for Health Law and Policy Innovation. "Notably, 74 percent of the 42 state Medicaid programs for which information is available limit treatment to individuals with advanced fibrosis or cirrhosis. Such restrictions contradict the American Association for the Study of Liver Disease and the Infectious Disease Society of America treatment guidelines which support treatment for all hepatitis C-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver-related diseases."

"Rates of advanced liver disease complications and associated healthcare costs are rising in the U.S.," added Taylor. "Although there is a high risk of progression to decompensated cirrhosis and liver cancer among patients with advanced fibrosis, limiting access to people who have already progressed to late-stage disease as compared to treating earlier to prevent these liver-related

complications seems counter-intuitive as a public health strategy."

Restrictions based on drug and/or alcohol use were also common. Among the state Medicaid programs for which information was available, 88 percent of states include drug and/or alcohol use or abuse in their eligibility criteria, with 50 percent requiring a period of abstinence of three to 12 months and 64 percent requiring negative urine drug screening.

"This is particularly concerning because the majority of new and existing cases of hepatitis C in the U.S. exist among people who inject, or have injected drugs," said Taylor. "Rather than excluding people who use alcohol or drugs from hepatitis C treatment, even those with cirrhosis, they should be a priority group due to both improved individual health outcomes and potential hepatitis cure as prevention benefit."

Since 2002, the National Institutes of Health hepatitis C guidelines have supported hepatitis C treatment regardless of injection drug use. International guidelines from the American Association for the Study of Liver Disease/Infectious Diseases Society of America, the European Study for the Association of the Liver, the International Network for Hepatitis in Substance Users, and the World Health Organization, now all recommend treatment for hepatitis C infection among people who use drugs. "There is compelling evidence that hepatitis C treatment is safe and effective among people who inject drugs," said Taylor.

Taylor's team searched state Medicaid websites from June 23 to December 7, 2014. Data extracted included whether sofosbuvir was covered and coverage criteria based on liver disease stage; HIV coinfection; prescriber type; and drug/alcohol use. One quarter of states require HIV/HCV coinfected persons to be receiving antiretroviral therapy or have suppressed HIV RNA levels (no detectable HIV virus in the blood). Two thirds of states have restrictions based on prescriber type.

"The Medicaid restrictions generally apply to the poorest and most underserved patients with hepatitis C infection, are highly stigmatizing, and not based on evidence," said co-author and associate professor Jason Grebely, Ph.D., of the Kirby Institute at UNSW Australia. "The data suggests that state Medicaid policies for access to new hepatitis C therapies should be reviewed and revised in line with national and international clinical recommendations."

Tracy Swan, co-author and hepatitis/HIV project director at Treatment Action Group, said, "It is unacceptable for treatment to be held hostage by state Medicaid programs. Medicaid programs have never forced people to wait for treatment until they are so sick that they are left with a higher liver cancer risk even if they are cured. We would never refuse treatment for cancer or other infectious diseases¬, nor do we withhold treatment for these illnesses from people who drink alcohol or use drugs."

"In distinct contrast to the situation in the U.S., Australia's Pharmaceutical Benefits Advisory Committee (PBAC) recently recommended two highly effective sofosbuvir-based regimens for Pharmaceutical Benefits Scheme (PBS) listing, without drug use or disease stage-related restrictions," said co-author and professor Greg Dore of the Kirby Institute. "Assuming that price negotiations are completed and Federal Cabinet approval gained, Australia should have the broadest access to interferon-free therapy internationally, with PBS listing expected in December 2015 or April 2016."

"Access to treatment should be based on clinical criteria and medical evidence," Taylor concluded. "The current restrictions do not make clinical, public health, or long-term economic sense, and should be removed. It is critically important that patients have access to highly effective drugs that not only cure them but will also lower the associated costs of long-term management of the disease. Based on the study findings, states need to review and revise their access criteria to align with clinical recommendations."

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