

Putting NICE guidance into practice

**Resource impact report:**

**Bulevirtide for treating chronic hepatitis D (TA896)**

Published: June 2023

# Summary

NICE has recommended bulevirtide as an option for treating chronic hepatitis D in adults with compensated liver disease only if:

• there is evidence of significant fibrosis (METAVIR stage F2 or above or Ishak stage 3 or above) and

• their hepatitis has not responded to peginterferon alfa-2a (PEG IFN) or

• they cannot have interferon-based therapy.

Bulevirtide is only recommended if the company provides it according to the commercial arrangement (see section 2 of guidance).

We estimate that around:

* 80 adults with chronic hepatitis D are eligible for treatment with bulevirtide based on expected population growth.
* 64 adults will start treatment with bulevirtide each year by 2027/28 adjusted for expected population growth.

**Table 1 Estimated number of people in England receiving treatment with bulevirtide each year**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **2023/24** | **2024/25** | **2025/26** | **2026/27** | **2027/28** |
| Uptake % | 15 | 45 | 66 | 77 | 80 |
| People starting treatment with bulevirtide | 12 | 35 | 52 | 61 | 64 |
| People continuing treatment from a previous year | 0 | 12 | 47 | 99 | 160 |
| **Total number of people** | **12** | **47** | **99** | **160** | **224** |
| It is anticipated people continue treatment for more than 5 years on average and therefore there will also be people receiving treatment who started treatment in the previous years**.** | | | | | |

This report is supported by a local resource impact template. This is because the company has a commercial arrangement which makes bulevirtide available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company’s responsibility to let relevant NHS organisations know details of the discount.

This technology is commissioned by NHS England. Providers are NHS hospital trusts.

1. Bulevirtide
   1. NICE has recommended bulevirtide as an option for treating chronic hepatitis D in adults with compensated liver disease only if:

• there is evidence of significant fibrosis (METAVIR stage F2 or above or Ishak stage 3 or above) and

• their hepatitis has not responded to peginterferon alfa-2a (PEG IFN) or

• they cannot have interferon-based therapy.

Bulevirtide is only recommended if the company provides it according to the commercial arrangement (see section 2 of guidance).

* 1. People with hepatitis D also have hepatitis B. There are no other licensed treatments specifically for hepatitis D. Standard care usually involves treating symptoms and the hepatitis B.
  2. People co-infected with hepatitis D, with evidence of significant fibrosis, can be offered a 48-week course of PEG IFN. The clinical experts explained that using PEG IFN to treat hepatitis D is off label, can have serious side effects, and is not effective for most people.
  3. Testing for METAVIR stage usually involves a biopsy, which is invasive and may have side effects, and many people decline it. NICE's guideline on diagnosing and managing chronic hepatitis B recommends transient elastography (FibroScan), which is a non-invasive assessment.

1. Resource impact of the guidance
   1. We estimate that around:

* 80 adults with chronic hepatitis D are eligible for treatment with bulevirtide based on expected population growth.
* 64 adults will start treatment with bulevirtide each year by 2027/28 adjusted for expected population growth.

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**Table 2 Estimated number of people in England receiving treatment with bulevirtide using NICE assumptions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **2023/24** | **2024/25** | **2025/26** | **2026/27** | **2027/28** |
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## Savings and benefits

* 1. Hepatitis D is very rare and bulevirtide is the first licensed treatment in this area, addressing an unmet need. The clinical experts highlighted that treatment would reduce the viral load in infected people, prevent the spread of infection and reduce the stigma around this blood-borne virus.

1. Implications for commissioners and providers
   1. Bulevirtide is commissioned by NHS England. Providers are NHS hospital trusts.
   2. Bulevirtide falls within the programme budgeting category 01X – Infectious diseases, Infectious diseases.
2. How we estimated the resource impact

## The population

* 1. The [British Liver Trust](https://britishlivertrust.org.uk/about-us/media-centre/statistics/) estimates there are around 151,000 people infected with Hepatitis B in England. Applying population growth, this is expected to rise to 157,300 by 2027/28.
  2. Of these, the [Annual report from the sentinel surveillance of blood borne virus testing in England: data for January to December 2020](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1006297/hpr1321_sentBBV_main-report.pdf) estimates 3.6% are co-infected with Hepatitis D.
  3. Clinical expert opinion estimated that around 21% of those would be HDV RNA positive.
  4. The [28-year study of the course of hepatitis Delta infection: a risk factor for cirrhosis and hepatocellular carcinoma](https://pubmed.ncbi.nlm.nih.gov/19208358/) estimates around 80% would be eligible within the marketing authorisation. (9% ineligible due to decompensated cirrhosis, 9% due to hepatocellular carcinoma and 2% due to liver transplantation).
  5. The company submission estimated that 13.3% of these would be treated annually with PEG IFN. This represents a new population each year.
  6. The [Side Effects of Interferon-α Therapy](https://link.springer.com/article/10.1007/s11096-005-1319-7) study estimated that 87.5% of people don’t respond to Peg-IFN treatment or cannot have interferon-based therapy (50% of patients are eligible for interferon-based therapy, of which 25% achieve a sustained response).
  7. The [28-year study of the course of hepatitis Delta infection: a risk factor for cirrhosis and hepatocellular carcinoma](https://pubmed.ncbi.nlm.nih.gov/19208358/) also estimated that 72.2% of people would have significant fibrosis (METAVIR stage greater than or equal to F2).
  8. Table 3 shows the number of people eligible for treatment with bulevirtide.

### Table 3 Number of people eligible for treatment in England

|  |  |  |
| --- | --- | --- |
| **Population** | **Proportion of previous row (%)** | **Number of people** |
| Adult population forecast at 2027/28 |  | 46,263,200 |
| Prevalence of Hepatitis B in England 2027/281 | 0.340% | 157,343 |
| People co-infected with Hepatitis D2 | 3.60% | 5,664 |
| People who are HDV RNA positive3 | 21.00% | 1,190 |
| People who are eligible within MA of bulevirtide4 | 80.00% | 952 |
| People who are treated annually with peginterferon alfa-2a (PEG IFN)5 | 13.30% | 127 |
| People who don’t respond to Peg-IFN treatment or cannot have interferon-based therapy6 | 87.50% | 111 |
| People with significant fibrosis (METAVIR stage greater than or equal to F2)4 | 72.20% | 80 |
| 1 [British Liver Trust](https://britishlivertrust.org.uk/about-us/media-centre/statistics/)  2 [Annual report from the sentinel surveillance of blood borne virus testing in England: data for January to December 2020](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1006297/hpr1321_sentBBV_main-report.pdf)  3 Clinical expert opinion  4 [28-year study of the course of hepatitis Delta infection: a risk factor for cirrhosis and hepatocellular carcinoma](https://pubmed.ncbi.nlm.nih.gov/19208358/)  5 Company submission  6 [Side Effects of Interferon-α Therapy](https://link.springer.com/article/10.1007/s11096-005-1319-7) | | |

## Assumptions

* 1. The resource impact template assumes that:
* Standard care is the most relevant comparator.
* Bulevirtide is administered at 2 mg once daily by subcutaneous injection as monotherapy or in co-administration with a nucleoside/nucleotide analogue for treatment of underlying HBV infection.
* Bulevirtide will be dispensed in the homecare setting after the first prescription.
* Drugs prescribed in secondary care and dispensed by home delivery incur £50 per month administrative costs to cover any prescribing overheads. This can be amended in the template to reflect local circumstances.
* Administration costs in clinic are based on the [2023-25 NHS Payment Scheme, 2023/24 prices workbook](https://www.england.nhs.uk/publication/2023-25-nhs-payment-scheme/).
* There are no additional monitoring requirements for people receiving bulevirtide compared with standard care.

# About this resource impact report

This resource impact report accompanies the NICE guidance on [Bulevirtide for treating chronic hepatitis D](https://www.nice.org.uk/guidance/ta896) and should be read with it. See [terms and conditions](http://www.nice.org.uk/terms-and-conditions) on the NICE website.

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