

# Patient Enrollment Form Guide

Complete the Patient Enrollment Form (PEF) to get your patients started on BKEMV (eculizumab-aeab) and initiate their enrollment in Amgen By Your Side, a patient support program. This guide is designed to help you understand the different fields on the form and how to complete the form accurately for submission.

## Three steps to initiate the patient enrollment process for BKEMV:



The office must complete all required fields on pages 1 and 2 as indicated by the **X**, including the prescriber signature and date within the Prescriber section



The patient must complete page 3, including the patient consent ("I Consent" check box), patient signature and date within the Patient Consent and Authorization section and answer the questions in the Co-pay Program Enrollment section



Send both the front and back of the patient's insurance card(s) along with all 6 pages of the PEF

### Two ways to submit the Patient Enrollment Form:

- Email: [BKEMVABYS@amgen.com](mailto:BKEMVABYS@amgen.com)
- Fax: 1-866-500-0987

## INDICATIONS

BKEMV<sup>®</sup> (eculizumab-aeab) is indicated for the treatment of:

- patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

BKEMV is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

## IMPORTANT SAFETY INFORMATION

### WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

**Ecuzumab products, complement inhibitors, increase the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.**

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of BKEMV, unless the risks of delaying therapy with BKEMV outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor. See Warnings and Precautions for additional guidance on the management of the risk of serious infections caused by meningococcal bacteria.**

Please see additional Important Safety Information throughout.

**If you have any questions while completing the form, please contact Amgen By Your Side at 1-855-888-4004.**

**BKEMV<sup>®</sup> (eculizumab-aeeb)  
PATIENT ENROLLMENT FORM**

Once complete, submit pages 1-6 by fax 1-866-500-0987 or email BKEMVABYS@amgen.com

Complete all required fields, including prescriber's signature and date, to initiate patient enrollment process. For support and/or assistance obtaining patient signature, call Amgen By Your Side at 1-866-402-9822. (X indicates a required field)

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**1 PATIENT INFORMATION**

X First name \_\_\_\_\_ X Last name \_\_\_\_\_

X Gender:  Male  Female X Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(MM/DD/YYYY)

X Email address \_\_\_\_\_ Primary language \_\_\_\_\_

X Mobile phone \_\_\_\_\_ Primary  Home phone \_\_\_\_\_ Primary

X Address \_\_\_\_\_

X City \_\_\_\_\_ X State \_\_\_\_\_ X ZIP code \_\_\_\_\_

Alternate contact name \_\_\_\_\_ Alternate contact phone \_\_\_\_\_

**4 PRESCRIBER INFORMATION**

X First name \_\_\_\_\_ X Last name \_\_\_\_\_

X Address \_\_\_\_\_

X City \_\_\_\_\_ X State \_\_\_\_\_ X ZIP code \_\_\_\_\_

X NPI # \_\_\_\_\_ X State license # \_\_\_\_\_ X Tax ID # \_\_\_\_\_

Clinic/hospital affiliation \_\_\_\_\_

X Office contact name \_\_\_\_\_

X Office contact phone \_\_\_\_\_ X Fax number \_\_\_\_\_

X Office contact email address \_\_\_\_\_

Preferred communication  Phone  Email

Prescriber specialty \_\_\_\_\_

**2 INSURANCE INFORMATION** (Please include front and back copies of insurance card(s) with this form)

X Primary insurance \_\_\_\_\_ Secondary insurance \_\_\_\_\_

X Policy # \_\_\_\_\_ Policy # \_\_\_\_\_

X Policyholder's first and last name \_\_\_\_\_ Policyholder's first and last name \_\_\_\_\_

X Insurance company phone \_\_\_\_\_ Insurance company phone \_\_\_\_\_

X Group # \_\_\_\_\_ Group # \_\_\_\_\_

X Policyholder's Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ (MM/DD/YYYY) X Policyholder's Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ (MM/DD/YYYY)

Patient is uninsured to my knowledge.

**5 PREFERRED INFUSION FACILITY**  
If none, Amgen By Your Side can provide options.

The infusion facility is the same as the prescribing office.

Facility name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP code \_\_\_\_\_

Phone \_\_\_\_\_ Fax number \_\_\_\_\_

Facility NPI # \_\_\_\_\_ Tax ID # \_\_\_\_\_

**3 RISK EVALUATION AND MITIGATION STRATEGY**

BKEMV is available only through the BKEMV REMS, a restricted distribution program. To prescribe or dispense BKEMV, REMS certification is required.

- Healthcare providers who prescribe BKEMV must enroll and be certified in BKEMV REMS.
- Healthcare settings and pharmacies that dispense BKEMV must enroll and be certified in BKEMV REMS and must verify prescribers are certified.
- Patients are required to receive the required vaccinations per ACIP guidelines.

Please answer the following questions after enrolling at BKEMVREMS.com

**Have you been certified as a prescriber in the BKEMV REMS program?**

Yes

No (if no, go to BKEMVREMS.com to become REMS certified prior to prescribing BKEMV for your patient)

**Has the patient been vaccinated according to ACIP Guidelines, or administered antibacterial drug prophylaxis if urgent BKEMV therapy was indicated?**

Yes

No (if no, please review vaccination requirements per ACIP guidelines)

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Complete prescription information and physician signature on next page >>

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## 1 Patient Information

Provide the patient's demographic and contact information; only one patient phone number is required, mobile OR home

- Required fields are needed to conduct a benefits investigation, contact the patient for any follow-up, and provide support from Amgen By Your Side
- Alternate contact information is optional
  - It may help to include a caregiver's contact information

## 2 Insurance Information

Provide the patient's primary insurance information (required to conduct a benefits investigation). Results will be delivered after the patient authorization is received

Include secondary insurance information, if applicable, to improve the accuracy of the benefits investigation

If the patient does not have any insurance, fill in the circle next to "Patient is uninsured to my knowledge"

- Please include the front and back of your patient's insurance card(s), if available, along with the completed Patient Enrollment Form

## 3 Risk Evaluation and Mitigation Strategy

BKEMV is available only through the BKEMV Risk Evaluation and Mitigation Strategy (REMS), a restricted distribution program. To prescribe or dispense BKEMV, REMS certification is required. Additional information on the BKEMV REMS program can be found at BKEMVREMS.com.

## 4 Prescriber Information

Provide the prescriber's name, contact information, NPI, tax ID, and state license numbers, which are required for processing

## 5 Preferred Infusion Facility

If you have a preference for the infusion facility where your patient will receive BKEMV, complete this section

- If you do not have a preference, Amgen By Your Side will provide options based on the patient's insurance and proximity to the patient

**Disclaimer:** The information provided on this form is for demonstration purposes only and does not represent any real person.

### IMPORTANT SAFETY INFORMATION (CONT'D)

#### WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

- Patients receiving eculizumab products are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, BKEMV is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called BKEMV REMS.

Please see additional Important Safety Information throughout.

**6 DIAGNOSIS AND CLINICAL INFORMATION** USA-959-80292 01/26

Select appropriate ICD-10 diagnosis code below (required for benefits investigation)

<b>GENERALIZED MYASTHENIA GRAVIS (gMG)</b>	<b>PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)</b>
<input type="radio"/> G70.00: Myasthenia gravis without (acute) exacerbation	<input type="radio"/> D59.5: Paroxysmal nocturnal hemoglobinuria
<input type="radio"/> G70.01: Myasthenia gravis with (acute) exacerbation	<b>ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)</b>

Has the patient tested positive for AchR antibodies?  
 Yes  
 No

Medications tried/previous therapy:  
 Azathioprine  Plasmapheresis  Rituximab  
 Efgartigimod  Prednisone  Ravulizumab  
 Iplacopan  Pyridostigmine  None/new diagnosis  
 IVg  Other: \_\_\_\_\_  
 Mycophenolate Mofetil

Is patient switching from SOLIRIS® (eculizumab)?  
 Yes  
 No

D59.30: Hemolytic-uremic syndrome, unspecified  
 D59.32: Hereditary atypical hemolytic uremic syndrome  
 D59.39: Other hemolytic uremic syndrome

**7 PRESCRIPTION (Required)**

Patient first name \_\_\_\_\_ Patient last name \_\_\_\_\_ Date of Birth (MM/DD/YYYY) \_\_\_\_\_

Prescription information: BKEMV (eculizumab-aeb) Allergies: \_\_\_\_\_ No known drug allergies (NKDA)

NDC: 55513-0180-01 Single-dose vial of 300 mg of BKEMV in 30 mL (10 mg/mL)

Patient Weight: \_\_\_\_\_ lbs or \_\_\_\_\_ kg

Note: For patients switching from SOLIRIS® to BKEMV, no induction dose required. Patient can start on maintenance dose 2 weeks (+/- 2 days) after last dose of SOLIRIS®.

Rx BKEMV 10 mg/mL HCPCS Code: Q5152 Per Unit

**Induction Dose:**  
 SIG: infuse intravenously \_\_\_\_\_ mg weekly for the first 4 weeks, followed by the 5th week.  
 Other: \_\_\_\_\_

Q1Y of 300 mg/30 mL. Vials: \_\_\_\_\_ Refills: 0

**No induction dose; patient is on therapy**

**Administration instructions: Administer only as an intravenous (IV) infusion. Do not administer as an intravenous push or bolus. Administer over 35 minutes in adults and 1 to 4 hours in pediatric patients via gravity feed, a syringe-type pump, or an infusion pump.**

Advised solutions of BKEMV are stable for 64 hours at 2°C to 8°C (36°F to 46°F) or 24 hours at room temperature.

State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Signature below indicates prescription authorization and prescriber certification.

Prescriber signature/Dispense as written \_\_\_\_\_ Date (MM/DD/YYYY) \_\_\_\_\_  
 Written or e-signature only; stamps not acceptable.

Prescriber signature (substitutions allowed) \_\_\_\_\_ Date (MM/DD/YYYY) \_\_\_\_\_

**Prescriber Certification:** I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered BKEMV in accordance with the label use of the product. I represent that my patient has requested and authorized the disclosure of their personal information to Amgen, Inc. and its affiliates and their respective employees or agents (collectively, "Amgen") for Amgen to administer the Amgen By Your Side program (the "Program"), which provides patient-focused support, including providing logistical and non-medical assistance for BKEMV, as presented, and educating about the insurance process. I further represent that I have explained to the patient, and the patient (if adult) they understand and have consented to, the following: 1) Amgen will use the patient's name, date of birth, contact information, prescriptions, and other necessary health information to administer the Program; 2) Amgen will then disclose the patient's personal information to the patient's insurer(s) for the same purposes; 3) the patient can withdraw their consent by contacting Amgen at 1-844-469-4297 or visiting www.amgen.com/DataSubjectRights, but if the patient does not agree to, or withdraws consent for, these uses and disclosures, the patient cannot receive these patient support services for this medication which necessarily requires Amgen to process the patient's information and 4) the patient can view more details about Amgen's privacy practice at www.amgen.com/privacy. I authorize Amgen to transmit this prescription on my behalf to the appropriate pharmacy designated by the patient utilizing their benefits plan by any means allowed under applicable law. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use BKEMV or any other Amgen product or service, for any other person; (b) my decision to prescribe BKEMV was based solely on my professional determination of medical necessity; and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Amgen may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Amgen makes no representation or guarantee concerning coverage or reimbursement for any item or service. On behalf of the patient, Amgen expects the prescriber to coordinate with Amgen By Your Side to provide, to the best of the prescriber's ability, in-network infusion services and work with Amgen By Your Side to effectively communicate both in-network and out-of-network choices and the corresponding financial obligations of the patient connected to each choice. Should the prescriber knowingly perform out-of-network services without the knowledge and consent of the patient, the prescriber cannot balance bill the patient for the out-of-network services.

State requirements: I certify that the present form, when submitted as part of this Patient Enrollment Form, complies with my state's prescription requirements (e.g., e-prescribing, state-specific prescription form, fax language). I understand that non-compliance with my state's specific prescription requirements will result in outreach to me to obtain a compliant prescription.

By filling out and signing this form, the enrollment process Amgen By Your Side has initiated, however, your patient must sign a Patient Authorization to complete enrollment in Amgen By Your Side. Please note that your patient will not benefit from the services and support offered by the Program unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Amgen will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

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This page is to be completed by the patient. If the patient is unable to complete this page in-office, Amgen By Your Side can reach out to obtain patient consent. USA-959-80292 01/26

**8 PATIENT CONSENT AND AUTHORIZATION (Required—please see language on pages 4-5)**

Patient first name \_\_\_\_\_ Patient last name \_\_\_\_\_ Date of Birth (MM/DD/YYYY) \_\_\_\_\_

You must read the Consent to Health Data Processing on page 5 and then select one of the below responses. Select "I consent" to proceed with enrollment. If you select "I do not consent," you will not be able to enroll in Amgen By Your Side.

I consent to the collection, processing, and disclosure of my Health Data for the purposes set forth on page 5.  
 I do not consent to the collection, processing, or disclosure of my Health Data for the purposes set forth on page 5.

By signing below, I am indicating that I have read and understood the Authorization for Use and Disclosure of Protected Health Information (pages 4-5), that I am legally authorized to consent, and that I am providing my consent as the patient or the patient's legal representative for Amgen and its contractors and business partners to use and share the personal information I provide for the purposes described within the Authorization for Use and Disclosure of Protected Health Information.

Patient name \_\_\_\_\_ Name of Legal Representative (if needed) \_\_\_\_\_  
 Signature of Patient (or Legal Representative) \_\_\_\_\_ Date (MM/DD/YYYY) \_\_\_\_\_

Is there someone else with whom we can discuss your protected health information?  Yes  No

Name \_\_\_\_\_ Relationship \_\_\_\_\_ Phone number \_\_\_\_\_

**9 CO-PAY PROGRAM ENROLLMENT (Complete this section if you want to apply for the Amgen SupportPlus Co-Pay Program)**

To check eligibility for the Amgen® SupportPlus Co-Pay Program you must answer the questions below and agree to the Terms & Conditions by checking the box below.

What type of insurance do you use to pay for your BKEMV prescription and administration at the doctor's office? (Please select one option)

Commercial insurance (eg, self-purchased or through an employer)  
 Government-provided (eg, Medicare Part D, Medicaid)  
 I don't have insurance  
 I don't know

Are you eligible for Medicare but receive prescription drug coverage from a former employer, union, or welfare plan?  
 Yes  
 No

By checking this box, I agree that I have read, understand, and accept the Terms & Conditions of the Amgen SupportPlus Co-Pay Card Program on page 6.

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**6 Diagnosis and Clinical Information**

Confirm the diagnosis code by filling in the circle next to the patient's diagnosis (required to conduct a benefits investigation)

- For gMG patients only, fill in the circle next to "Yes" if the patient has ever tested positive for AchR antibodies
- Fill in the circles next to any previous therapies that the patient has received
- Answer Soliris switching question: (Yes or No)

**7 Prescription**

- Complete the prescription information section. Dosing information can be found at BKEMV.com/dosing
- Include patient name and date of birth within prescription section
- Prescriber signature is required for processing the Patient Enrollment Form
  - Must be a written signature; stamps and digital signatures are not accepted

**8 Patient Consent and Authorization**

- Patient must sign and date form
- Patient must check "I consent" circle in order to be enrolled in Amgen By Your Side
- If the patient can't sign the form at your office, Amgen By Your Side can follow up to obtain consent

**9 Co-pay Program Enrollment**

The patient should complete the co-pay questions if they would like to be considered for Co-Pay Program eligibility. The program is for eligible commercially insured patients. The patient must also fill in the circle attesting to reviewing the Co-Pay Program Terms & Conditions, which are located on page 6 of the Patient Enrollment Form.

Pages 4–6 of the PEF include the patient authorization and consent language and Co-Pay Program Terms and Conditions. Once the PEF is submitted, you can provide these 3 pages to the patient for their reference.

Please ensure that all six pages of the enrollment forms are submitted by fax to 1-866-500-0987 or emailed to [BKEMVABYS@amgen.com](mailto:BKEMVABYS@amgen.com). Incomplete forms may delay enrollment.

**IMPORTANT SAFETY INFORMATION (CONT'D)**

**WARNING: SERIOUS MENINGOCOCCAL INFECTIONS**

**Contraindications:** BKEMV is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

Please see additional Important Safety Information throughout.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### Other Infections

Use caution when administering BKEMV to patients with any other systemic infection. Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported.

Eculizumab products block terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections with *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Additionally, *Aspergillus* infections have occurred in immunocompromised and neutropenic patients. Children treated with eculizumab products may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Administer vaccinations for the prevention of *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) infections according to ACIP recommendations. Patients receiving eculizumab products are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

### Monitoring Disease Manifestations after BKEMV Discontinuation

#### Treatment Discontinuation for PNH:

Monitor patients after discontinuing BKEMV for at least 8 weeks to detect hemolysis.

#### Treatment Discontinuation for aHUS:

After discontinuing BKEMV, monitor patients with aHUS for signs and symptoms of thrombotic microangiopathy (TMA) complications for at least 12 weeks. Clinical signs and symptoms of TMA include changes in mental status, seizures, angina, dyspnea, or thrombosis.

In addition, the following changes in laboratory parameters may identify a TMA complication: occurrence of two, or repeated measurement of any one of the following: a decrease in platelet count by 25% or more compared to baseline or the peak platelet count during BKEMV treatment; an increase in serum creatinine by 25% or more compared to baseline or nadir during BKEMV treatment; or, an increase in serum LDH by 25% or more over baseline or nadir during BKEMV treatment.

If TMA complications occur after BKEMV discontinuation, consider reinstatement of BKEMV treatment, plasma therapy, or appropriate organ-specific supportive measures.

### Thrombosis Prevention and Management

The effect of withdrawal of anticoagulant therapy during eculizumab products treatment has not been established. Therefore, treatment with eculizumab products should not alter anticoagulant management.

### Infusion-Related Reactions

Administration of eculizumab products may result in infusion-related reactions, including anaphylaxis or other hypersensitivity reactions. In clinical trials, no patients experienced an infusion-related reaction which required discontinuation of eculizumab. Interrupt BKEMV infusion and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

### Adverse Reactions

The most frequently reported adverse reactions in:

- the PNH randomized trial ( $\geq 10\%$  overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea
- the aHUS single arm prospective trials ( $\geq 20\%$ ) are: headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, and pyrexia
- the gMG placebo-controlled clinical trial ( $\geq 10\%$ ) in adult patients is musculoskeletal pain

### Drug Interactions

- Concomitant use of eculizumab products with plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion (PE/PI), or in patients with gMG on concomitant IVIg treatment can reduce serum eculizumab product concentrations and requires a supplemental dose of BKEMV.
- Concomitant use of eculizumab products with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of eculizumab products. Closely monitor for reduced effectiveness of BKEMV.

**Please see Full Prescribing Information and Medication Guide for BKEMV.**