Application for individual reimbursement of Inotersen (Tegsedi®)

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:	Neurology ☐ Cardiology ☐ Other (Please specify) _____
Contact Details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE-Managed Access Protocol for Inotersen 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 ≥18-82 years at the time of application? **Yes** ☐ **No** ☐

Section 1 and section 2 must be completed.

Section 1: Confirmed diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with stage 1 or stage 2 polyneuropathy

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

2. Was the diagnosis of ATTR amyloidosis confirmed on tissue biopsy? **Yes** ☐ **No** ☐

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

3. Does the patient have a confirmed diagnosis of hATTR amyloidosis with a documented transthyretin (TTR) mutation? **Yes** ☐ **No** ☐

If yes, what is the patient's known mutation of the TTR gene?

_____

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

4. Has the patient a confirmed diagnosis of hATTR amyloidosis with stage 1 or 2 polyneuropathy? **Yes** ☐ **No** ☐

If yes, please indicate the patient's stage of polyneuropathy disability using the table below:

PND score	Score description	*FAP stage	Stage description	Please choose one:
0	No impairment	0	No symptoms	☐
I	Sensory disturbances, preserved walking capabilities	1	Unimpaired ambulation, mostly mild sensory and motor neuropathy in the lower limbs	☐
II	Impaired walking capabilities but ability to walk without stick or crutches	2	Assistance with ambulation needed; mostly moderate impairment progression to the lower limbs, upper limbs and trunk	☐
IIIA	Walking only with the help of 1 stick or crutch	2	Assistance with ambulation needed; mostly moderate impairment progression to the lower limbs, upper limbs and trunk	☐
IIIB	Walking only with the help of 2 sticks or crutches	2	Assistance with ambulation needed; mostly moderate impairment progression to the lower limbs, upper limbs and trunk	☐
IV	Confined to a wheelchair or bedridden	3	Wheel-chair bound or bedridden; severe sensory and motor neuropathy of all limbs	☐

FAP: Familial amyloid polyneuropathy, PND: Polyneuropathy disability
*hATTR amyloidosis with polyneuropathy was formerly known as FAP

5. What is the indication for inotersen treatment? (*please tick one*)

Polyneuropathy ☐

Cardiomyopathy ☐

Both of the above ☐

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. Does the patient have severe heart failure symptoms (defined as New York Heart Association [NYHA] class III or IV)?

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

Please submit an up to date echocardiography report for all applicants at the time of application: **Enclosed** ☐

7. Has the patient had a liver transplant? **Yes** ☐ **No** ☐

8. Is a liver transplant planned for the patient? **Yes** ☐ **No** ☐

9. Please provide the following information regarding diagnostic testing results obtained at the time of application for all applicants:

		Date recorded	Enclosed
1.	Full blood count		☐
2.	Full renal profile		☐
3.	Full liver profile		☐
4.	HBA1c		☐
5.	TSH		☐
6.	Vitamin B12		☐
7.	BNP/NT-proBNP		☐
8.	Immunoglobulins		☐
9.	Serum protein electrophoresis		☐
10.	Urine electrophoresis		☐
11.	Serum free light chains		☐
12.	Immunofixation assay		☐
13.	Nerve conduction studies		☐

BNP: B-type natriuretic peptide, NT-proBNP: N-terminal pro b-type natriuretic peptide, TSH: Thyroid stimulating hormone

Part 4: Patient Medication History

10. 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:

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

Please provide details:

Medicine	Strength	Dose	Indication

Additional space for supporting information

The following confirmations are required when prescribing inotersen:

- Confirmation that Inotersen (Tegsedi®) 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 by:

Email (using secure email, e.g. HSE email or healthmail): mmp@hse.ie

Or

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

Please note that the MMP will always acknowledge receipt of each application.

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.