National Institute for Health and Care Excellence

Health Technology Evaluation

Bepirovirsen with nucleoside or nucleotide analogues for treating chronic hepatitis B [ID6608]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	GlaxoSmithKline (company)	Yes, GSK believes a single technology appraisal (STA) to be the appropriate evaluation route to the National Institute for Health and Care Excellence (NICE). The topic is highly relevant and timely, as the treatment of chronic hepatitis B virus (HBV) infection remains a key priority for the National Health Service (NHS), demonstrated by the commitment to the government 2030 policy on HBV (1).	Thank you for your comment. No action required.
	British HIV Association	A single technology appraisal of a new therapy offering functional cure for Hepatitis B is appropriate.	Thank you for your comment. No action required.
Wording	GlaxoSmithKline (company)	GSK suggests altering the remit to cover the combination of therapies: *'To appraise the clinical and cost effectiveness of bepirovirsen with*	Thank you for your comment. The remit and title have been updated to 'bepirovirsen

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		nucleos(t)ide analogues (NA) within its marketing authorisation for treating chronic hepatitis B.'	with nucleoside or nucleotide analogues'
	British HIV Association	Yes	Thank you for your comment. No action required.
Timing Issues	GlaxoSmithKline (company)	This appraisal should be considered with urgency. HBV infection causes significant morbidity and can also cause severe complications such as liver cirrhosis, liver failure, and cancer (1). The current standard of care - NAs - often requires lifelong therapy and functional cure (FC) rates remain low, typically only 1% (1, 2). Thus there is a need for alternative treatment options. Bepirovirsen offers a much-needed paradigm shift in the treatment pathway for patients with chronic HBV, providing a finite, 6-month therapeutic option that removes the challenges of lifelong treatment. The timely appraisal of bepirovirsen for chronic HBV treatment is critical, as this evaluation may offer further resources to support ongoing UK initiatives to reduce the incidence of HBV. The UK's efforts form part of the UK Health Security Agency (UKHSA) hepatitis strategy, which is explicitly aligned with the World Health Organization's Global Health Sector Strategy (GHSS) for HIV, viral hepatitis and sexually transmitted infections (2022–2030) (1, 3). The GHSS sets global targets to reduce viral hepatitis incidence by 90% and mortality by 65% by 2030. The UK has committed to achieving these goals as part of its pledge to eliminate viral hepatitis, including HBV, as a public health problem by 2030	Thank you for your comment. The appraisal will follow scheduled timelines.

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	British HIV Association	More widespread opt-out testing for BBVs has identified people living with Chronic Hepatitis B, and new international guidelines recommend earlier treatment to prevent complications. Offering functional cure with reduce the need for longterm treatment, HCC surveillance, monitoring and outpatient appointments.	Thank you for your comment. The appraisal will follow scheduled timelines.
Additional comments on the draft remit		No comments	

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	GlaxoSmithKline (company)	• GSK suggests that the background wording to describe HBV transmission be updated to remove the emphasis on sexual contact, as this adds to the stigma narrative (page 1): • ~~*It is transmitted through blood to blood contact (e.g. through sharing of blood contaminated needles by drug users) and sexual contact. It is also transmitted from mother to infant during, or soon after, birth.*~~ • *'Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus. The majority of the disease burden of hepatitis B in the UK is among people who previously acquired the infection in endemic countries, commonly through vertical transmission; however, transmission risk is also higher within populations associated with injecting drug use, residing in prison or detention settings, and sex work.'*	Thank you for your comment. This section has been modified to remove emphasis on sexual contact and blood to blood transmission.

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		• GSK suggests updating the language to avoid *'other than White British' on* page 1, for example to:
		  • *'The prevalence estimates were higher in men, and individuals born overseas who are now living in the UK, particularly those of Black, Black British, Caribbean or African ethnic origin and other ethnic groups (4).'*
		• GSK suggests that the wording around the management of chronic HBV be updated for completeness (page 1):
		  ○ ~~*Current treatment of chronic hepatitis B involves management of complications including liver disease and hepatic cancer, and treatment with antivirals.*~~
		  ○ '*Current treatment of chronic HBV involves long-term antiviral therapy to suppress viral replication to reduce the risk of liver disease progression. It consists of routine monitoring and screening for hepatocellular carcinoma, and management of complications such as cirrhosis or liver cancer.'*
			Section updated as suggested.
			
			Section updated as suggested.

	British HIV Association	The remit should include that Chronic Hepatitis B is a leading cause of liver disease and liver cancer (https://doi.org/10.1016/j.jhep.2024.10.031). Achieving a functional cure reduces the risk of liver cirrhosis and Hepatocellular carcinoma (HCC). (https://doi.org/10.1016/j.virusres.2024.199507). This will reduce longterm costs of progression to cirrhosis, liver failure, liver transplant and HCC treatment.	Thank you for your comment. 'Hepatitis B can also cause liver disease and liver cancer and is the leading cause of liver cancer worldwide.' Has

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			been added to the background
	UK Health Security Agency	HBV is a bloodborne virus that infects and damages the liver. Persistent infection over time can lead to cirrhosis, liver failure, cancer and deaths- this impact on liver disease, cancer and deaths should be made clearer in the scope. While hepatitis B-related mortality over this time has consistently been well below the WHO absolute target, the upper estimate for the number of hepatitis B-related deaths reported in 2024 was the highest since 2001 at 207. Hepatitis B-related HCC deaths have also been gradually increasing over time, with estimates of between 51 to 71 deaths in 2005 and 75 to 139 deaths in 2024. HBV can cause an acute or chronic infection; the risk of developing chronic hepatitis B infection depends on age at acquisition. Young infants are at highest risk of acquiring chronic infection. Most healthy adults who have an acute symptomatic infection will clear the infection. However, around 5% of these individuals will develop a chronic infection (hepatitis B surface antigen (HBsAg) in the blood for 6 months or longer. These individuals have a greatly increased risk of developing cirrhosis and/or hepatocellular carcinoma (HCC, primary liver cancer) in later life. Over 95% of people with newly diagnosed chronic hepatitis B infection in the UK are migrants. Most acquired the infection in their country of origin, either at birth or in early childhood. The remaining 5% likely acquired chronic hepatitis B in the UK, either through MTCT or through transmission associated with adult risk behaviours such as unprotected sexual intercourse and injecting drug use. Therefore blood to blood contact (such as through sharing of needles by people who inject drugs) should be lower in the scope.	Thank you for your comment. The background has been updated to note the impact of hepatitis B on liver failure and liver cancer. The background has been modified to remove emphasis on sexual contact and

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		Safe and effective vaccines are available and prevent and control HBV infection. In the UK there is a selective and universal childhood HBV vaccination programme. Note that NICE CG165 is not commonly used in clinical practice and has been superceded by other clinical guidelines such as: EASL Clinical Practice Guidelines on the management of hepatitis B virus infection - Journal of Hepatology	blood to blood transmission.
Population	GlaxoSmithKline (company)	GSK agrees with the proposed population. We would however, like to note that the anticipated marketing authorisation indication is “People with chronic hepatitis B who take [redacted]	Thank you for your comment. The population is intended to be broadly inclusive. Narrowing the population (for example, to be within the anticipated marketing authorisation) can be justified in the submission.
	British HIV Association	Yes	Thank you for your comment. No action required.
	UK Health Security Agency	It would be good to assess the population groups who would benefit from Bepirovirsen, including by treatment experience and serological markers.	Thank you for your comment. Any particular groups that are clinically distinct

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			and have potentially different cost-effectiveness will be considered during the appraisal process.
Subgroups	GlaxoSmithKline (company)	No subgroups are planned to be considered separately.	Thank you for your comment. No action required.
	British HIV Association	People with HIV-Hepatitis B are at increased risk of developing liver fibrosis, cirrhosis and hepatocellular carcinoma. Initial trials of Bepiroversin did not include people with HIV, but an ongoing trial (B-FOCUS) is currently in process, expected to report in 2027.	Thank you for your comment. 'People with HIV coinfection' have been added as a subgroup
Comparators	GlaxoSmithKline (company)	GSK agrees that tenofovir disoproxil and entecavir are appropriate comparators for this submission based on bepirovirsen's anticipated marketing authorisation, expected positioning in the treatment pathway, and clinical expert input. However, GSK proposes the removal of peginterferon alfa-2a (PEG-IFNα) from the comparators list for the following reasons: • Consistent with NICE methods and UK treatment guidelines, comparators should represent treatments commonly used in the NHS. ○ From a UK clinical-pathway perspective, patients who are eligible for PEG-IFNα will have already received it prior to consideration for NA and the inclusion of bepirovirsen. PEG-IFNα is positioned as a first-line treatment, and patients who are unable to receive or tolerate PEG-IFNα transition directly to NAs (5). Bepirovirsen is to be considered only once patients are stabilised on long-term NA therapy. Accordingly, PEG-IFNα does not represent a clinically appropriate	Thank you for your comment. The comparators in the scope are intended to be broad inclusive of current clinical practice. If a comparator in the scope is deemed not to be relevant, please justify this in the submission.

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		comparator for bepirovirsen, as the eligible patient populations and positions in the pathway do not overlap (5). ○ Current clinical guidelines and UK practice patterns further support the limited use of PEG-IFNα. In clinical practice, PEG-IFNα is reserved for only selected patients, including those with low surface antigen, high viral load, and younger or male patients, with favourable predictors or specific therapeutic goals (5). International guidance from the European Association for the Study of the Liver (EASL) (6) and WHO (7) position potent NAs (e.g. tenofovir disoproxil and entecavir) as a majority therapy due to their superior tolerability, sustained viral suppression, and low resistance rates. Accordingly, recent UK landscape analyses show PEG-IFNα use in only a small minority of patients: ▪ [redacted] (8) ▪ [redacted] (9) ○ UK Health Security Agency (UKHSA) data reporting solely on tenofovir disoproxil fumarate and entecavir use, indicating that NA based regimens dominate routine care (1).	
	British HIV Association	Comparison with people who are not on treatment should be included.	Thank you for your comment. No treatment has been added to established clinical management in the list of comparators.

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	Gilead Sciences (comparator)	Tenofovir Alafenamide Fumarate (Vemlidy) is licenced in the UK for treatment of HBV. Although not reimbursed, there is a population that are prescribed this due to renal dysfunction and bone health issues.	Thank you for your comment. Tenofovir alafenamide fumarate has been added to established clinical management in the list of comparators.
Outcomes	GlaxoSmithKline (company)	GSK agrees that the following outcomes are appropriate: • Hepatitis B surface antigen (HBsAg) level • HBV DNA level • Mortality • Adverse effects of treatment • Health-related quality of life (HRQoL). However, GSK would like to highlight that functional cure (FC) should also be included, which is defined as sustained suppression (24 weeks or longer) of HBV DNA (<lower limit of quantification) and HBsAg not detected, with or without HBsAb, after a finite duration of therapy and off all chronic HBV treatment. This is a composite endpoint and also the primary endpoint of the bepirovirsen Phase III trials. Importantly, regulatory perspectives increasingly support the relevance of FC, with the EMA's draft guidelines noting that functional cure has become an evolving treatment goal (10). This position is consistent with the EASL	Thank you for your comment. 'functional cure' has been added to the list of outcomes.

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		recommendations, which outline functional cure as the recommended therapeutic goal in chronic HBV management (11). GSK recommends amending the outcome listed as “liver function (including alanine aminotransferase [ALT] level and presence of cirrhosis)” to “liver function” only. Liver function is a broad clinical construct assessed through a combination of biochemical and synthetic markers (such as bilirubin and albumin), alongside a range of liver enzymes (including aspartate aminotransferase [AST], ALT, alkaline phosphatase [ALP] and gamma-glutamyl transferase [GGT]), and supported by imaging and clinical evaluation. 1. ALT level: Importantly, ALT alone does not measure liver function: it reflects hepatocellular inflammation or injury rather than the liver’s synthetic or excretory capabilities. As such, ALT should not be classified as a liver function outcome, nor is it an appropriate comparative efficacy measure for bepirovirsen versus NA therapy. ALT is primarily a safety biomarker and not indicative of liver synthetic function, so should not be used as a comparative efficacy endpoint. Transient ALT elevations are expected during immune reactivation associated with achieving FC, including with bepirovirsen, and typically represent mechanism related immune activity rather than worsening liver health. Consequently, comparing ALT between bepirovirsen and standard of care would be clinically misleading, as ALT flares are biologically expected alongside FC and do not represent a meaningful efficacy or liver function signal. For these reasons,	The outcome has been updated to ‘liver function’

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		ALT is not suitable as a comparative endpoint and should not be retained within the scope. 2. Cirrhosis: Individuals with cirrhosis were explicitly excluded from the B-Well clinical trials and are not eligible for bepirovirsen treatment under the anticipated label. Cirrhosis is a long term, progressive clinical outcome that typically develops over many years and cannot be meaningfully assessed within the timeframe or design of the B-Well programme. Therefore, cirrhosis cannot be directly observed in the study but will be reflected in the model extrapolations of long-term complications	
	British HIV Association	Yes	Thank you for your comment. No action required.
	UK Health Security Agency	It would be useful to include HBeAg (loss and development of anti-HBeAg). Also loss of HBsAg and development of anti-HBsAg.	Thank you for your comment. 'hepatitis B e antigen level' has been added to the outcomes
Equality	GlaxoSmithKline (company)	Chronic HBV disproportionally affects certain patient populations, including minority ethnic groups (as well as those born in HBV endemic countries), communities experiencing socioeconomic deprivation, people who inject drugs (PWID), people living in prisons or other detention settings, men who have sex with men (MSM), and people with recorded diagnosis of HIV, hepatitis C virus, or syphilis (1, 4, 12). Several of these patient groups are protected under the Equality Act 2010 (13). Compared with the general patient population, these patient groups face a	Thank you for your comment. The issues raised have been added to the equalities impact assessment (EIA) form

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		higher risk of HBV infection, have worse clinical outcomes, and encounter established differential access to healthcare. The stigma associated with disease may also be a barrier to care within these high-risk groups, which may discourage these individuals from taking treatment (1, 4, 12). NAs are the mainstay of treatment for chronic HBV in the UK, and most patients require lifelong NA treatment to maintain viral suppression. While all UK patients currently have access to NAs through the NHS, the aforementioned high-risk patient groups may not fully benefit from NAs due to the lifelong pill burden, and hence there is a need for a short-term treatment option to improve adherence as well as retention in care (14).	
	UK Health Security Agency	It would be important to consider service access for vulnerable populations including migrants, people who inject drugs	Thank you for your comment. The issues raised have been added to the equalities impact assessment (EIA) form
Other considerations	GlaxoSmithKline (company)	Treatment with bepirovirsen is associated with costs that are largely incurred upfront, while benefits are expected to accrue over the extended time horizon. This is particularly relevant in the context of chronic HBV, which is often asymptomatic over many years but is associated with a progressively increasing risk of serious complications, including cirrhosis, liver failure and hepatocellular carcinoma. These outcomes have a substantial impact on both survival and quality of life. In such cases, the choice of discount rate may have a material impact on the cost-effectiveness results. NICE's Methods Guide allows for the application of a lower 1.5% discount rate for health benefits in circumstances where the benefits are substantial, sustained over the long term, and relate to the	Thank you for your comment. The use of non-reference case discount rate can be considered by committee during the course of the appraisal. This may be presented in addition to reference case discounting.

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		prevention of future ill-health. Bepirovirsen meets these criteria: its mechanism of action enables the possibility of functional cure, with enduring health benefits extending beyond the trial period and into later disease stages.	
	British HIV Association	The role for Bepiroversin for people with HIV-HBV coninfection, people with HIV-HBV_HDV coinfection and people with HBV-HDV coinfection	Thank you for your comment. 'People with HIV coinfection' have been added as a subgroup
	UK Health Security Agency	UKHSA may be able to share relevant epidemiological data to inform the health economic evaluation	Thank you for your comment. Your offer is graciously noted. If required, members of the NICE technical team or the EAG will be in contact.
Questions for consultation	GlaxoSmithKline (company)	**Is bepirovirsen expected to displace existing treatment for chronic hepatitis B?** Bepirovirsen is expected to partially displace existing treatments in the NHS. While treatment with NAs (e.g. tenofovir disoproxil and entecavir) suppress viral replication, they rarely induce FC (2, 15, 16). FC is defined as sustained suppression (24 weeks or longer) of HBV DNA (<lower limit of quantification) and HBsAg not detected, with or without HBsAb. FC is now recommended as the optimal endpoint of chronic HBV treatment, and is the only endpoint demonstrating lasting remission from disease off all chronic HBV therapy (17).	Thank you for your comment. No action required.

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		Bepirovirsen is anticipated to be used as an add-on for a finite treatment duration (24 weeks). If FC is achieved, it may enable discontinuation of lifelong NAs in some patients. Therefore, bepirovirsen would supplement rather than replace existing treatments initially, but could reduce the need for lifelong antivirals and monitoring in patients who achieve FC. **Where do you consider bepirovirsen will fit into the existing care pathway for chronic hepatitis B? Please select from the following, will bepirovirsen be:** ~~A. Prescribed in primary care with routine follow-up in primary care~~ ~~B. Prescribed in secondary care with routine follow-up in primary care~~ ~~C. Prescribed in secondary care with routine follow-up in secondary care~~ **D. Other (please give details):** For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. GSK anticipates treatment decisions for bepirovirsen to be made by a multidisciplinary team in a specialist centre set out by NHS England, and bepirovirsen to be prescribed by a specialist centre (or delegated spoke hospital) with routine follow-up in the same centre. This aligns with the NICE guidance the comparators (tenofovir disoproxil and entecavir) (5), as well as for hepatitis C virus medicines (18). **Would bepirovirsen be a candidate for managed access?** No; the efficacy and safety of bepirovirsen has been observed for up to 15 months in patients from the B-Well studies, and up to 36 months in patients	

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		from the B-Clear study (19-21). **Do you consider that the use of bepirovirsen can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** GSK believes that there are additional qualitative and public health benefits with bepirovirsen that would not be captured by generic preference-based utility measures. Bepirovirsen demonstrates a statistically significant and clinically meaningful FC rate, which will improve patient wellbeing, including: 1. The psychological impact of disease disclosure due to the stigma associated with chronic HBV 2. Stigma associated with taking tenofovir disoproxil (which is also a known treatment for HIV) 3. The daily lifelong pill burden 4. Fear of disease progression and liver complications. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** To support the benefits of bepirovirsen that may not be captured by the quality-adjusted life year (QALY) calculation, GSK will provide evidence from the bepirovirsen clinical trial programme (including B-Well 1, B-Well 2, B-Sure and B-Clear), real-world evidence, scientific literature, and expert clinical input. **Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product**	

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		Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. Treatments stated within the scope relevant to this indication (tenofovir disoproxil and entecavir) are used in NHS practice as per their summaries of product characteristics (SmPC). **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:** • **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which will be licensed;** • **could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;** • **could have any adverse impact on people with a particular disability or disabilities**.	

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		Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts. Please see the equality section above.	
	British HIV Association	Bepioversin will be: C. Prescribed in secondary care with routine follow-up in secondary care	Thank you for your comment. No action required.
Additional comments on the draft scope	GlaxoSmithKline (company)	**References** 1. UK Health Security Agency. Hepatitis B in England 2025. Available at: https://www.gov.uk/government/publications/hepatitis-b-in-england/hepatitis-b-in-england-2025 [accessed March 2026]. 2. Slaets L, De Ridder F, Lenz O, Beumont M, Meyvisch P, Verbinned P. Systematic review with meta-analysis: hepatitis B surface antigen decline and seroclearance in chronic hepatitis B patients on nucleos(t)ide analogues or pegylated interferon therapy. GastroHep. 2020;2:106–16. 3. World Health Organization (WHO). Elimination of hepatitis by 2030. Available at: https://www.who.int/health-topics/hepatitis/elimination-of-hepatitis-by-2030#tab=tab_1 [accessed April 2026]. 4. UK Health Security Agency. Hepatitis B in England 2024. Available at: https://www.gov.uk/government/publications/hepatitis-b-in-england/hepatitis-b-in-england-2024 [accessed March 2026]. 5. National Institute for Health and Care Excellence (NICE). Hepatitis B (chronic): diagnosis and management. Available at: https://www.nice.org.uk/guidance/cg165/chapter/Recommendations [accessed Feb 2026]. 2017. 6. European Association for the Study of the L. EASL Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol. 2025;83(2):502–83.	

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		7. World Health Organization (WHO). Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. Available at: https://www.who.int/publications/i/item/9789240090903 [accessed March 2026]. 2024. 8. GSK data on file. Adelphi Real World Disease Specific Programmes™. Burden of Chronic Hepatitis B in the United Kingdom: Real-World Evidence on Healthcare Use and Patient-Reported Outcomes. . 2025. 9. IQVIA. Chronic hepatitis B. Landscape assessment for England 2025. In preparation for the launch of bepirovirsen. 2025. 10. European Medicines Agency (EMA). Guideline on the clinical evaluation of medicinal products intended for the treatment of chronic hepatitis B (CHB). Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-clinical-evaluation-medicinal-products-intended-treatment-chronic-hepatitis-b-chb-revision-1_en.pdf [accessed April 2026]. 2025. 11. Cornberg M, Lok AS, Terrault NA, Zoulim F, Faculty E-AHTEC. Guidance for design and endpoints of clinical trials in chronic hepatitis B - Report from the 2019 EASL-AASLD HBV Treatment Endpoints Conference(double dagger). J Hepatol. 2020;72(3):539–57. 12. Cooper B. Eliminating Hepatitis B. Available at: https://www.drbeccycooper.co.uk/eliminating-hepatitis-b/#:~:text=In%20my%20roles%20both%20on%20the%20Health,Liver%20Disease%20and%20Liver%20Cancer%2C%20I%20am [accessed Feb 2026]. 2025. 13. Legislation UK. Equality Act 2010. Available at: https://www.legislation.gov.uk/ukpga/2010/15/contents [accessed March 2026]. 14. Mutimer D, Elsharkawy A, Hathorn E, Arunkumar S. Age, ethnicity and proximity to clinic determine retention in care of chronic hepatitis B patients. J Viral Hepat. 2023;30(3):223–7.	

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		15. Lok ASF. Toward a Functional Cure for Hepatitis B. Gut Liver. 2024;18(4):593–601. 16. Terrault NA, Lok ASF, McMahon BJ, Chang KM, Hwang JP, Jonas MM, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018;67(4):1560–99. 17. Ghany MG, Buti M, Lampertico P, Lee HM, Faculty A-EH-HTEC. Guidance on treatment endpoints and study design for clinical trials aiming to achieve cure in chronic hepatitis B and D: Report from the 2022 AASLD-EASL HBV-HDV Treatment Endpoints Conference. J Hepatol. 2023;79(5):1254–69. 18. National Institute for Health and Care Excellence (NICE). Hepatitis C: Scenario: Active hepatitis C infection. Available at: https://cks.nice.org.uk/topics/hepatitis-c/management/active-hepatitis-c-infection/ [accessed March 2026]. 2025. 19. GSK. Data on file. Primary clinical study report. Phase 3 Study of Bepirovirsen in Nucleos(t)ide Analoguetreated Participants with Chronic Hepatitis B (B-Well 1). . 2026. 20. GSK. Data on file. Primary clinical study report. Phase 3 Study of Bepirovirsen in Nucleos(t)ide Analoguetreated Participants with Chronic Hepatitis B (B-Well 2). . 2026. 21. Yuen MF, Lim SG, Plesniak R, Tsuji K, Janssen HLA, Pojoga C, et al. Efficacy and Safety of Bepirovirsen in Chronic Hepatitis B Infection. N Engl J Med. 2022;387(21):1957–68.	