

NCPE Assessment

Plain English Summary

February, 2024

Drug name: Bulevirtide (pronounced bul-EH-vir-tide) for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease.

Brand name: Hepcludex®

HTA ID: 22067

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What is bulevirtide used for?

Bulevirtide is an antiviral medicine used to treat chronic (long-term) hepatitis delta virus (HDV) infection in adults with compensated liver disease (when the liver is damaged but is still able to work), when the presence of viral RNA (genetic material) has been confirmed by blood tests. HDV is an 'incomplete' virus, because it cannot replicate in cells without the help of another virus, the hepatitis B virus. Because of this, patients infected with the virus always also have hepatitis B. Bulevirtide, works by attaching to and blocking a receptor (target)

through which the hepatitis delta and hepatitis B viruses enter liver cells. By blocking the entry of the virus into the cells, bulevirtide limits the ability of HDV to replicate, preventing the spread of the virus in the liver and thereby reducing inflammation.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider not funding bulevirtide unless its cost effectiveness (value for money) can be improved relative to existing treatments. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional [criteria](#) outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that bulevirtide may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is very poor value for money.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about bulevirtide. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about bulevirtide from the following online options:

- the NCPE Technical Summary Document
- Hepcludex® European Public Assessment Report (EPAR) – ([Summary for the public](#)) or
- searching for bulevirtide on our website (www.ncpe.ie);
- searching for bulevirtide on the European Medicines Agency (EMA) website (www.ema.europa.eu).

Please refer to the NCPE website for updated information on the reimbursement status of this medicine.