Eculizumab▼ Vaccination/Prophylaxis antibiotic Certificate

Eculizumab is authorized under controlled distribution for use in the treatment of adults and children with paroxysmal nocturnal haemoglobinuria (PNH). Drug distribution will only be possible after written confirmation that the patient received or will receive meningococcal vaccination and/or antibiotic prophylaxis is submitted by the prescriber to Amgen. Therefore, it is mandatory that this certificate is completed for each patient and returned to E-mail: customerservice-nl@amgen.com. It is also required that all healthcare professionals ensure that they have read and understood the Physician's Guide before prescribing eculizumab for any patient. The physician should also discuss the Patient's/Parent's Information Brochure with the patient/parent(s)/legal guardian(s) during consultation and provide it to the patient or parent(s)/legal guardian(s) along with the Patient Safety Card.

Send with 1st order by email when a code can be provided - otherwise send a certificate with each order placement

To: **Amgen** Date: _____

Fax: _____

E-mail: _____

Name of prescriber:	
Hospital/Clinic:	Phone:
Address:	Fax:
City, Postal code, Country:	Email:

Please select as appropriate:

☐ Patient code_____

(Please create a code convenient for the institution at initial order, and utilize the same code for subsequent orders)

☐ No code will be used, certificate will be provided with each order placement
(If it is not possible to provide a patient code, please send a copy of this **certificate with each order placement**)
Indication: ☐ PNH

Vaccination / antibiotic prophylaxis

☐ I, the undersigned, _____hereby undertake to ensure or confirm that all eculizumab vials are intended to patients whom have been vaccinated against meningococcus:

(Recommendation: vaccines against serogroups A, C, Y, W 135 and B or as per regional regulations)

☐ at least 2 weeks before receiving the first dose of the eculizumab.

☐ less than 2 weeks before receiving the first dose of eculizumab and therefore will receive appropriate antibiotic prophylaxis at the latest from the 1st day of treatment with eculizumab until 2 weeks after vaccination against meningococcal disease.

☐ will receive antibiotic prophylaxis from day 1 of treatment and throughout the duration of treatment (as vaccination against meningococcal disease is contraindicated or not possibleat the time).

(*continued on back of page)*

Commitment

☐ I, the undersigned, _____hereby undertake to ensure and confirm that: I must explain eculizumab treatment to the patient/parent(s)/legal guardian(s) and I must deliver to thepatient/ parent(s)/legal guardian(s) all necessary information, including the Patient Safety Card and relevant patient educational materials before treatment initiation.

I understand that I can request additional copies of eculizumab educational materials consisting of: Patient Safety Card, Physician's Guide, Patient's/Parent's Information Brochure under educationalmaterials.NL@amgen.com.

Sorbitol Warning

☐ I understand that eculizumab with the brandname BEKEMV contains sorbitol and is therefore contraindicated in patients with hereditary fructose intolerance (HFI), regardless of their age, and in babies and children (under 2 years of age) who may not yet be diagnosed with HFI as after intravenous administration of a sorbitol-containing medicine like eculizumab, patients with HFI may present severe metabolic abnormalities and life-threateningsymptoms including hypoglycemia, metabolic acidosis, seizures, coma.

Patient's Privacy Statement

☐ I hereby undertake to inform the patient, that for the purposes of supplying eculizumab, Amgen will process their pseudonymised personal data. Details of the processing and protection of personal data, as well as his/her rights, in the Privacy Statement are available on https://www.amgen.nl/privacy-verklaring.

Date: (MM-DD-YYYY) _____ **Signature:** _____

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information.
You can help by reporting any side effects you may get to Nederlands Bijwerkingencentrum Lareb, website: www.lareb.nl.