

FDA Approves Mavyret for Acute Hepatitis C

Treating hepatitis C early can alleviate symptoms and prevent transmission of the virus.

June 13, 2025 By [Liz Highleyman](#)

On June 11, the Food and Drug Administration (FDA) expanded the approval of Mavyret (glecaprevir/pibrentasvir), from AbbVie, to include treatment of acute hepatitis C, meaning infection within the previous six months. This enables providers to start treatment immediately at the time of diagnosis.

Over years or decades, chronic hepatitis C virus (HCV) infection can lead to serious liver complications, including fibrosis, [cirrhosis](#) and [liver cancer](#). Early infection can cause symptoms such as fatigue, fever, nausea, abdominal pain and muscle and joint aches. What's more, people with early HCV infection often have a high viral load and can transmit the virus to others.

Mavyret and other modern direct-acting antivirals (DAAs) are highly effective, curing more than 90% of people with chronic hepatitis C who complete therapy. Treatment typically lasts two to four months, depending on prior treatment history and severity of liver damage. Studies have shown that treatment of acute hepatitis C works even better.

About one in five people naturally clear HCV without treatment, although this is somewhat less likely for people with HIV/HCV coinfection. Given the poor tolerability and modest efficacy of the older interferon-based therapy before the advent of DAAs, experts generally recommended waiting six months to start treatment to see whether the immune system would clear the virus on its own.

Today, given the good tolerability of DAAs and the high likelihood of a cure, and considering the benefits of symptom relief and preventing transmission, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America [recommend treatment](#) for almost everyone with either acute or chronic HCV infection. But many people living with hepatitis C are unaware of their status, and [most people who could benefit from treatment are not getting it](#).

Until now, no DAA regimens were FDA-approved for the treatment of acute hepatitis C, although some doctors prescribed it off-label. This week's approval makes Mavyret the first and only DAA option with this expanded indication.

Mavyret, initially approved for chronic hepatitis C in 2017, is a combination pill containing glecaprevir (an HCV protease inhibitor) and pibrentasvir (a NS5A inhibitor). It is approved for adults and children ages 3 years and older with no liver cirrhosis or compensated cirrhosis. Mavyret is pangenotypic, meaning it is effective against all HCV genotypes. The usual treatment duration is eight weeks.

The expanded approval is supported by findings from the Phase III M20-350 trial ([NCT04903626](#)), which enrolled 286 previously intreated adults with acute hepatitis C at 70 sites worldwide. They received Mavyret once-daily for eight weeks. Almost all (96%) achieved a sustained virological response, or undetectable HCV viral load at 12 weeks after completion of treatment, which is considered a cure. No participants experienced virological failure. Treatment was well tolerated, and most adverse events were mild to moderate.

“The physical, emotional, and economic burden of a curable condition like hepatitis C is far too great in the United States and around the world,” John Ward, MD, director of the Coalition for Global Hepatitis Elimination, said in an [AbbVie news release](#). “If treated early with safe and effective therapies, providers can cure virtually all patients with hepatitis C before it escalates to chronic disease and eventually cirrhosis or liver cancer. The public health community now has a good opportunity to cure nearly all persons to support eliminating the toll of this deadly virus. No one should die of hepatitis C.”

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