FDA Approves New Type of Treatment for Hepatitis B

1 in 5 people treated with Hibsago (bepirovirsen) achieved a functional cure after stopping antivirals.

October 27, 2026 By Liz Highleyman

On October 20, the Food and Drug Administration (FDA) approved Hibsago (bepirovirsen), from GSK, the first of a new class of medication for chronic hepatitis B. In a late-stage clinical trial, the treatment led to a functional cure, or sustained hepatitis B virus (HBV) suppression and hepatitis B surface antigen (HBsAg) loss, in nearly 20% of people who stopped antiviral therapy.

“This is the start of a new era in treating people living with chronic hepatitis B,” Norah Terrault, MD, chief of gastroenterology and hepatology at the University of Southern California Keck Medical Center, said in a news release. “Bepirovirsen offers patients the potential to achieve functional cure after a short period of treatment, a long-standing goal for patients and physicians alike.”

The FDA approved Hibsago for adults with chronic hepatitis B who have been on antivirals for at least six months, have suppressed HBV viral load and a HBsAg level of 3,000 international units per milliliter or less and have not progressed to liver cirrhosis. It is not recommended for people with hepatitis B and D coinfection. Hibsago is a once-weekly injection that can be self-administered after the first dose.

#NEWS The U.S. Food and Drug Administration (FDA) today approved the 1st drug that can lead to a functional #cure in some people living with chronic hepatitis B (CHB), giving a new, innovative treatment option! Press release https://t.co/dq7HlpNUE2 #HepatitisB #HBV #HepB https://t.co/8Ld7Wgca00

— Hepatitis B Foundation (@HepBFoundation) October 20, 2026

“Chronic hepatitis B is a major public health challenge, affecting around 2.4 million people in the U.S. and accounting for approximately 56% of all global liver cancer cases,” said Chari Cohen, DrPH, MPH, president of the Hepatitis B Foundation. “Not only is this the first functional cure approved for hepatitis B, but it is also the first new therapy we have had approved in the U.S. in 10 years.”

While nucleoside/nucleotide analog antivirals, such as Viread (tenofovir disoproxil fumarate), Vemlidy (tenofovir alafenamide) and Baraclude (entecavir), can control HBV replication indefinitely, they rarely lead to a cure. The virus remains present in liver cells and can reactivate when treatment is interrupted.

But adding Hibsago for six months can lead to a functional cure, as indicated by sustained undetectable HBV DNA viral load and HBsAg loss for at least six months after stopping antivirals. Hibsago is an antisense oligonucleotide that both interferes with HBV replication by binding to viral mRNA and stimulates an immune response, potentially enabling the immune system to gain control of the virus.

Hibsago does not eliminate viral genetic material (covalently closed circular DNA, or cccDNA) hidden in the nucleus of liver cells, so it produces a functional rather than a so-called sterilizing cure. Achieving a functional cure reduces the risk of long-term complications, including cirrhosis and liver cancer, and makes HBV transmission much less likely.

The FDA approval is supported by findings from the Phase III B-Well trials. The studies enrolled adults with chronic hepatitis B in 29 countries who were currently on nucleoside/nucleotide analogs with viral suppression. B-Well 1 (NCT05630807) included 981 participants and B-Well 2 (NCT05630820) included 857 people. They did not yet have cirrhosis, more than 90% had a normal alanine aminotransferase (ALT) liver enzyme level and nearly two thirds had an HBsAg level of 1,000 IU/or less. People with hepatitis C, hepatitis D or HIV coinfection were excluded.

Participants in both trials were randomly assigned to received Hibsago or a placebo, administered by subcutaneous injection once weekly for 24 weeks, while staying on their antivirals. Eligible patients who maintained viral suppression, experienced HBsAg loss and had normal ALT at 48 weeks stopped their nucleoside/nucleotide analogs, with follow-up continuing through 72 weeks.

As reported at this year’s EASL Liver Congress and published in The New England Journal of Medicine, results from the two trials were similar: 20% of B-Well 1 participants and 19% of those in B-Well 2 achieved a functional cure at 72 weeks in the Hibsago groups. In contrast, no one in the placebo groups achieved sustained viral suppression and HBsAg loss.

Functional cure rates were higher for people who started with lower HBsAg levels. The benefit was greatest for those who started with an HBsAg level below 1,000 IU/ml, who saw a 26% functional cure rate. However, only 5% to 10% of patients with 1,000 to 3,000 IU/mL at baseline were functionally cured. People who experienced large ALT increases—an indicator of flaring liver inflammation—were also more likely to cured.

A 20% functional cure rate may not seem very impressive—for example, compared to the 95% cure rate with direct-acting antivirals for hepatitis C—but it's a big improvement over nucleoside/nucleotide analog antivirals alone, which have a functional cure rate below 5%. Adding pegylated interferon for a year or more only increases the cure rate to around 10%.

Hibsago is generally safe and well tolerated. The most common adverse events are injection site reactions, fever, fatigue and headache. The prescribing information includes warnings about the possibility of extreme ALT elevations, low platelet counts, worsening kidney function and severe inflammatory reactions. In the B-Well trials, however, only 3% of Hibsago recipients stopped treatment due to adverse events. While elevated ALT was classified as an adverse reaction, it may actually be an indication that treatment is working.

The label also notes that people with HIV and HBV coinfection should not stop taking drugs like tenofovir that are dually active against both viruses without consulting an HIV healthcare provider. Some newer antiretroviral regimens, however, do not include any drugs that are active against HBV. Achieving a functional cure for hepatitis B could potentially enable coinfected people to safely use these regimens.

"For many people living with chronic hepatitis B, treatment can mean taking antiviral medication for years to keep the virus suppressed," said Wendy Carter, DO, acting director of the Office of Infectious Diseases in the FDA's Center for Drug Evaluation and Research. "Hibsago provides a new treatment approach that gives some patients the possibility of maintaining control of the virus after all chronic HBV treatment has ended. This approval represents an important advance for people living with this serious disease."

Click here for full prescribing information for Hibsago.
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