BEKEMV® (eculizumab) Vaccination/Prophylaxis antibiotic Certificate

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to Fimea (www.fimea.fi) or Amgen (nordic.baltic.drugsafety@amgen.com).

BEKEMV 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 cs-nordics@amgen.com. It is also required that all healthcare professionals ensure that they have read and understood the Physician's Guide before prescribing BEKEMV 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.

Please send before 1st order by email

To: **Amgen** Email: cs-nordics@amgen.com Date:

Name of prescriber: Phone:

Hospital/Clinic: Email:

Address:

Postal code, City: Country: Finland

Information about the patient:
Combined Date of birth and 3 characters invented by the prescriber will create a unique patient code that is required for all orders.

Patient code (reference in BEKEMV orders)

Date of birth: 3 characters:

D	D	M	M	Y	Y	Y	Y	?	?	?

Indication:

☐ BEKEMV is **NOT** used in this patient for the treatment of atypical haemolytic uremic syndrome (aHUS), refractory generalized myasthenia gravis (gMG) or neuromyelitis optica spectrum disease (NMOSD).

Vaccination / antibiotic prophylaxis

The patient mentioned above *(please check one box)*

☐ has been vaccinated against meningococcus at least 2 weeks before receiving the first dose of BEKEMV*.

☐ has been vaccinated against meningococcus less than 2 weeks before receiving the first dose of BEKEMV* and therefore will receive appropriate antibiotic prophylaxis at the latest from the 1st day of treatment with BEKEMV until 2 weeks after the 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 possible at the time).

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

(continued on next page)

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Commitment

☐ I, the undersigned, _____ hereby undertake to ensure and confirm that:
I must explain BEKEMV treatment to the patient/parent(s)/legal guardian(s) and I must deliver to the patient/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 BEKEMV educational materials consisting of: Patient Safety Card, Physician's Guide, Patient's/Parent's Information Brochure from Amgen medical information, tel. +358 9 54 900 500, email medinfo.finland@amgen.com.

Sorbitol Warning

☐ I understand that 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 BEKEMV, patients with HFI may present severe metabolic abnormalities and life-threatening symptoms including hypoglycemia, metabolic acidosis, seizures, coma.

Patient's Privacy Statement

☐ I hereby undertake to inform the patient, that for the purposes of supplying BEKEMV, 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.fi/tietosuoja-huhtikuu-2018.

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