**ALL SECTIONS OF THIS FORM MUST BE COMPLETED**

# Odevixibat 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<br>(Please tick and insert number) | GMS ☐ DPS ☐ PPSN ☐<br>Number: |

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

**Please refer to the HSE Managed Access Protocol for Odevixibat (Bylvay®) when completing Part 3 of this application form**

## Part 3: Reimbursement criteria - Initiation

## Part 3(a): Patient age, weight and dosage

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

**1.** This patient is aged six months or older at the time of application: **Yes** ☐ **No** ☐

**2.** This patient's weight is ≥ 4 kg at the time of application: **Yes** ☐ **No** ☐

**a)** Please provide:

**i.** Patient's weight in kilograms (kg): ☐

**ii.** Date taken (should be within one month of the date of application): ☐

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

*If **Yes**, please complete **(a)** below. If **No**, please complete **(b)** on the next page.*

**a)** Please provide details of the patient's current dose and the number of Bylvay® capsules needed to achieve that dose based on the patient's body weight.
*Please refer to Tables 1 and 2 in section 4.2 of the SmPC.*

| **Patient's body weight (kg)** | **Current daily dose (mcg/kg/day) e.g. 40 mcg/kg/day** | **Current total daily dose (mcg)** | **Bylvay® capsules administered per day** | | | |
|---|---|---|---|---|---|---|
| | | | **Body weight < 19.5 kg** | | **Body weight > 19.5 kg** | |
| | | | **Strength (mcg)** | **Number** | **Strength (mcg)** | **Number** |
| | | | **200** | | **400** | |
| | | | **600** | | **1200** | |

If ***No***, please complete **(b)** below.

**b)** Please indicate the number of Bylvay® capsules needed to achieve the recommended initiation dose of 40 mcg/kg/day based on the patient's body weight.

*Please refer to Tables 1 and 2 in section 4.2 of the SmPC.*

| **Patient's body weight (kg)** | **Recommended initiation dose (mcg/kg/day)** | **Total daily dose (mcg)** | **Bylvay® capsules administered per day** | | | |
|---|---|---|---|---|---|---|
| | | | **Body weight < 19.5 kg** | | **Body weight > 19.5 kg** | |
| | **40** | | **Strength (mcg)** | **Number** | **Strength (mcg)** | **Number** |
| | | | **200** | | **400** | |
| | | | **600** | | **1200** | |

## Part 3(b): Patient diagnosis

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

**4.** Patient has a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC):

**Yes** ☐ **No** ☐

**5.** Please indicate the following:

**a)** Age at presentation with jaundice: ☐ **week(s) old** *(0 / zero indicates 'at birth')*

**b)** Age at presentation with abnormal liver function tests: ☐ **week(s) old** *(0 / zero indicates 'at birth')*

**c)** Presence of any extrahepatic manifestations**: Yes** ☐ **No** ☐

If ***Yes,*** (presence of extrahepatic manifestations), please provide further information in the space below:

**6.** Please provide a copy of the genetic testing report confirming the diagnosis of PFIC:

| | |
|---|---|
| **Enclosed** | ☐ |

**7.** Is the subtype of PFIC known? **Yes** ☐ **No** ☐

**a)** If ***Yes***, please provide the subtype of PFIC (e.g. PFIC1, PFIC2, PFIC3):

**PFIC** ☐

**8.** Does the patient have pathologic variations of the ABCB11 gene that predict complete absence or lack of function of the bile salt export pump (BSEP) protein (i.e. patients with BSEP3 subtype of PFIC2)? **Yes** ☐ **No** ☐ **Not known** ☐

**a)** If ***Not known***, please provide further information in the space below:

| |
|---|
| |

**9.** Please provide copies of the following investigations performed to support the diagnosis of PFIC:

| | | |
|---|---|---|
| **Liver biopsy** | **Enclosed** | ☐ |
| **Liver function tests (to include serum bile acid level)** | **Enclosed** | ☐ |
| **Liver ultrasound** | **Enclosed** | ☐ |

**a)** If ***No*** liver biopsy investigation has been performed, please outline the reason(s) in the space below:

| |
|---|
| |

## Part 3(c): Patient clinical status

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

**10.** Does the patient have any contraindications for treatment outlined in the SmPC for Bylvay®, i.e. hypersensitivity to the active substance or any of the excipients listed in section 6.1 of the SmPC? **Yes** ☐ **No** ☐

**11.** Does the patient have the following exclusion criteria outlined in section 2.4.1 of the Managed Access Protocol?

**a)** Conditions, medications or surgical procedures that impair either gastrointestinal motility, or enterohepatic circulation of bile acids, including bile salt transport to biliary canaliculi which have the potential to reduce the efficacy of odevixibat: **Yes** ☐ **No** ☐

**b)** Severe hepatic impairment (Child-Pugh C): **Yes** ☐ **No** ☐

**c)** Past medical history or ongoing presence of other types of liver disease: **Yes** ☐ **No** ☐

**d)** Decompensated liver disease, coagulopathy, history or presence of clinically significant ascites, variceal haemorrhage, and/or encephalopathy: **Yes** ☐ **No** ☐

## Part 3(d): Patient's medical treatment

**To enable a positive recommendation, information relating to the patient's current medical treatment must be provided.**

**12.** Please provide details of the patient's current medications in the table below:

| Medication | Strength | Dose | Indication |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

**ALL SECTIONS OF THIS FORM MUST BE COMPLETED**

**Space for additional medications if required:**

## Part 4: Patient Baseline Parameters

**To enable a positive recommendation, evidence relating to the patient's baseline parameters must be provided, and taken within one month of the date of application.**

| | | |
|---|---|---|
| **Serum bile acid level** | **Enclosed** | ☐ |
| **Liver function tests** | **Enclosed** | ☐ |
| **Pruritus assessment** (e.g. evaluation report / measurement scale of the severity of pruritus) | **Enclosed** | ☐ |

## Additional space for supporting information if required

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| **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.