HOW TO IDENTIFY ELIGIBLE PATIENTS FOR HIBSAGO (bepirovirsen)

INDICATION

HIBSAGO is indicated in combination with nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy to treat of chronic hepatitis B virus (HBV) infection adults without cirrhosis who have been on NrtI therapy for ≥6 months with suppressed HBV DNA and who have HBV surface antigen (HBsAg) levels ≤3,000 IU/mL as determined by an FDA-authorized test.

Factors to consider when identifying eligible patients for HIBSAGO[1]

Who is eligible for HIBSAGO

In order to be eligible for HIBSAGO, patients must meet the following criteria:

- Adults with chronic hepatitis B
- Already receiving nucleos(t)ide analog (NA)* for at least 6 months
- Have suppressed HBV DNA on NA therapy
- Have HBsAg ≤3,000 IU/mL
- Do not have cirrhosis

Who is not eligible for HIBSAGO

HIBSAGO is contraindicated in patients with:

- Acute hepatic impairment, or cirrhosis who have mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C)
- Platelet count <100 x 10^9/L prior to initiation of treatment

Who is not recommended for HIBSAGO

- HIBSAGO is not recommended in patients with hepatitis D virus coinfection

Baseline quantitative HBsAg[1]

Quantitative HBsAg (qHBsAg) is a blood test that measures HBsAg levels and is used to identify patients who may be appropriate for HIBSAGO.

Ordering qHBsAg testing[2-5]

qHBsAg testing can be ordered through your institution's laboratory or a third-party commercial laboratory, including but not limited to Labcorp, Quest Diagnostics, Mayo Clinic Laboratories, and Sonic.†

qHBsAg testing may not be included in standard panels and is typically ordered separately or as an add-on.

For billing purposes, the qHBsAg CPT testing code is 87467. CMS and covering commercial insurers reimburse qHBsAg testing; plan coverage and out-of-pocket costs may vary.‡§

Additional testing for eligibility[1]

Before starting HIBSAGO, patients should also be tested for HBV DNA, ALT, AST, total bilirubin, platelet count, eGFR, and uACR.

HIBSAGO should be prescribed only when appropriate laboratory monitoring can be performed.

Motivation to pursue functional cure,‖ and commitment to treatment and monitoring, should also be considered through shared decision-making with your patients.

IMPORTANT SAFETY INFORMATION

WARNING: ON-TREATMENT HEPATIC FLARES AND THROMBOCYTOPENIA

On-Treatment Hepatic Flares

HIBSAGO may cause on-treatment hepatic flares with increases in alanine aminotransferase (ALT) of >20-40x upper limit of normal (ULN) associated with decline in HBsAg. Some cases were associated with hyperbilirubinemia. Most occurred within the first 12 weeks and resolved when treatment was interrupted or discontinued. Do not initiate HIBSAGO in patients with evidence of acute hepatic impairment or cirrhosis. ALT and total bilirubin must be measured prior to treatment and frequently monitored during treatment. Treatment interruption, followed by dose reduction or discontinuation, may be necessary based on liver laboratory results.

Thrombocytopenia

HIBSAGO may cause reductions in platelet counts that may result in sudden and unpredictable thrombocytopenia, which can be life-threatening. Obtain platelet count prior to treatment; HIBSAGO is contraindicated in patients with platelet count <100 x 10^9/L. Monitor platelet counts weekly during treatment and more frequently if platelet count falls <75 x 10^9/L. Do not re-dose unless platelet count returns to ≥100 x 10^9/L. Permanently discontinue HIBSAGO if platelet count falls <50 x 10^9/L.

*NA=nucleos(t)ide analog for treatment of chronic hepatitis B, herewith used interchangeably with NrtI.

†The laboratories listed are provided for information purposes only and are not endorsed by GSK. Healthcare providers are responsible for selecting and using testing methods that are appropriate and compliant with the FDA-approved Prescribing Information for HIBSAGO.

‡Insurance coverage for chronic hepatitis B biomarker testing may vary by test type, indication, testing laboratory, payer, and individual patient plan. Providers are encouraged to verify coverage requirements (such as prior authorization and medical necessity criteria), payer policies, and lab billing guidelines before ordering testing. Laboratories may offer patient assistance programs; availability and eligibility vary by provider.

§CPT codes are provided for informational purposes only and do not guarantee coverage or reimbursement. Providers should verify applicable coding and payer requirements.

‖Functional cure was defined as HBsAg loss (LOD=0.05 IU/mL) and undetectable HBV DNA (<LLOQ) sustained for ≥24 weeks off all HBV treatment, with or without hepatitis B surface antibodies present.[1,6,7]

Please see additional Important Safety Information for HIBSAGO on the next page.
Please see full Prescribing Information, including Boxed Warning, for HIBSAGO.

HIBSAGO (bepirovirsen)
Subcutaneous Use 150 mg/mL

IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

HIBSAGO is contraindicated in patients:

- with acute hepatic impairment or cirrhosis who have mild, moderate, or severe hepatic impairment (Child-Pugh Class A, B, or C).
- with a platelet count <100 x 10^9/L prior to initiation of treatment.

WARNINGS AND PRECAUTIONS

On-Treatment Hepatic Flares

Increases in ALT ≥3x ULN to 69x ULN were observed during treatment with HIBSAGO, most within the first 12 weeks. Isolated cases of ALT increases associated with an increase in total bilirubin resolved when treatment was permanently discontinued.

Thrombocytopenia

In addition to sudden and unpredictable thrombocytopenia, a gradual, dose-dependent decline in platelet count was observed in most patients that continued to worsen while on HIBSAGO. If a patient develops signs or symptoms of thrombocytopenia, pause HIBSAGO and obtain a platelet count as soon as possible. Instruct patients to report any symptoms of thrombocytopenia to their healthcare provider immediately. Consider the risks and benefits of treatment with HIBSAGO when treating patients who may be particularly susceptible to platelet count decreases.

Worsening Renal Function

Mean estimated glomerular filtration rate (eGFR) declined within 4 weeks of initiation and continued to decline during treatment. These changes were generally reversible after treatment discontinuation.

Obtain eGFR and urine albumin-creatinine ratio (uACR) in all patients prior to initiation of treatment. Monitor eGFR frequently during and after treatment; treatment interruption or discontinuation may be necessary. Although no cases of glomerulonephritis were observed with HIBSAGO, glomerulonephritis has been observed with other antisense oligonucleotides; if suspected or confirmed, permanently discontinue HIBSAGO.

Inflammatory and Immune Effects

Influenza-like symptoms, laboratory test changes (eg, decreases in complement factors C3 and C4), purpuric leg rashes, cutaneous leukocytoclastic vasculitis, dermatitis, pruritus/erythematous plaque, and polyarthralgia were observed. In addition, serious inflammatory and immune adverse reactions were reported, including immune thrombocytopenia, autoimmune hemolytic anemia, systemic inflammatory response syndrome, and a cryoglobulinemic flare.

Consider the risks and benefits of HIBSAGO in patients who may be susceptible to inflammatory and immune effects, including solid organ transplant recipients, patients with autoimmune hepatitis, patients with a history of or conditions associated with vasculitis, or extrahepatic disorders related to HBV immune-mediated effects. If signs and symptoms suggestive of vasculitis/immune-associated events occur, and no alternative cause is identified, permanently discontinue treatment with HIBSAGO.

Serious Adverse Reaction with Improper Administration

Improper HIBSAGO administration, including not rotating injection sites, has been associated with the serious adverse reaction of omental infarction in one participant. Ensure injection sites are rotated from one week to the next and that the two injections making up each dose are separated by at least 2 inches (5 cm). Never inject into areas where the skin is tender, bruised, red, or hard.

Post-Treatment Exacerbations of HBV Infection After NrtI Discontinuation

Severe acute exacerbations of HBV infection may occur after discontinuation of anti-HBV therapy. If NrtI therapy is discontinued after completing HIBSAGO treatment, frequent monitoring is recommended for at least one year to detect acute exacerbations of HBV infection and the possible need for resumption of HBV treatment.

Risk of Human Immunodeficiency Virus-1 (HIV-1) Virologic Failure in Patients with HBV/HIV-1 Coinfection Who Discontinue NrtI Therapy

Patients who are taking NrtI for HIV-1 and HBV coinfection must not stop taking their NrtI unless an HIV healthcare provider has directed them to do so.

Risk of Hepatitis Flare in Patients with HBV/Hepatitis D Virus (HDV) Coinfection

HIBSAGO is not recommended in patients with HDV coinfection due to the potential for an exacerbated risk of clinically significant ALT increases.

Unknown Effect on Preventing Transmission of HBV

There are no data on the effect of HIBSAGO in preventing transmission of HBV. Patients must be advised to use appropriate precautions to prevent transmission of HBV.

ADVERSE REACTIONS

The most common adverse reactions (≥10%), excluding laboratory abnormalities, reported with HIBSAGO included injection site reactions, pyrexia, fatigue, and headache.

Selected laboratory abnormalities worsened from baseline, including but not limited to, increases in ALT and total bilirubin, decreases in platelets and eGFR.

DRUG INTERACTIONS

- Monitor patients for signs of bleeding and thrombocytopenia if HIBSAGO is taken concomitantly with anticoagulants, antiplatelets, or drugs that decrease platelet count.
- Monitor patients for signs of worsening renal function during concomitant administration of HIBSAGO with drugs that may impair renal function.
- Concomitant administration of HIBSAGO and peginterferon alfa-2a is not recommended due to the potential for an exacerbated risk of increased ALT, decreased platelet count, and immune-mediated effects.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

There are insufficient data on HIBSAGO use in pregnancy or during breastfeeding. Consider the benefits of breastfeeding together with the mother's clinical need for HIBSAGO.

Pediatric Use

HIBSAGO's safety and effectiveness have not been established in patients under 18 years of age.

Renal Impairment

HIBSAGO can cause worsening renal function. No dosage adjustment is recommended for mild renal impairment. Data are insufficient for moderate or severe renal impairment or end-stage renal disease (ESRD).

Please see additional Important Safety Information for HIBSAGO on the previous page. Please see full Prescribing Information, including Boxed Warning, for HIBSAGO.

ALT=alanine aminotransferase; AST=aspartate aminotransferase; CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; DNA=deoxyribonucleic acid; eGFR=estimated glomerular filtration rate; FDA=US Food and Drug Administration; HBsAg=hepatitis B surface antigen; HBV=hepatitis B virus; LLOQ=lower limit of quantification; LOD=limit of detection; NrtI=nucleos(t)ide analog reverse transcriptase inhibitor; uACR=urine albumin-to-creatinine ratio.

References: 1. HIBSAGO. Prescribing Information. GSK; 2026. **2.** Hepatitis B surface antigen, quantitative, monitor. CPT 87467. Labcorp. Accessed September 1, 2026. https://www.labcorp.com/tests/007130/hepatitis-b-surface-antigen-quantitative-monitor **3.** Hepatitis B surface antigen, quantitative, monitoring (not for diagnosis). CPT 87467. Quest Diagnostics. Accessed September 1, 2026. https://testdirectory.questdiagnostics.com/test/test-detail/94333/hepatitis-b-surface-antigen-quantitative-monitoring-not-for-diagnosis?cc=MASTER **4.** Hepatitis B virus surface antigen, quantitative, serum. CPT 87467. Mayo Clinic Laboratories. Accessed September 1, 2026. https://www.mayocliniclabs.com/api/sitecore/TestCatalog/DownloadTestCatalog?testId=621764 **5.** Anti-hepatitis B surface antigen (anti-HBs): updated reagent. Clinical Pathology Laboratories. August 28, 2025. Accessed October 19, 2026. https://www.cpllabs.com/clinicians/client-communications/anti-hepatitis-b-surface-antigen-anti-hbs-updated-reagent/ **6.** Hou J, et al. *N Engl J Med*. 2026;394(24):2395-2406. **7.** Ghany MG, et al. *J Hepatol*. 2023;79(5):1254-1269.

Trademarks are property of their respective owners.

©2026 GSK or licensor.
PMUS-BPRLBND260015 October 2026
Produced in USA. 0002-0050-98

HIBSAGO (bepirovirsen)
Subcutaneous Use 150 mg/mL