

# BEKEMV™ ▼ (eculizumab)

## A guide to transitioning patients.

BEKEMV™ is indicated in adults and children for the treatment of:

- Paroxysmal nocturnal haemoglobinuria (PNH).

Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history.

- Atypical haemolytic uraemic syndrome (aHUS).

For further details on dosing, special warnings, precautions and adverse events please refer to BEKEMV™ SmPC at <https://www.medicines.org.uk/emc/product/15378/smpc#about-medicine>

BEKEMV™ is contraindicated in babies and young children below 2 years of age since they may not yet be diagnosed with hereditary fructose intolerance (HFI). Medicines containing sorbitol/fructose given intravenously may therefore be life-threatening, and are contraindicated in this population.

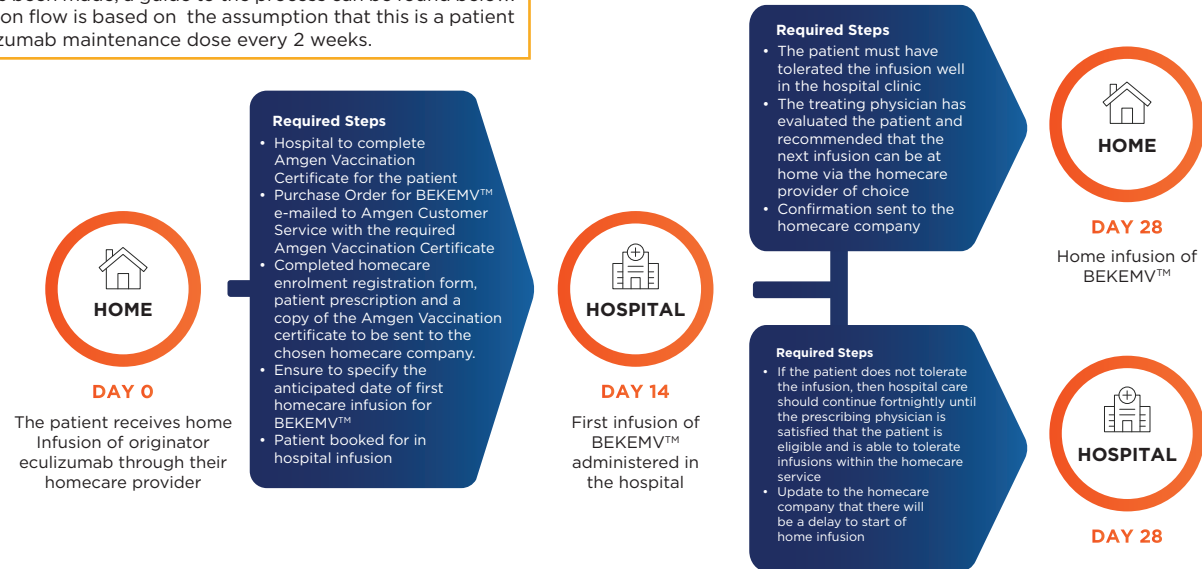
Prior to shipment, Amgen requires written confirmation from the prescribing physician that the patient has been vaccinated against meningococcal infection and/or is receiving antibiotic prophylaxis. This confirmation is mandatory and must be sent to Amgen for each patient.

All physicians who intend to prescribe BEKEMV™ must ensure they are familiar with the physician's guide to prescribing. Physicians must discuss the benefits and risks of BEKEMV™ therapy with patients and provide them with a patient information brochure and a patient safety card. These are available at <https://www.medicines.org.uk/emc/product/15378/rmms#about-medicine>

# A GUIDE TO TRANSITION FROM ORIGINATOR ECULIZUMAB TO BEKEMV™ (ECULIZUMAB BIOSIMILAR). AN EXAMPLE OF A HOMECARE PATIENT

Following assessment of the patient, it is a clinical decision made by the prescriber to transition the patient to a biosimilar. Once a clinical decision has been made, a guide to the process can be found below. This transition flow is based on the assumption that this is a patient on an eculizumab maintenance dose every 2 weeks.

The blood monitoring requirements for the patient are to be decided by the prescribing team



Home infusion may be considered for patients who have tolerated infusions well in the clinic. The decision of a patient to receive home infusions should be made after evaluation and recommendation from the treating physician.

There is limited safety data supporting home-based infusions, additional precautions in the home setting, such as availability of emergency treatment of infusion reactions or anaphylaxis are recommended. Please refer to section 4.2 of the SmPC for more information.

<https://www.medicines.org.uk/emc/product/15378/smpc#about-medicine>

**NB: If a patient is transitioning to a new homecare provider then communication will need to be made with both the previous homecare provider and the new homecare provider the patient is transitioning to.**

# A GUIDE TO TRANSITION FROM ORIGINATOR ECULIZUMAB TO BEKEMV™ (ECULIZUMAB BIOSIMILAR). AN EXAMPLE OF A HOSPITAL PATIENT

Following assessment of the patient, it is a clinical decision made by the prescriber to transition the patient to a biosimilar. Once a clinical decision has been made, a guide to the process can be found below. This transition flow is based on the assumption that this is a patient on an eculizumab maintenance dose every 2 weeks.



**DAY 0**

The patient receives infusion of originator eculizumab in hospital

## Required Steps to Transition

- Hospital to complete Amgen Vaccination Certificate for the patient
- Purchase Order for BEKEMV™ e-mailed to Amgen Customer Service with the required Amgen Vaccination Certificate
- On receipt of the required, fully completed forms, Amgen will dispatch the product



**DAY 14**

First infusion of BEKEMV™ administered in the hospital

If patient has tolerated day 14 infusion and if the patient is to have ongoing infusion in the hospital then refer to the subsequent orders section of the 'How to order document' and order when required



**DAY 28**

Second infusion of BEKEMV™ administered in the hospital

## BEKEMV™ ▼(eculizumab) Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SPC) before prescribing BEKEMV. **Pharmaceutical Form:** One vial of 30 mL containing 300 mg eculizumab (10 mg/mL). **Indication:** BEKEMV is indicated in adults and children for the treatment of: Paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history; Atypical haemolytic uraemic syndrome (aHUS). **Dosage:** In Paroxysmal nocturnal haemoglobinuria: *Adult patients (≥ 18 years of age) Initial phase:* 600 mg weekly for the first 4 weeks; *maintenance phase:* 900 mg week 5, followed by 900 mg every 14 (± 2) days *In Atypical haemolytic uraemic syndrome: Adult patients (≥ 18 years of age) Initial phase:* 900 mg weekly for the first 4 weeks; *maintenance phase:* 1,200 mg week 5, followed by 1,200 mg every 14 (± 2) days *Paediatric patients (above 2 years of age) with PNH or aHUS ≥40 kg initial and maintenance phases:* treated with the adult dosing recommendations. **30 to <40 kg initial phase:** 600 mg weekly for the first 2 weeks; *maintenance phase:* 900 mg at week 3; then 900 mg every 2 weeks. **20 to <30 kg initial phase:** 600 mg weekly for the first 2 weeks; *maintenance phase:* 600 mg at week 3; then 600 mg every 2 weeks. **10 to <20 kg initial phase:** 600 mg weekly x 1; *maintenance phase:* 300 mg at week 2; then 300 mg every 2 weeks. **5 to <10 kg initial phase:** 300 mg weekly x 1; *maintenance phase:* 300 mg at week 2; then 300 mg every 3 weeks. For adult and paediatric aHUS patients above 2 years of age supplemental dosing of BEKEMV is required in the setting of concomitant PE/PI (plasmapheresis or plasma exchange, or fresh frozen plasma infusion) - please see SPC for dosing details. **Administration:** Dilute to a concentration of 5 mg/mL, see SPC for further information on administration and diluents. Administer via an intravenous infusion over 25 – 45 minutes (35 minutes +/- 10 minutes) in adults and 1-4 hours in paediatric patients via gravity feed, a syringe-type pump, or an infusion pump. Patients should be monitored for 1 hour post infusion. **Elderly:** No evidence to suggest that special precautions are required, although experience is limited. **Renal impairment:** No dose adjustment. **Hepatic impairment:** The safety and efficacy have not been studied in patients with hepatic impairment. **Contraindications:** Hypersensitivity to eculizumab or to any of the excipients listed in the SPC. BEKEMV is contraindicated in babies and young children below 2 years of age since they may not yet be diagnosed with hereditary fructose intolerance (HFI). Medicines containing sorbitol/fructose given intravenously may therefore be life-threatening, and are contraindicated in this population. Must not initiate therapy in patients with unresolved *Neisseria meningitidis* infection or patients who are not currently vaccinated against *Neisseria meningitidis* (unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination). **Special warnings and precautions:** BEKEMV is not expected to affect the aplastic component of anaemia in patients with PNH. **Meningococcal infection:** Increased risk of meningococcal infection. All patients must be vaccinated against meningococcal infections at least 2 weeks prior to receiving BEKEMV unless the risk of delaying BEKEMV therapy outweighs the risks of developing a meningococcal infection. Patients initiated with BEKEMV less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Vaccines against serogroups A, C, Y, W135 and B where available are recommended in preventing the commonly pathogenic meningococcal serogroups. Patients must receive vaccination according to current national vaccination guidelines. Vaccination may further activate complement. As a result, patients with complement-mediated diseases, including PNH and aHUS may experience increased signs and symptoms of their underlying disease, such as haemolysis (PNH) or thrombotic microangiopathy (TMA) (aHUS). Therefore, patients should be closely monitored for disease symptoms after recommended vaccination. Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Cases of serious or fatal meningococcal infections have been reported. All patients should be monitored for early signs of meningococcal infections and evaluated immediately if infection is suspected and treated with appropriate antibiotics if necessary. Patients should be informed of signs and symptoms of infection and steps taken to seek medical care immediately. Physicians must discuss the benefits and risks of BEKEMV therapy with patients and provide them with a patient information brochure and a patient safety card. **Other systemic infections:** Use with caution in patients with active systemic infections. Patients may have increased susceptibility to infections, especially with *Neisseria* and encapsulated bacteria. Serious infections with *Neisseria species* (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported. Patients should be provided with information from the package leaflet to increase their awareness of potential serious infections and the signs and symptoms of them. Physicians should advise patients about gonorrhoea prevention. **Infusion reactions:** Administration may result in infusion reactions or immunogenicity that could cause allergic or hypersensitivity reactions, including anaphylaxis. Anaphylactic reaction has been reported as an uncommon side effect (≥1/1000 to <1/100). BEKEMV treatment should be interrupted in all patients who experience severe infusion reactions and appropriate medical therapy administered. **Immunogenicity:** Infrequent antibody responses have been detected in eculizumab-treated patients

across all clinical studies. **Immunisation:** Prior to initiating BEKEMV therapy, it is recommended that PNH and aHUS patients initiate immunisations according to current immunisation guidelines. Patients less than 18 years of age must be vaccinated against *Haemophilus influenzae* and pneumococcal infections, and strictly need to adhere to the national vaccination recommendations for each age group. **Anticoagulant therapy:** Treatment with BEKEMV should not alter anticoagulant treatment. **PNH laboratory monitoring:** Patients should be monitored for signs and symptoms of intravascular haemolysis, including serum lactate dehydrogenase (LDH) levels. PNH patients receiving BEKEMV therapy should be similarly monitored for intravascular haemolysis by measuring LDH levels and may require dose adjustment within the recommended 14 ± 2 day dosing schedule during the maintenance phase (up to every 12 days). **aHUS laboratory monitoring:** Patients should be monitored for signs and symptoms of TMA by measuring platelet counts, serum LDH and serum creatinine, and may require dose adjustment within the recommended 14±2 day dosing schedule during the maintenance phase (up to every 12 days). **Discontinuation for PNH:** Patients who discontinue should be monitored for serious intravascular haemolysis or other reactions for at least 8 weeks. If serious haemolysis occurs, consider: blood transfusion (packed RBCs), or exchange transfusion if the PNH RBCs are >50% of the total RBCs by flow cytometry; anticoagulation; corticosteroids or reinstitution of BEKEMV. **Discontinuation for aHUS:** Patients who discontinue should be monitored closely for signs and symptoms of severe TMA complications. Monitoring may be insufficient to predict or prevent severe TMA complications after discontinuation of BEKEMV. Severe TMA complications post discontinuation can be identified by (i) any two, or repeated measurement of anyone, of the following: a decrease in platelet count of 25% or more as compared to either baseline or to peak platelet count during BEKEMV treatment; an increase in serum creatinine of 25% or more as compared to baseline or to nadir during BEKEMV treatment; or, an increase in serum LDH of 25% or more as compared to baseline or to nadir during BEKEMV treatment; or (ii) any one of the following: a change in mental status or seizures; angina or dyspnoea; or thrombosis. If severe TMA complications occur after BEKEMV discontinuation, consider reinstitution of BEKEMV treatment, supportive care with PE/PI, or appropriate organ-specific supportive measures including renal support with dialysis, respiratory support with mechanical ventilation or anticoagulation. **Educational materials:** All physicians who intend to prescribe BEKEMV must ensure they are familiar with the physician's guide to prescribing. Physicians must discuss the benefits and risks of BEKEMV therapy with patients and provide them with a patient information brochure and a patient safety card. **Excipients:** This medicine contains 50 mg sorbitol (E420) in each mL. Patients with HFI must not be given this medicine unless strictly necessary. Babies and young children (below 2 years of age) may not yet be diagnosed with HFI. Medicines containing sorbitol/fructose given intravenously may be life-threatening and should be contraindicated in this population. A detailed history with regard to HFI symptoms has to be taken of each patient prior to being given BEKEMV. BEKEMV contains less than 1 mmol of sodium (23 mg) per dose, that is to say essentially "sodium free". **Traceability:** In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. **Interaction with other medicinal products:** No interaction studies have been performed. **Fertility:** The use of adequate contraception to prevent pregnancy and for at least 5 months after the last dose should be considered for women of childbearing potential. **Pregnancy:** There are no well controlled studies in pregnant women treated with eculizumab, please refer to the SPC for further information. **Breast-feeding:** Limited data available please refer to the SPC for further information. **Undesirable effects:** In all clinical studies, the most serious adverse reaction was meningococcal sepsis which is a common presentation of meningococcal infections in patients treated with eculizumab. **Very common adverse reactions (≥1/10):** Headache. **Common adverse reactions (≥1/100 to <1/10):** pneumonia, upper respiratory tract infection, bronchitis, nasopharyngitis, urinary tract infection, oral herpes, leucopenia, anaemia, insomnia, dizziness, dysgeusia, hypertension, cough, oropharyngeal pain, diarrhoea, vomiting, nausea, abdominal pain, rash, pruritus, alopecia, arthralgia, myalgia, pyrexia, fatigue, influenza like illness. Please refer to the SPC for a full list of adverse reactions. Other cases of *Neisseria species* have been reported including sepsis with *Neisseria gonorrhoeae*, *Neisseria sicca/subflava*, *Neisseria spp* unspecified. Cases of haemolysis have been reported with missed or delayed eculizumab dose in PNH clinical trials. Cases of TMA complication have been reported in the setting of missed or delayed eculizumab dose in aHUS clinical trials. The most common adverse reaction reported in paediatric PNH patients was headache. **Legal Category:** POM. **Presentation, Basic Cost and Marketing Authorisation Number Great Britain (GB):** BEKEMV 300 mg concentrate for solution for infusion: PLGB 13832/0077 – 1 pack of 30mL vial, £3,150. **Marketing Authorisation Holder GB:** Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, CB4 0WA, UK. Further information is available from Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, CB4 0WA, UK. BEKEMV is a trademark owned by Amgen Inc. **Date of PI preparation:** January 2024 (Ref. GB-959-1223-80003)

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



## Electronic Certificate

**Version:** 3 . 0

**Document Number:** GB-959-0224-80001

**Document Name:** A guide to transitioning patients from Originator Eculizumab to BEKEMV

**Country:** Great Britain

**Product:** BEKEMV

**Branding:** Branded

**Type:** GRP Material

**Sub Type:** Leave Behind

**Classification:**

**Material Intent:** Promotional

**Expiration Date:** 20 Mar 2026

### Certification Statement

We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority (where applicable) for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Andrew Taylor - Medical Signatory Certification (andtaylo@amgen.com)	Meaning: As the Medical Signatory, I approve this document for use. Date: 20-Mar-2024 11:53:54 GMT+0000
Kirsty Shepherd - Second Signatory Certification (ksheph01@amgen.com)	Meaning: As the Second Signatory, I approve this document for use. Date: 20-Mar-2024 12:25:59 GMT+0000