Medicines for Routine Prevention of Recurrent Attacks of Hereditary Angioedema (berotralstat [Orladeyo®] or lanadelumab [TAKHZYRO®]) Application Form.

For MMP Use Only	
Case Reference	*Date Received*

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Please indicate which treatment this application refers to:

Berotralstat (Orladeyo®) ☐ **Lanadelumab (TAKHZYRO®)** ☐

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:

Part 2: Consultant Details

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

Please refer to the HSE-Managed Access Protocol medicines for routine prevention of recurrent attacks of hereditary angioedema 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. Patient is aged 12 years or older at the time of application? Yes ☐ No ☐

Please provide the following measurements for the patient at the time of application:

2. What is the patient's weight in kilogram (kg)?

_____kg

Section 1 and section 2 must be completed.

Section 1: Confirmed diagnosis of type I or type II hereditary angioedema

3. Patient has a documented clinical history consistent with hereditary angioedema (HAE) i.e. subcutaneous or mucosal, non-pruritic swelling episodes without accompanying urticaria. Yes ☐ No ☐

If yes, what is the patient's diagnosis? Type I HAE (C1-inhibitor deficiency) ☐

Type II HAE (C1-inhibitor dysfunction) ☐

Please provide the following information regarding diagnostic testing results obtained at the time of application and attach a copy of the laboratory investigation:

	Reference range	Level	Date recorded
C1-inhibitor level	0.15 - 0.43 g/L		
C1-inhibitor functional level	> 70%		
C4 level	0.14 to 0.54 g/L		
C1q level	50-250 mg/L		

Section 2: Evidence of clinically significant hereditary angioedema attacks

For reimbursement approval, evidence relating to clinically significant HAE attacks must be satisfied. Refer to section 2.5 of the managed access protocol.

Please provide details:

Number of clinically significant HAE attacks in the eight weeks prior to application:	_____over eight weeks

Dates that symptoms of HAE attack(s) were first experienced and dates that symptoms were resolved. (*Please list for all clinically significant HAE attacks in previous 8 weeks*):

	Date of onset:	Date resolved:		Date of onset:	Date resolved:
1			11		
2			12		
3			13		
4			14		
5			15		
6			16		
7			17		
8			18		
9			19		
10			20		

Provide description of symptoms most frequently experienced during clinically significant HAE attacks, including common location(s) (e.g. peripheral, abdominal, or laryngeal angioedema):

Provide description of the impact of the clinically significant HAE attack(s) on activity and any other details relevant to application:

Were any acute medications used to treat an attack e.g. icatibant (Firazyr®) or a C1-esterase inhibitor (Cinryze® or Berinert®)? Yes ☐ No ☐

Provide detail (*if applicable*):
Acute medicine:

Dose:

Outline which acute attacks listed above required medical intervention (numbers in table above):

Part 4: Patient Medication History

Evidence of inadequate response to previously trialled oral long term-prophylaxis (LTP) treatment(s), or where oral LTP treatments(s) are not tolerated or are contraindicated.

For reimbursement approval, option 1, 2 and/or 3 must be satisfied (please tick which apply and complete requested detail below) Refer to section 2.6.2 of the managed access protocol.

Option 1: Patient has had a trial[(i)] with oral LTP treatment(s)[(ii)] and has resulted in an inadequate response[(iii)]. ☐

[(i)] an adequate trial of a medicine is defined as treatment of at least two consecutive months in duration.
[(ii)] oral long term prophylaxis medicines include androgens (e.g. danazol or stanozolol) or anti-fibrinolytic (e.g. tranexamic acid).
[(iii)] an inadequate response is defined as a lack of reduction in clinically significant attack frequency despite optimised treatment.

Please provide details:

Oral LTP medicine 1	
Dose	
Duration of treatment (include start and stop dates)	

If applicable:

Oral LTP medicine 2	
Dose	
Duration of treatment (include start and stop dates)	

Option 2: Patient did not tolerate oral LTP treatment(s) and experienced a clinically significant adverse reaction which led to discontinuation of treatment prior to completion of an adequate trial. ☐

Please provide details:

Oral LTP medicine 1	
Dose	
Duration of treatment (include start and stop dates)	
Provide details of the clinically significant adverse reaction which led to discontinuation prior to completion of an adequate trial	
Was the adverse reaction reported to the Health Products Regulatory Authority (HPRA)? Yes ☐ No ☐ If yes, please provide the date the adverse reaction was reported: _____	

If applicable:

Oral LTP medicine 2	
Dose	
Duration of treatment (include start and stop dates)	
Provide details of the clinically significant adverse reaction which led to discontinuation prior to completion of an adequate trial	
Was the adverse reaction reported to the Health Products Regulatory Authority (HPRA)? Yes ☐ No ☐ If yes, please provide the date the adverse reaction was reported: _____	

Option 3: Patient in whom oral LTP treatment(s) is/are contraindicated. Please provide details: ☐

Provide details of the oral LTP treatment(s) and the contraindication, including supporting evidence:

Additional space for supporting information

Completed forms should be returned to:
HSE-Medicines Management Programme, Email: mmp@hse.ie

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.