AMGEN

BEKEMV® ▼(eculizumab) Vaccination/Antibiotic Prophylaxis Certificate

▼ This medicinal product is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events can also be reported to Amgen Limited on +44 (0) 1223 436441.

BEKEMV is authorised under controlled distribution for use in the treatment of adults and children with paroxysmal nocturnal haemoglobinuria (PNH) and atypical haemolytic uraemic syndrome (aHUS). BEKEMV is contraindicated in babies and young children below 2 years of age. Drug distribution will only be possible after written confirmation that the patient has 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-uk@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. An annual vaccination reminder will be sent to the relevant Healthcare Professionals as a general reminder to check each patient's vaccination status.

Please send with 1st order by email

To: **Amgen** Date: _____

E-mail: cs-uk@amgen.com

Name of prescriber:	
Hospital/Clinic:	Phone:
Address:	Fax:
City, Postal code, Country:	Email:
Information about the Patient Identifier (Date of birth and patient code) is mandatory for all orders.	
Date of birth (dd-mm-yyyy):	
Patient code (please enter Blueteq or hospital number at initial order, and utilise the same code for subsequent orders):	

(continued on back page)

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Commitment

I, the undersigned,_____hereby undertake to ensure and confirm that: I must explain BEKEMV treatment for PNH/aHUS 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 for patients on treatment with BEKEMV the vaccination status against meningococcus must be kept up to date, according to current national vaccination guidelines or if vaccination against meningococcal disease is contraindicated or not possible the patient should receive antibiotic prophylaxis from day 1 of treatment with BEKEMV and throughout the duration of the treatment period.

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 by contacting Amgen Medical Information by email to gbinfoline@amgen.com or telephone 01223 436441.

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 the risk of infection, this patient either:

- Is vaccinated against all serotypes of Neisseria meningitidis meningococcal infection for which vaccines are available, in accordance with current national vaccination guidelines, at least two weeks before receiving the first dose of BEKEMV.
  OR
- Will receive prophylactic antibiotics from the first day of treatment with BEKEMV and until 2 weeks after being vaccinated against meningococcal infection.

Sorbitol Warning

I understand that BEKEMV contains sorbitol and is therefore contraindicated in babies and young children below 2 years of age since they may not yet be diagnosed with hereditary fructose intolerance (HFI). Patients with HFI must not be given this medicine unless strictly necessary. After intravenous administration of a sorbitol containing medicine like BEKEMV, patients with HFI may present with severe metabolic abnormalities and life threatening symptoms including hypoglycaemia, 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 and the patient can read details of the processing and protection of personal data, as well as his/her rights, in the Privacy Statement available on https://www.amgen.co.uk/privacy-and-terms/privacy-statement

☐ **I confirm that I have read, understood, and comply with all these requirements.**

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