Application for individual reimbursement of Eculizumab (Soliris®) for the treatment of Paroxysmal Nocturnal Haemoglobinuria (PNH)

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 prescribing consultant:		
Specialty of prescribing consultant	Haematology ☐	Nephrology ☐
Medical Council number:		
Contact Details:	Hospital:	
	Address:	
	Telephone:	
	Email:	

Part 3: Patient Clinical History

Please indicate which, if any, PNH features are present (*please tick all (or any) which apply and complete requested detail):*

1. Haemolysis	Yes	☐	No	☐
2. Haemoglobinuria	Yes	☐	No	☐
3. Anaemia	Yes	☐	No	☐
4. Severe fatigue or weakness	Yes	☐	No	☐
5. Headaches	Yes	☐	No	☐
6. Thrombosis	Yes	☐	No	☐
7. Shortness of breath	Yes	☐	No	☐
8. Recurring infections and/or flu-like symptoms	Yes	☐	No	☐
9. Fever due to infection	Yes	☐	No	☐
10. Chest pain	Yes	☐	No	☐
11. Dysphagia	Yes	☐	No	☐
12. Abdominal pain	Yes	☐	No	☐
13. Oesophageal spasms	Yes	☐	No	☐

14. Any other symptoms (please outline below)

Section 1 <u>and</u> section 2 must be completed.

<u>Section 1: Confirmed diagnosis of PNH</u>

1. Patient has a diagnosis of PNH confirmed by flow cytometry

Yes ☐ No ☐

If yes, **please attach a copy** of the flow cytometry report

Please provide the following information regarding diagnostic testing results obtained at the time of application:

	Reference range*	Level	Date recorded
White cell count	4.0 to 11.0 x 10^9/L		
Red blood cells	4.6 to 5.7 x 10^{12}/L (M) 4.0 to 5.2 x10^{12}/L (F)		
Haemoglobin	13.5 to 18.0 g/dL (M) 11.5 to 16.4 g/dL (F)		
Platelets	140 to 450 x 10^9/L		
Reticulocyte	50 to 100 x 10^9/L		
Haptoglobin	0.45 to 2.05 g/L		
Lactate dehydrogenase (LDH)	135 to 250 IU/L		
Serum ferritin	23 to 393 µmol/L		
Total Bilirubin (serum)	0 to 21 µmol/L		

*reference range taken from St James's Hospital Laboratory Medicine available at http://search.stjames.ie/Labmed/

N.B Please attach a copy of all laboratory results: FBC (including haptoglobin, reticulocyte count and coagulation profile), biochemistry profile and serum ferritin.

Section 2: Transfusion history

For reimbursement approval, please provide the following information relating to transfusions.

1. Patient has a history of blood transfusions

   Yes ☐ No ☐

If yes, please provide details:

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Part 4: Patient Medication History

Please outline (i) all current concomitant medicines and (ii) any relevant previous medicines/ treatments

Part 5: Dosing information

Proposed initial dose of eculizumab	
Proposed maintenance dose of eculizumab	
Proposed duration of treatment	
Site of administration (hospital name)	

Additional space for supporting information

Treating physician declaration

- I declare that the information provided in this form is completed and correct, to the best of my knowledge
- I understand that the patient must be an Irish citizen or permanent Irish resident to be eligible for reimbursement of eculizumab
- I have attached copies of all relevant reports and forms as evidence of eligibility
- I agree to prescribe a best-value biological (BVB) medicine for eculizumab in line with any future recommendations of the MMP
- I agree to provide outcome data to the HSE when requested
- I ensure that the patient has received, or will receive a meningococcal vaccination, at the time of initiating treatment

Name of Prescribing Consultant (print) ……

Signature of Prescribing Consultant ……

Institution ……

Date ……

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. healthmail) to: mmp@hse.ie

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.