BEKEMV® (eculizumab) vaccination/antibiotic prophylaxis 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 (eculizumab) is authorized under controlled distribution. Drug distribution is only possible after Amgen is provided with written confirmation that, as a prescriber, you have understood that every patient treated with eculizumab received or will receive meningococcal vaccination and/or antibiotic prophylaxis. Therefore, it is mandatory that this certificate is completed by each prescriber 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

Prescriber Code:
Please state your physician ID number, and utilize the same code for subsequent orders.

Physician ID
(reference in BEKEMV orders)

Physician ID

(continued on next page)

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I, the undersigned, _____ hereby undertake to ensure and confirm that:

Commitment

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.

Risk of meningococcal infection and vaccination/antibiotic prophylaxis

Due to its mechanism of action, I understand the use of BEKEMV increases the patient's susceptibility to meningococcal infections/sepsis (Neisseria meningitidis). Meningococcal diseases can be caused by any serogroup.

- To reduce this risk of infection, all patients must be vaccinated against all serotypes of Neisseria meningitidis meningococcal infection for which vaccines are available, in accordance with national vaccination guidelines at least two weeks before receiving the first dose of BEKEMV.
- If a patient starts BEKEMV treatment less than 2 weeks after meningococcal vaccination, they must be treated with appropriate antibiotic prophylaxis from the first day of treatment with BEKEMV until 2 weeks after being vaccinated against meningococcal infection.

Sorbitol Warning

I understand that BEKEMV contains sorbitol and is therefore contraindicated in patients with hereditary fructose intolerance (HFI), and in all babies and children (under 2 years of age) who may not yet be diagnosed with HFI.

I understand that 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.

☐ I confirm that I have read and understood all statements and I will ensure that I do not treat patients who are contraindicated, and that all patients I treat with BEKEMV will have adequate meningococcal protection in accordance with the above requirements.

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