CONFIDENTIAL **ALL SECTIONS OF THIS FORM MUST BE COMPLETED**

Iptacopan (FABHALTA®) Reimbursement Application Form

For MMP Use Only	
Case Reference:	*Date Received:*

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: Prescriber Details	
Name of Consultant	
Medical Council Number	
Contact Details	Hospital:
	Address:
	Phone:
	Email:

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Please refer to the HSE Managed Access Protocol for iptacopan (FABHALTA®) when completing Part 3 of this application form

Part 3: Reimbursement criteria

Part 3(a): Patient diagnosis

1. The patient is aged 18 years or older at the time of application: **Yes:** ☐ **No:** ☐

2. The patient has a confirmed diagnosis of PNH: **Yes:** ☐ **No**: ☐

3. The patient has prior approval via the centralised funding process for eculizumab for PNH: **Yes:** ☐ **No:** ☐

If the response to Question 3 is **Yes,** please proceed to ***part 3(b): Patient clinical status*** and complete the remainder of the application form.

If the response to Question 3 is **No**, please complete **ALL** sections of this application form.

For a positive recommendation, evidence to confirm a diagnosis of paroxysmal nocturnal haemoglobinuria (PNH) must be provided as part of the application.
Please refer to section 2.3 of the managed access protocol for further detail.

Please provide:

i. A flow cytometry report — **Enclosed** ☐

ii. A full blood count (including absolute neutrophil count, B12, folate, serum ferritin) and a haemolytic blood panel (including haemoglobin, bilirubin, haptoglobin, lactate dehydrogenase, reticulocyte count) — **Enclosed** ☐

iii. A biochemistry profile — **Enclosed** ☐

iv. Bone marrow investigations (aspirate, biopsy) — **Enclosed** ☐

v. Genetic testing confirming a phosphatidylinositol glycan anchor biosynthesis class A (PIGA)-gene mutation (if available) — **Enclosed** ☐

vi. Please indicate which, if any, PNH features are present (Please tick all (or any) which apply):

Clinical feature	**Yes**	**No**
Haemolysis		
Haemoglobinuria		
Anaemia		
Severe fatigue or weakness		
Headaches		
Thrombosis		
Dyspnoea		
Recurring infections and/or flu-like symptoms		
Fever due to infection		
Chest pain		
Dysphagia		
Abdominal pain		
Oesophageal spasms		
Pulmonary hypertension		
Other (outline below)		

Part 3(b): Patient clinical status

This section must be completed for ALL patients

1. Does the patient have any contraindications for treatment outlined in the SmPC for FABHALTA®? **Yes:** ☐ **No:** ☐

2. Does the patient have a diagnosis of hereditary complement deficiency? **Yes:** ☐ **No:** ☐

Please provide the following information in relation to thrombosis history.

3. Please outline whether the patient has a history of, or is at risk of thrombosis.

_____

_____

_____

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

To enable a positive recommendation, evidence to confirm the presence of haemolytic anaemia must be provided as part of the application.

4. Does the patient currently have haemolytic anaemia? **Yes:** ☐ **No:** ☐

Please provide a full blood count and a haemolytic blood panel (including haemoglobin, bilirubin, haptoglobin, lactate dehydrogenase, reticulocyte count) **if not provided earlier in section 3(a).** **Enclosed** ☐

5. I confirm that the patient will be vaccinated against Neisseria meningitidis and Streptococcus pneumoniae infections and/or will receive prophylactic antibiotics. ☐

Part 3(c): Patient Medication History

1. Please confirm:
    i. the patient's current drug therapy at the time of application
    ii. any relevant previous treatments

Please provide details:

Medicine	Strength	Dose	Indication	Current (c)/ Previous (p)

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

2. The patient is currently in receipt of FABHALTA® or another complement inhibitor used in the treatment of PNH :

   Yes: ☐ **No:** ☐

   If yes, please provide further details:

_____

_____

_____

_____

Please provide the following information in relation to transfusion history.

3. Please outline the transfusion history of the patient for the previous 12 months:

_____

_____

_____

_____

Additional space for supporting information if required

ALL SECTIONS OF THIS FORM MUST BE COMPLETED

Completed forms should be returned to:
Scan the completed form and return via secure email (e.g. HSE email or Healthmail) to: 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 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.