

# FDA approves new treatment for hepatitis C infection

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(HealthDay)—The U.S. Food and Drug Administration has approved a new drug for chronic hepatitis C infection that some experts hope will cut down on side effects from current therapies.

Hepatitis C infection triggers an inflammation of the liver that can lead to reduced liver function, liver failure and even death over time.

According to the U.S. Centers for Disease Control and Prevention, 3.2 million Americans—many of them in the "baby boomer" generation—are infected with the hepatitis C virus.

The new drug, called Olysio (simeprevir), is approved as part of a combination antiviral drug regimen to treat certain classes of adult patients with hepatitis C. These include people who have cirrhosis or other liver disease but whose liver is still functioning, people who haven't been previously treated for their hepatitis infection, or those whose infection has not improved after prior treatment.

The approval of Olysio is promising, one expert said, because it might someday free some patients from having to rely on interferon, which can have difficult side effects.

"The approval of Olysio is the first step toward once daily interferon-free treatment of hepatitis C," said Dr. Douglas Dieterich, director of outpatient hepatology at the Icahn School of Medicine at Mount Sinai in New York City.

The FDA's approval was based on the results of six clinical trials that evaluated Olysio in combination with peginterferon-alfa and ribavirin, two other drugs commonly used to treat hepatitis C virus infection.

The three-drug combination was effective in 80 percent of patients who had never been treated for hepatitis C, the study found, compared to 50 percent effectiveness in patients who got an inactive placebo plus peginterferon-alfa and ribavirin.

The three-drug combination was also 79 percent effective in patients who had received prior treatment but had relapsed, compared to 37 percent effectiveness in people who got only the two older drugs, the FDA said.

Olysio is from the protease inhibitor class of drugs, and it works by blocking a key protein the virus needs to reproduce. It's the third such drug approved by the FDA to treat chronic hepatitis C infection. The other two drugs are Victrelis (boceprevir) and Incivek (telaprevir), both approved in 2011.

Another expert was optimistic about the treatment.

Olysio "is an important new addition to the hepatitis C virus treatment regimens, offering improved efficacy, easier administration with once-a-day dosing and an improved side effect profile," said Dr. David Bernstein, chief of the division of hepatology at North Shore University Hospital in Manhasset, N.Y.

The clinical trials for Olysio also found that patients with a specific strain of the hepatitis C virus commonly found in the United States were less likely to respond to treatment with the drug. The drug's label therefore tells doctors to screen patients for the presence of this strain before beginning treatment with Olysio and to consider other treatments

for patients with this strain.

Common side effects among patients who took the three-drug combo included sensitivity to light, itching and nausea. Some patients had severe light sensitivity that required hospitalization. Patients will be advised to limit their sun exposure and to use sun protective measures when taking Olysio with peginterferon-alfa and ribavirin, the FDA said.

Dieterich believes that patients now have more options than ever before in treating hepatitis C infection.

The approval of Olysio "represents the first once-daily protease inhibitor, which when used with interferon and ribavirin, has about an 80 percent success rate in curing hepatitis C in 24 weeks," he said. "This could be the beginning of the end for hepatitis C, if everyone that has it gets tested and treated, as the CDC recommends for baby boomers."

Olysio is marketed by Janssen Pharmaceuticals.

**More information:** The U.S. National Institute of Allergy and Infectious Diseases has more about [hepatitis C](#).

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