Application for individual reimbursement of Eculizumab for the treatment of atypical Haemolytic Uremic Syndrome (aHUS)

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

Sections 1- 5 must be completed.

Section 1: Confirmed diagnosis of aHUS

1. Patient has a diagnosis of aHUS
   Yes ☐ No ☐

2. Has an ADAMTS13 been performed (to rule out TTP)?
   Yes ☐ No ☐ *If yes, positive* ☐ *negative* ☐

3. Has a STEC been performed (to rule out Shiga toxin producing-E-coli HUS)?
   Yes ☐ No ☐ *If yes, positive* ☐ *negative* ☐

Please attach a copy of ADAMTS13 and STEC results

Section 2: Classification of aHUS (*please tick the appropriate box(es) which apply and complete requested detail):*

	YES	NO
Familial		
Sporadic		
1. Idiopathic		
2. Pregnancy associated		
3. HELLP syndrome		
4. Drug induced		
5. Organ transplantation		
6. HIV infection		
7. Cancer		

Any further details (please outline below)

Section 3:

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 x10^9/L		
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		
Urea (blood)	2.8 to 8.1 mmol/L		
Creatinine (serum)	59 to 104 µmol/L (M) 45 to 84 µmol/L (F)		
eGFR	mls/min/1.73m^2		
C3	0.83 to 1.8 g/L		
C4	0.14 to 0.54 g/L		
CFH (if available)			
CFI (if available)			
Complement antibody screen			

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

Please attach a copy of all laboratory results

Section 4: Genetic Mutations

Genetic mutations detected Yes ☐ No ☐ Date of testing ☐

CFH	Yes			No	
CFH R1/3	Yes			No	
MCP	Yes			No	
CFI	Yes			No	
CFB	Yes			No	
C3	Yes			No	
THBD	Yes			No	

Further details

Section 5: Renal

The patient is on dialysis **Yes** ☐ **No** ☐

If yes, frequency of dialysis ……

duration of dialysis ……

The patient has had a renal transplant **Yes** ☐ **No** ☐

*If **yes**, date of transplant* ……..

*If **no**, is a renal transplant planned?* **Yes** ☐ **No** ☐

If **no,** *is the patient suitable for renal transplantation?* **Yes** ☐ **No** ☐

List extrarenal manifestations

Part 4: Patient Medication History

Please outline all previous treatments with plasma exchange (PE), immunosuppressive drugs (e.g. rituximab) or other therapy used for the treatment of aHUS

Please outline all current medication

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 ……

Irish Medical Council (IMC) Number ……

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.