## Application for individual reimbursement of patisiran (Onpattro<sup>®</sup>), vutrisiran (Amvuttra<sup>®</sup>) or inotersen (Tegsedi<sup>®</sup>)

For MMP Use Only			
Case Reference		Date Received	
	ALL SI	ECTIONS OF THIS FORM MUST BE COMPLETED	
Please indicate which	n treatr	nent this application refers to: Please tick one	
Patisiran (Onpattro®)		Vutrisiran (Amvuttra <sup>®</sup> )  Inotersen (Tegsedi <sup>®</sup> )	
Date of Application:			
		Part 1: Patient Details	

Part 1: Patient Details					
Name of patient:					
Date of birth:					
Address:					
GMS / DPS / PPS Number:		GMS	DPS	PPSN	
(Please tick and insert number)		nber:			1

Part 2: Prescriber Details			
Name of Consultant:			
Medical Council Number:			
Speciality of Prescribing			
Consultant:	Neurology Cardiology		
	Other (Please specify)		
Contact Details:	Hospital:		
	Address:		
	Telephone:		
	Email:		

Please refer to the <u>HSE-Managed Access Protocol-Medicines used in hereditary</u> <u>transthyretin amyloidosis in adult patients with stage 1 or stage 2</u> <u>polyneuropathy</u> 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. Please confirm patient age at the time of application

Section 1 and section 2 must be completed.

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

For a positive recommendation, evidence confirming the patient's diagnosis must be provided (Refer to section 2.3 of the managed access protocol)

2. Was the diagnosis of ATTR amyloidosis confirmed on tissue biopsy? Yes  $\Box$  No  $\Box$ 

Please attach a biopsy report, where relevant.	Enclosed 🗌
<ul> <li>3. Does the patient have a confirmed diagnosis of hATTR amyloidosis with a documented transthyretin (TTR) mutation?</li> <li>Yes If yes, what is the patient's known mutation of the TTR gene?</li> </ul>	] No 🗆
Please attach a copy of the genetic testing investigation for <u>all applicants</u> :	Enclosed
4. Has the patient a confirmed diagnosis of hATTR amyloidosis with stage 1 o polyneuropathy? Yes	r 2 <b> No</b>

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ND 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	
TTR amylo	bedridden amyloidotic polyneuropa oidosis with polyneuropa	thy was form	lyneuropathy disability erly known as FAP ase <i>tick one</i> ) Polyne Cardio	uropathy myopathy the above

<u>Secti</u>	on 2: Evidence of patient clinical h	istory		
For a positive recommendation, criteria relating to patient clinical history must be satisfied.				
(Refe	(Refer to section 2.4 of the managed access protocol)			
6	Does the patient have severe heart f	ailure symptoms (defined as New Yo	rk	
0.	Heart Association [NYHA] class III or			
	Yes, Class III	Yes, Class IV No		
Plea	se submit an up to date echocardi		the time of	
	lication:		Enclosed	
7. Has the patient had a liver transplant? Yes No.			Yes No	
8.	Is a liver transplant planned for the p	atient?	Yes No	
9.	Please provide the following informat		ts obtained	
	at the time of application for all app			
1.	Full blood count	Date recorded	Enclosed	
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			

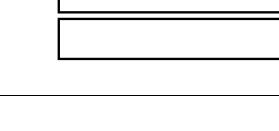
BNP: B-type natriuretic peptide, NT-proBNP: N-terminal pro b-type natriuretic peptide, TSH: Thyroid stimulating hormone

Part 4: Patient Medication History				
<b>10.</b> Is the patient currently in receipt of any other interfering ribonucleic acid drugs or other TTR stabilisers (including medicines through an early access scheme), or other treatments for hATTR amyloidosis?				
If yes, please provide detail:				
<b>11.</b> Please confirm the patient's medical treatment at the time of application.				
Please provide details: Medicine	Strength	Dose	Indication	
Part 5: Dosing Information         For hospital administered medicines (patisiran/vutrisiran),				

outline proposed location of administration (hospital or site name)

For patisiran applications outline:

- Patient weight
- proposed dose of patisiran



### Additional space for supporting information

#### 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 <u>www.pcrs.ie</u>.

Completed forms should be returned to:	Authorisation of Request
Scan the completed form and return via a secure email (e.g. HSE email or healthmail) to: mmp@hse.ie	Signature of Consultant
<u>mmp@nse.ie</u>	Institution