

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

## Bepirovirsen for treating chronic hepatitis B ID6608

## Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of bepirovirsen 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 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. 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.<sup>1</sup> In contrast, infection in infancy and early childhood leads to chronic hepatitis in about 95% of cases.<sup>1</sup> 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.<sup>2</sup>

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%.<sup>3</sup> The prevalence estimates were higher in men, those of an ethnic origin other than white British, particularly those of black, black British, Caribbean or African ethnic origin and other ethnic group.<sup>3</sup>

Current treatment of chronic hepatitis B involves management of complications including liver disease and hepatic cancer, and treatment with antivirals. 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.

<b>Intervention(s)</b>	Bepirovirsen
<b>Population(s)</b>	People with chronic hepatitis B

<p><b>Comparators</b></p>	<p>Established clinical management without bepirovirsen including:</p> <ul style="list-style-type: none"> <li>• tenofovir disoproxil</li> <li>• entecavir</li> <li>• peginterferon alfa-2a</li> </ul>
<p><b>Outcomes</b></p>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• hepatitis B surface antigen level</li> <li>• hepatitis B DNA level</li> <li>• liver function (including ALT level and presence of cirrhosis)</li> <li>• mortality</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<p><b>Economic analysis</b></p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p><b>Other considerations</b></p>	<p>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.</p>

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

Is bepirovirsen expected to displace existing treatment for chronic hepatitis B?

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.

Would bepirovirsen be a candidate for managed access?

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?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product 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.

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.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation>).

### 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. 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)