**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Evaluation**

# Bepirovirsen with nucleoside or nucleotide analogues for treating chronic hepatitis B

**Final scope**

## Remit/evaluation objective

To appraise the clinical and cost effectiveness of bepirovirsen with nucleoside or nucleotide analogues within its marketing authorisation for treating chronic hepatitis B.

## Background

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus. It is transmitted through the body fluids of a person. The virus can also be transmitted through perinatal transmission from mother to child. It can also be transmitted through blood to blood contact (e.g. injecting drugs using shared needles or 'needlestick' injuries) and sexual contact. Infected individuals develop an acute infection, which may or may not result in symptoms. The majority of those infected during adulthood make a full recovery and acquire immunity from future infection. Less than 5% of infected adults will develop chronic hepatitis B, defined as viraemia and hepatic inflammation that persists for more than 6 months after acute infection with hepatitis B virus.[1] In contrast, infection in infancy and early childhood leads to chronic hepatitis in about 95% of cases.[1] People with chronic hepatitis B often do not have any symptoms. However, symptoms of chronic hepatitis B infection that can present include fever, fatigue, and jaundice.[2] Hepatitis B can also cause liver disease and liver cancer. It is the leading cause of liver cancer worldwide.[3]

The UK Health Security Agency estimated that in 2022 there were around 270,000 people living with hepatitis B which is 0.6% of the population, although the proportion is higher in London at 1.5%.[4] 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 the other ethnic group.[4]

Current treatment of chronic hepatitis B 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. There are currently 3 antiviral treatments recommended by NICE for the treatment of chronic hepatitis B. NICE technology appraisal 96 recommends peginterferon alfa-2a. NICE technology appraisal 153 recommends entecavir. NICE technology appraisal 173 recommends tenofovir disoproxil.

## The technology

Bepirovirsen (brand name unknown, GSK) does not currently have a marketing authorisation in the UK for treating chronic hepatitis B. It has been studied in clinical trials compared with placebo in people with chronic hepatitis B on a stable treatment regimen.

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| **Intervention(s)** | Bepirovirsen with nucleoside or nucleotide analogues |
| **Population(s)** | People with chronic hepatitis B |
| **Subgroup(s)** | • People with HIV coinfection<br>• People with prior treatment experience |
| **Comparators** | Established clinical management without bepirovirsen including:<br>• tenofovir disoproxil<br>• entecavir<br>• peginterferon alfa-2a<br>• tenofovir alafenamide fumarate<br>• no treatment |
| **Outcomes** | The outcome measures to be considered include:<br>• hepatitis B surface antigen level<br>• hepatitis B e antigen level<br>• hepatitis B DNA level<br>• functional cure<br>• functional cureliver function<br>• mortality<br>• adverse effects of treatment<br>• health-related quality of life. |

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| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br><br>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.<br><br>Costs will be considered from an NHS and Personal Social Services perspective.<br><br>The availability and cost of biosimilar and generic products should be taken into account. |
| **Other considerations** | Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator. |

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| **Related NICE recommendations** | **Related technology appraisals:**<br>Tenofovir disoproxil for the treatment of chronic hepatitis B. NICE technology appraisal guidance 173.<br>Entecavir for the treatment of chronic hepatitis B. NICE technology appraisal guidance 153.<br>Adefovir dipivoxil and peginterferon alfa-2a for the treatment of chronic hepatitis B. NICE technology appraisal guidance 96.<br>**Related NICE guidelines:**<br>Virtual Touch Quantification to diagnose and monitor liver fibrosis in chronic hepatitis B and C (2020) NICE guideline HTG385.<br>Hepatitis B (chronic): diagnosis and management (2017) NICE guideline CG165.<br>Hepatitis B and C testing: people at risk of infection. (2013) NICE guideline PH43. |

**References**


1. World Health Organisation (2025). Hepatitis B. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b (accessed January 2026)

2. NHS (2025). Hepatitis B. https://www.nhs.uk/conditions/hepatitis-b/ (accessed January 2026)

3. Tan et al. (2024). Liver cancer in 2021: Global Burden of Disease study. Journal of Hepatology 82, pg 851-860

4. UK Health Security Agency (2025). Hepatitis B in England 2024. https://www.gov.uk/government/publications/hepatitis-b-in-england/hepatitis-b-in-england-2024 (accessed February 2026)