Application for individual reimbursement of tafamidis (Vyndaqel®) 61mg capsules

For MMP Use Only	
Case Reference	*Date Received*

Date of Application:	Nominated Community Pharmacy: (Name & address – leave blank if uncertain)

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 Prescribing Consultant:	
Medical Council Number:	
Speciality of Prescribing Consultant:	Cardiology ☐ Neurology ☐ Other (Please specify) _____
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE-Managed Access Protocol for Tafamidis when completing part 3 and 4 of this application form

Part 3: Patient Clinical History

Please indicate whether the patient meets the following criteria (*please tick which apply and complete requested detail*):

1. Is the patient aged ≥18-90 years at the time of application? **Yes** ☐ **No** ☐

2. Does the patient have a history of heart failure with:

- at least one prior hospitalisation for heart failure or,
- clinical evidence of heart failure (without hospitalisation), manifested in signs or symptoms of volume overload or elevated intracardiac pressures requiring treatment with a diuretic for improvement? **Yes** ☐ **No** ☐

Section 1 and section 2 must be completed.

Section 1: Confirmed diagnosis of wild-type or hereditary transthyretin amyloidosis (ATTR) in adult patients with cardiomyopathy

For a positive recommendation, evidence relating to patient diagnosis must be satisfied. (*Refer to section 2.3 and 2.4 of the managed access protocol*)

3. Has light chain amyloidosis been excluded? **Yes** ☐ **No** ☐

4. Does the patient have a confirmed diagnosis of ATTR amyloidosis with cardiomyopathy (ATTR-CM), defined as either wild-type or hereditary? **Yes** ☐ **No** ☐

If yes, what is the diagnosis? (please tick one) **Wild-type ATTR** ☐ **Hereditary ATTR** ☐

5. Please confirm that the diagnosis of wild-type or hereditary ATTR amyloidosis has been established by the following[1]:

(a) Presence of amyloid deposits in biopsy tissue (where relevant)? **Yes** ☐ **No** ☐

If yes, please confirm site of biopsy: Cardiac ☐ Non-cardiac ☐

Please attach a biopsy report, where relevant. **Enclosed** ☐

(b) Diagnosis of ATTR-CM by nuclear scintigraphy (PYP/DPD/HMDP[2])? **Yes** ☐ **No** ☐

If yes, what is the uptake? **Grade 2** ☐ **Grade 3** ☐ **Other** ☐

Please attach copy of the nuclear scintigraphy report, where relevant. **Enclosed** ☐

(c) Evidence of cardiac end-diastolic interventricular septal wall thickness >12 mm? **Yes** ☐ **No** ☐

(d) Evidence of heart failure symptoms defined as New York Heart Association [NYHA] class II, III or IV?

Yes, Class II ☐ **Yes, Class III** ☐ **Yes, Class IV** ☐ **No** ☐

Please submit a recent echocardiography report for *all applicants*: **Enclosed** ☐

(e) Confirmation of TTR genotype (wild-type or hereditary) by genetic testing? **Yes** ☐ **No** ☐

Please attach a copy of the genetic testing investigation for *all applicants*: **Enclosed** ☐

[1] Applications for reimbursement approval will only be considered for patients with a confirmed diagnosis of wild-type or hereditary ATTR amyloidosis, established by biopsy or nuclear scintigraphy or both

[2] PYP: pyrophosphate; DPD: diphosphono-1,2-propanodicarboxylic acid; HMDP: hydroxymethylene diphosphonate

Section 2: Evidence of patient clinical history

For a positive recommendation, evidence relating to patient clinical history must be satisfied. (*Refer to section 2.4 of the managed access protocol*)

6. Please provide the following information regarding diagnostic testing results obtained at the time of application for <u>all applicants</u>:

		Date recorded	Enclosed
1.	Full renal profile		☐
2.	Full liver profile		☐
3.	BNP/NT-proBNP		☐
4.	Serum free light chains		☐
5.	Immunofixation assay		☐

BNP: B-type natriuretic peptide, NT-proBNP: N-terminal pro b-type natriuretic peptide

Part 4: Patient Medication History

Please confirm the patient's medical treatment at the time of application.

Please provide details:

Medicine	Strength	Dose	Indication

7. Is the patient currently in receipt of tafamidis (Vyndaqel®) 61 mg capsules through the Pfizer early access programme? **Yes** ☐ **No** ☐

8. Is the patient currently in receipt of any other interfering ribonucleic acid drugs or other TTR stabilisers (including medicines through an early access scheme)?

Yes ☐ **No** ☐

***If yes*, please provide detail:**

Additional space for supporting information

The following confirmations are required when prescribing tafamidis:

- Confirmation that tafamidis (Vyndaqel®) is being prescribed for a MMP approved patient in accordance with the MAP established in line with the terms of reimbursement approval given by the HSE.
- Confirmation that the prescriber will assist the HSE/MMP in their conduct of audits* through provision of information as requested, to provide assurance that the product is being prescribed in line with HSE reimbursement approval and the MAP.
- Confirmation that the patient is aware that the application for reimbursement approval is being made on their behalf and that audits may occur during which their personal data will be reviewed.

* Follow-up data may be requested by the HSE/MMP for audit purposes and provision of same is a condition of ongoing reimbursement.

Completed forms should be returned to:

Post: Prof. Michael Barry, HSE-Medicines Management Programme, Department of Pharmacology and Therapeutics, Trinity Centre for Health Sciences, St James's Hospital, Dublin 8

Or

Scan the completed form and return via a 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.