Application for individual funding of fostemsavir (Rukobia®) for the treatment of multi-drug resistant human immunodeficiency virus type 1 (HIV-1) infection

For MMP Use Only	
Case Reference	*Date Received*

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

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:
Please specify the hospital from which fostemsavir will be supplied:	

Part 2: Consultant Details

Name of consultant:	
Medical Council number:	
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE Managed Access Protocol for fostemsavir when completing parts 3, 4 and 5 of this application form

Part 3: Patient Diagnosis

For a positive recommendation, patients must be aged 18 or older at time of application.

1. Please confirm the patient age at the time of application ☐

Confirmed diagnosis of multi-drug resistant human immunodeficiency virus type 1 (MDR HIV-1)

For a positive recommendation, evidence confirming patient diagnosis must be provided. Please refer to section 2.3 of the managed access protocol for further detail.

Please indicate whether the patient meets the following criteria

2. Patient has a confirmed diagnosis of MDR HIV-1. **Yes** ☐ **No** ☐

If **yes**, please provide:

A. A copy of a test confirming the diagnosis of HIV-1. ☐ **Enclosed**

B. A copy of a genotypic resistance test(s) confirming MDR HIV-1. ☐ **Enclosed**

Part 4: Patient Clinical History/Status

Virological failure with existing antiretroviral therapy (ART) regimens

1. Is the patient currently experiencing virological failure (>200 copies/mL of HIV-1 ribonucleic acid [RNA])?

Yes ☐ **No** ☐

Please provide a copy of the most recent HIV-1 RNA viral load test. ☐ **Enclosed**

Cannot construct a fully-active regimen with existing antiretrovirals (ARVs) due to previous intolerance to ARVs, contraindications to ARVs, drug-drug interactions and other relevant clinical factors.

Funding approval will only be supported in MDR HIV-1 when patients cannot construct a fully-active regimen with existing ARVs as outlined in section 2.4 of the managed access protocol

2. Please indicate if it is not possible to construct a fully-active regimen with existing ARVs due to previous intolerance to ARVs, contraindications to ARVs, drug-drug interactions, and other relevant clinical factors. **Yes** ☐ **No** ☐

Please provide information to demonstrate that existing ART regimens are not tolerated, or are not clinically advisable.

Have at least one fully active and available drug in two or fewer ARV classes

Funding approval will only be supported in MDR HIV-1 when patients have at least one fully active and available drug in two or fewer ARV classes.

3. Please indicate if there is at least one fully active and available drug in two or fewer ARV classes to include in the ART regimen. **Yes** ☐ **No** ☐

4. Please provide details of the proposed treatment regimen including fostemsavir in the box below.

Exclusion criteria

Refer to section 2.4 of the Managed Access Protocol - Patient clinical history/status, and to the Summary of Manufacturer's Product Characteristics (SmPC).

5. Indicate the current status of the patient in relation to the following clinical parameters (*please tick which apply and complete requested detail where relevant*)

The patient:	**Yes**	**No**
meets any of the contraindications to treatment as outlined in the relevant SmPC		
Has the HIV-1 Group 1 subtype CRF01_AE strain		

If **yes** has been answered in the above table, please provide relevant information in the box provided below:

Part 5: Patient's Medical Treatment

Funding of fostemsavir is supported for patients with MDR HIV-1 for whom it is not possible to construct a suppressive anti-viral regimen, and who meet the criteria outlined in this MAP.

For previous ART trialed, please provide information on duration of treatment(s), including start and stop dates and reason for cessation. Information can be provided in the relevant sections on pages 5 and 6.

Copies of prescriptions, and relevant sections of patient notes and/or clinic letters should be attached to validate treatments.

ART Regimen 1:

Medicines included in ART regimen	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

ART Regimen 2:

Medicines included in ART regimen	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

ART Regimen 3:

Medicines included in ART regimen	
Duration of treatment (include start and stop dates)	
Reason for treatment cessation	

Please outline below details of any other ART for HIV-1

Additional space for supporting information

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Completed forms should be returned by:
Email (using secure email, e.g. HSE email or healthmail) to mmp@hse.ie **Please note that the MMP will always acknowledge receipt of each application.** **Please note that anonymised information may be shared with the HSE-Primary Care Reimbursement Service to facilitate payments.**

Authorisation of Request	
Signature of Approved 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 names 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.