ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Bulevirtide Reimbursement Application Form

For MMP Use Only	
Case Reference:	*Date Received:*

Date of Application	
Part 1: Patient Details	
Name of Patient	
Date of Birth	
Address	
GMS / DPS / PPS Number (Please tick and insert number)	GMS ☐ DPS ☐ PPSN ☐ Number:

Part 2: Prescriber Details	
Name of Consultant	
Medical Council Number	
Contact Details	Hospital:
	Address:
	Phone:
	Email:

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Please refer to the HSE Managed Access Protocol for Bulevirtide (Hepcludex®) when completing Part 3 and 4 of this application form

Part 3: Reimbursement criteria - Initiation

Part 3(a): Patient age

To enable a positive recommendation, information relating to the patient's age must be provided.

1. This patient is aged 18-65 years at the time of application: **Yes:** ☐ **No**: ☐

Part 3(b): Patient diagnosis

To enable a positive recommendation, evidence relating to the patient's diagnosis must be provided.

1. Patient has a confirmed diagnosis of chronic hepatitis delta virus (HDV) infection?

   Yes: ☐ **No:** ☐

a. Please provide:

   i. A polymerase chain reaction (PCR) result for serum/plasma HDV-RNA: **Enclosed** ☐

   ii. Date taken: ☐

2. Patient has a confirmed diagnosis of compensated liver disease? **Yes:** ☐ **No:** ☐

a. Please provide:

   i. Child Pugh score: ☐

   ii. Date taken: ☐

3. Does the patient have significant fibrosis defined as METAVIR stage greater than or equal to F2 or a transient elastography (Fibroscan) score greater than or equal to 7.25 kPA?

   Yes: ☐ **No:** ☐

a. Please provide a copy of the investigation performed to provide evidence of significant fibrosis defined as METAVIR stage greater than or equal to F2 or a transient elastography (Fibroscan) score greater than or equal to 7.25 kPA:

Investigation report: Enclosed ☐

b. If relevant, other supporting information in relation to a diagnosis of significant fibrosis

Part 3(c): Patient clinical status

To enable a positive recommendation, the status of the patient in relation to the contraindications for treatment must be satisfied.

1. Does the patient have any contraindications for treatment outlined in the SmPC for Hepcludex®?
   Yes: ☐ **No:** ☐

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Part 3(d): Patient's medical treatment

To enable a positive recommendation, evidence of an inadequate response to pegylated-interferon alfa-2a (PEGIFNα) treatment or evidence of intolerability or a contraindication to PEGIFNα treatment is required.

Option 1: Is the patient currently in receipt of PEGIFNα to which they are experiencing an inadequate response?

Yes: ☐ **No:** ☐

Dose	
Duration of treatment (include start date and stop date when applicable)	
If stopped, reason for discontinuation	

Option 2: Patient did not tolerate PEGIFNα and experienced a clinically significant adverse reaction which led to discontinuation of treatment prior to completion of an adequate trial?

Yes: ☐ **No:** ☐

Dose	
Duration of treatment (include start date and stop date when applicable)	
Provide details of the clinically significant adverse reaction which led to discontinuation prior to completion of an inadequate trial:	
Was the adverse reaction reported to the Health Products Regulatory Authority (HPRA) **Yes:** ☐ **No:** ☐ If yes, please provide the date the adverse reaction was reported:_____	

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Option 3: Patient in whom PEGIFNα treatment is contraindicated?

Yes: ☐ **No:** ☐

Provide details of the contraindication, including supporting evidence:

Please tick to confirm:

I confirm that the underlying HBV infection is being simultaneously managed according to current treatment guidelines: ☐

Please indicate if this patient is currently accessing treatment with Hepcludex® via compassionate use / early access programme / ongoing clinical trial: **Yes:** ☐ **No:** ☐

Part 4: Response to Treatment

Please tick to confirm:

1. I confirm that treatment will only be continued as long as associated with clinical benefit. Consideration to discontinue the treatment will be given in case of sustained (6 months) hepatitis B virus surface antigen (HBsAg) seroconversion or loss of virological and biochemical response: ☐

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Additional space for supporting information if required

Completed forms should be returned to:
Scan the completed form and return via secure email (e.g. HSE email or Healthmail) to: mmp@hse.ie

Authorisation of Request	
Signature of **Prescribing Consultant**	
Institution	

Data Protection Notice

- The information on this form will be used by the Health Service Executive (HSE) to assess the suitability of the items listed to be provided under Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the HSE by the dispensing pharmacist to ensure that the named person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the HSE.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS privacy statement can be located at www.pcrs.ie.