CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761333Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
BKEMV™ (eculizumab-aeeb) REMS

I. Administrative Information

Risk: Serious meningococcal infections
Application Number: BLA 761333
Application Holder: Amgen Inc.
Initial REMS Approval: 05/2024

II. REMS Goal

The goal of the BKEMV REMS is to mitigate the risk of serious meningococcal infections.

1. Patients are vaccinated against meningococcal infections caused by *Neisseria meningitidis* serogroups A, C, W, Y, and B prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving complement inhibitors and receive antibacterial drug prophylaxis if needed.
2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

III. REMS Requirements

Amgen Inc. must ensure that healthcare providers, patients, healthcare settings, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe BKEMV must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide. 3. Enroll by completing and submitting the Prescriber Enrollment Form to the REMS.
Before treatment initiation	4. Assess the patient for unresolved meningococcal infection. 5. For patients with unresolved serious meningococcal infection: Not initiate BKEMV. 6. Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor. 7. For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.

	8. Counsel the patient using the Patient Safety Card and Patient Guide. Provide a copy of the materials to the patient. 9. Counsel the patient on the need to carry the Patient Safety Card.
During treatment	10. Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected. 11. Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.
At all times	12. Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Amgen Inc.

2. Patients who are prescribed BKEMV:	
Before treatment initiation	1. Get meningococcal vaccines for serogroups A, C, W, Y, and B as directed by your prescriber. 2. Take antibiotics as directed by your prescriber if you have to start BKEMV right away. 3. Receive counseling from the prescriber using the Patient Safety Card and Patient Guide. 4. Get the Patient Safety Card and Patient Guide from your prescriber.
During treatment	5. Get additional meningococcal vaccines as directed by your prescriber.
At all times during treatment and for 3 months after the last dose	6. Have the Patient Safety Card with you. 7. Inform your prescriber or get emergency medical care right away if you experience any of the following: fever; fever and a rash; fever with high heart rate; headache with nausea or vomiting; headache and fever; headache with stiff neck or stiff back; confusion; eyes sensitive to light; muscle aches with flu-like symptoms.

3. Healthcare settings and pharmacies that dispense BKEMV must:	
To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll by completing and submitting the Healthcare Setting and Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing BKEMV using the Healthcare Provider Safety Brochure. 5. Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

	6. For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, by contacting the prescriber before dispensing prescriptions up to 6 months after the first dose and document the findings.
Before dispensing, first dose	7. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 8. Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, up to 6 months after the first dose	9. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 10. For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, 6 months after the first dose and thereafter	11. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
To maintain certification to dispense	12. If the Authorized Representative changes, have a new Authorized Representative enroll by completing and submitting the Healthcare Setting and Pharmacy Enrollment Form to the REMS.
At all times	13. Report adverse events suggestive of meningococcal infections to Amgen Inc. 14. Not distribute, transfer, loan, or sell BKEMV, except to other certified healthcare settings or certified pharmacies. 15. Maintain records of staff's completion of REMS training. 16. Maintain records that all processes and procedures are in place and are being followed. 17. Comply with audits carried out by Amgen Inc. or a third party acting on behalf of Amgen Inc. to ensure that all processes and procedures are in place and are being followed.

4. Wholesalers-distributors that distribute BKEMV must:	
To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings and pharmacies. 2. Train relevant staff involved in BKEMV distribution on the REMS requirements.
At all times	3. Distribute only to certified healthcare settings and pharmacies. 4. Maintain records of all drug distributions.

5. Comply with audits carried out by Amgen Inc. or a third party acting on behalf of Amgen Inc. to ensure that all processes and procedures are in place and are being followed.

Amgen Inc. must provide training to healthcare providers who prescribe BKEMV.
The training includes the following educational materials: Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide. The training must be available online and in hardcopy format via mail.

Amgen Inc. must provide training to healthcare settings and pharmacies that dispense BKEMV.
The training includes the following educational material: Healthcare Provider Safety Brochure. The training must be available online and in hardcopy format via mail.

To support REMS operations, Amgen Inc. must:

1. Establish and maintain a REMS Website, www.BKEMVREMS.com. The REMS Website must include the capability to complete prescriber certification and enrollment by fax, email, and online, healthcare setting and pharmacy certification and enrollment by fax and email, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Website. The REMS Website must not link back to the promotional product website(s).
2. Make the REMS Website fully operational and all REMS materials available through the REMS Website and Coordinating Center by the date BKEMV is first commercially distributed.
3. Establish and maintain a REMS Call Center at 1-866-718-6927.
4. Establish and maintain a validated, secure database of all certified prescribers, and certified healthcare settings and pharmacies in the BKEMV REMS.
5. Ensure that healthcare settings and pharmacies are able to obtain authorization to dispense by phone and online.
6. Ensure prescribers are able to enroll by fax, email, and online.
7. Ensure healthcare settings and pharmacies are able to enroll by fax and email.
8. Ensure prescribers, and healthcare settings and pharmacies are able to report adverse events suggestive of meningococcal infections by phone.
9. Ensure that once a report suggestive of meningococcal infection is received, Amgen Inc. will follow up with the healthcare providers to obtain all required data. This requirement does not affect Amgen Inc.'s other reporting and follow-up requirements under the FDA regulations.
10. Provide the Prescriber Enrollment Form, Healthcare Provider Safety Brochure, Patient Safety Card, Patient Guide, Medication Guide, and the BKEMV Prescribing Information to healthcare providers who (1) attempt to prescribe BKEMV and are not yet certified or (2) inquire about how to become certified.
11. Provide the Healthcare Setting and Pharmacy Enrollment Form and Healthcare Provider Safety Brochure to healthcare settings and pharmacies that (1) attempt to order/dispense and are not yet certified or (2) inquire about how to become certified.
12. Notify prescribers, and healthcare settings and pharmacies within 2 business days after they become certified in the REMS.
13. Provide certified prescribers access to the database of certified healthcare settings and pharmacies.
14. Provide certified healthcare settings and pharmacies access to a database of certified prescribers.
15. Provide authorized wholesalers-distributors access to a database of certified healthcare settings and pharmacies.

To ensure REMS participants' compliance with the REMS, Amgen Inc. must:

16. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: BKEMV distribution and dispensing; certification of prescribers, and

healthcare settings and pharmacies; and audits of REMS participants. These records must be readily available for FDA inspections.

17. Verify annually that the designated Authorized Representative name and contact information correspond to those of the current designated Authorized Representative for each healthcare setting and pharmacy. If different, then the healthcare setting or pharmacy must be required to re-certify with a new Authorized Representative.
18. Establish and maintain a plan for addressing noncompliance with REMS requirements.
19. Monitor prescribers, and healthcare settings and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.
20. Audit certified healthcare settings and pharmacies no later than 180 calendar days after they receive their first shipment, and a representative sample of certified healthcare settings and pharmacies annually thereafter, to ensure that all processes and procedures are in place, functioning, and comply with the REMS requirements.
21. Audit wholesalers-distributors no later than 180 calendar days after their first commercial distribution of BKEMV and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and comply with the REMS requirements.
22. Take reasonable steps to improve operations of and compliance with the requirements in the BKEMV REMS based on monitoring and evaluation of the BKEMV REMS.

IV. REMS Assessment Timetable

Amgen Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (05/28/2024). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Amgen Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the BKEMV REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Healthcare Setting and Pharmacy:

2. Healthcare Setting and Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

3. Healthcare Provider Safety Brochure

Patient:

4. Patient Safety Card
5. Patient Guide

Healthcare Setting and Pharmacy:

6. Healthcare Provider Safety Brochure

Other Materials

7. REMS Website

VI. Statutory Elements

This REMS is required under Section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use:
   - Healthcare providers who prescribe BKEMV are specially certified under 505-1(f)(3)(A)
   - Healthcare settings and pharmacies that dispense BKEMV are specially certified under 505-1(f)(3)(B)
   - BKEMV is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for Submission of Assessments

Prescriber Enrollment Form

Instructions

To become certified in the BKEMV REMS and prescribe BKEMV:

1) Review the BKEMV Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2) Enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
   - online at www.BKEMVREMS.com
   - by fax at 1-866-718-8244
   - by scanning and emailing to Amgen@BKEMVREMS.com

The BKEMV REMS will verify completion of the **Prescriber Enrollment Form** and provide confirmation of certification via email within 2 business days after certification in the REMS.

Prescriber Agreement

By completing, signing, and submitting this form, I acknowledge and agree that:

- I have read and understand the BKEMV Prescribing Information (PI), **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
- I understand the:
  - Risk of serious meningococcal infections associated with BKEMV.
  - Early signs and symptoms of meningococcal infections and the need for immediate medical evaluation.
- I will enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
- Before treatment initiation, I must:
  - Assess the patient for unresolved meningococcal infection.
  - For patients with an unresolved serious meningococcal infection: NOT initiate BKEMV.
  - Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
  - For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
  - Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of these materials to the patient.
  - Counsel the patient on the need to carry the **Patient Safety Card** at all times and for 3 months after their last dose.
- During treatment, I must:
  - Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
  - Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.
- At all times, I must:
  - Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Amgen Inc. by phone at 1-800-772-6436 (1-800-77-AMGEN).
- I understand that if I do not maintain compliance with the requirements of the BKEMV REMS, I will no longer be able to prescribe BKEMV.
- I understand that BKEMV REMS and its agents or contractors may contact me to support the administration of the BKEMV REMS.

Prescriber Information (All Fields Required Unless Otherwise Indicated)

First Name:	MI (optional):	Last Name:
National Provider Identifier (NPI):	Email:	
Clinic/Practice Name:		
Address Line 1:	Address Line 2:	
City:	State:	Zip Code:
Phone (Ext opt):	Fax:	

Credentials: ☐ MD ☐ DO ☐ APRN* ☐ PA ☐ PharmD

Medical Specialty (please select one): ☐ Hematology/Oncology ☐ Immunology ☐ Internal medicine ☐ Nephrology ☐ Neurology ☐ Rheumatology ☐ Other (please specify):_____

Prescriber Signature: **Date (MM/DD/YYYY):**

* Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM).

Phone: 1-866-718-6927
Fax: 1-866-718-8244
www.BKEMVREMS.com

Healthcare Setting and Pharmacy Enrollment Form

Instructions

To become certified in the BKEMV REMS and dispense BKEMV, the healthcare setting and pharmacy that dispenses BKEMV must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy. The Authorized Representative must:

1) Review the **Healthcare Provider Safety Brochure**.
2) Enroll by completing and submitting this **Healthcare Setting and Pharmacy Enrollment Form** to the REMS,
   - by fax to the BKEMV REMS at 1-866-718-8244, or
   - by scanning and emailing to Amgen@BKEMVREMS.com

Authorized Representative Agreement

As the healthcare setting and pharmacy Authorized Representative, to become certified to dispense, I must:

- Review the **Healthcare Provider Safety Brochure**.
- Enroll by completing and submitting this **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing BKEMV using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.
- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the BKEMV REMS.

Before dispensing, up to 6 months after the first dose, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting this **Healthcare Settings or Pharmacy Enrollment Form** to the REMS.

At all times, all healthcare setting or pharmacy staff must:

- Report adverse events suggestive of meningococcal infections to Amgen Inc. by phone at 1-800-772-6436 (1-800-77-AMGEN).
- Not distribute, transfer, loan, or sell BKEMV, except to other certified healthcare settings and certified pharmacies.
- Maintain records of staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Amgen Inc. or a third party acting on behalf of Amgen Inc. to ensure that all processes and procedures are in place and are being followed.

Phone: 1-866-718-6927
Fax: 1-866-718-8244
www.BKEMVREMS.com

Healthcare Setting and Pharmacy Enrollment Form

Authorized Representative Information

Note: Fields marked with an * are REQUIRED.

*First Name:	Middle Initial:	*Last Name:
*Title/Position:		
*Office Phone Number:	*Office Fax Number:	*Email:
*Preferred Method of Communication (please select one): ☐ Fax ☐ Email ☐ Phone		
*Authorized Representative Signature:		*Date (MM/DD/YYYY):

Dispensing Healthcare Setting and Pharmacy Information

Note: Fields marked with an * are REQUIRED.

*Institution Name:		
*Institution Street Address:		
*City:	*State:	*Zip Code:
*Institution Phone Number:	Institution Fax Number:	
*Institution National Provider Identifier (NPI) #:	*Drug Enforcement Agency Number (DEA) #:	Institution Health Industry Number (HIN) #:
*Type of the institution (please select one): ☐ Hospital ☐ Infusion Site/ Outpatient Clinic ☐ Physician Practice ☐ Specialty Pharmacy/ Infusion Provider		

By completing and submitting this form as directed above and receiving certification confirmation, your healthcare setting or pharmacy will be certified in the BKEMV REMS. You will receive confirmation of your certification via email.

If the Authorized Representative is overseeing more than one healthcare setting or pharmacy, add details of the additional institutions within your healthcare system below:

Additional Dispensing Healthcare Setting and Pharmacy Location Information

Note: Fields marked with an * are REQUIRED.

*Institution Name:		
*Institution Street Address:		
*City:	*State:	*Zip Code:
*Institution Phone Number:	Institution Fax Number:	
*Institution National Provider Identifier (NPI) #:	*Drug Enforcement Agency Number (DEA) #:	Institution Health Industry Number (HIN) #:
*Type of the institution (please select one): ☐ Hospital ☐ Infusion Site/ Outpatient Clinic ☐ Physician Practice ☐ Specialty Pharmacy/ Infusion Provider		

Additional Dispensing Healthcare Setting and Pharmacy Location Information

Note: Fields marked with an * are REQUIRED.

*Institution Name:		
*Institution Street Address:		
*City:	*State:	*Zip Code:
*Institution Phone Number:	Institution Fax Number:	
*Institution National Provider Identifier (NPI) #:	*Drug Enforcement Agency Number (DEA) #:	Institution Health Industry Number (HIN) #:
*Type of the institution (please select one): ☐ Hospital ☐ Infusion Site/ Outpatient Clinic ☐ Physician Practice ☐ Specialty Pharmacy/ Infusion Provider		

BKEMV™ REMS

Healthcare Provider Safety Brochure

This brochure provides information for healthcare providers who will prescribe or dispense BKEMV. It describes:

- What is BKEMV?
- What is the BKEMV REMS?
- Prescriber Requirements
- Healthcare Setting and Pharmacy Requirements
- BKEMV REMS Resources
- Adverse Event Reporting

What is BKEMV?

BKEMV 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.

Limitation of Use

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

Risk of Serious Meningococcal Infections

- BKEMV, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains.
- Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors such as BKEMV.
- The initiation of BKEMV treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.
- At least 2 weeks prior to administration of the first dose of BKEMV, complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) according to current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.
- If urgent BKEMV therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.
- Vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Promptly treat known infections.
- Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.
- Inform patients of the signs and symptoms of serious meningococcal infection and instruct patients to seek immediate medical care if these signs and symptoms occur.
- Consider interruption of BKEMV in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

What is the BKEMV REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks.

Because of the risk of serious meningococcal infections, BKEMV is available only through the BKEMV REMS, a restricted distribution program.

Prescriber Requirements

What do Prescribers Need to do When Prescribing BKEMV?

Healthcare providers who prescribe BKEMV must be specially certified. To become certified in the BKEMV REMS and prescribe BKEMV, prescribers must:

1. Review the BKEMV Prescribing Information, **Healthcare Provider Safety Brochure** (this document), **Patient Safety Card**, and **Patient Guide**.
2. Complete and submit the **Prescriber Enrollment Form** to the REMS:
    - online at www.BKEMVREMS.com
    - by fax at 1-866-718-8244
    - by scanning and emailing to Amgen@BKEMVREMS.com

Before initiating a patient's BKEMV treatment, prescribers must:

- Assess the patient for unresolved meningococcal infections and not initiate BKEMV in any patient with these infections.
- Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
    - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:
        - The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least 2 weeks prior to receiving the first dose of BKEMV or receive antibacterial drug prophylaxis if BKEMV must be initiated immediately, and they have not previously been vaccinated.
        - Additional vaccines may be necessary during treatment with BKEMV.
        - Meningococcal vaccines do not prevent all meningococcal infections.
    - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the following signs and symptoms which, if experienced, should prompt the patient to seek immediate medical care:
        - fever
        - fever and a rash
        - fever with high heart rate
        - headache with nausea or vomiting
        - headache and fever
        - headache with stiff neck or stiff back
        - confusion
        - eyes sensitive to light
        - muscle aches with flu-like symptoms
- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care.
    - Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

During BKEMV treatment, prescribers must:

- Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.

At all times, prescribers must:

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Amgen Inc. at 1-800-772-6436 (1-800-77-AMGEN).
- Comply with the BKEMV REMS requirements to maintain certification to prescribe.

Before dispensing, certified healthcare settings and pharmacies must assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed. If you have not provided this information already, you may receive a call from the healthcare setting and pharmacy to collect information confirming that the patient has received the appropriate vaccinations or antibacterial drug prophylaxis.

Healthcare Setting and Pharmacy Requirements

What do Healthcare Settings and Pharmacies Need to Do to Dispense BKEMV?

BKEMV may only be dispensed by healthcare settings and pharmacies that are certified to dispense.

To become certified, the healthcare setting or pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy. To become certified, the Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document)
- Complete and submit the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS:
  - by fax at 1-866-718-8244
  - by scanning and emailing to Amgen@BKEMVREMS.com

By completing the Healthcare Setting and Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing BKEMV using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.
- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified.
- Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, up to 6 months after the first dose, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified.

At all times, all healthcare setting and pharmacy staff must:

- Report adverse events suggestive of meningococcal infections to Amgen Inc. by phone at 1-800-772-6436 (1-800-77-AMGEN).
- Not distribute, transfer, loan, or sell BKEMV, except to certified healthcare settings or certified pharmacies.
- Maintain records for staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and being followed.
- Comply with audits carried out by Amgen Inc. or a third party acting on behalf of Amgen Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.

BKEMV REMS Resources

Visit www.BKEMVREMS.com or call 1-866-718-6927 to learn more about the BKEMV REMS.

Adverse Event Reporting

Report adverse events suggestive of meningococcal infections, including the patient's clinical outcomes, immediately to Amgen Inc. at 1-800-772-6436 (1-800-77-AMGEN).

You are encouraged to report other adverse reactions of BKEMV to Amgen Inc. by phone at 1-800-772-6436 (1-800-77-AMGEN) or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This brochure does not provide all risk information for BKEMV.

Please see Prescribing Information for BKEMV, including BOXED WARNING regarding serious meningococcal infections for more detailed safety information.

AMGEN®

Patient Safety Card

Important Safety Information for Patients Taking BKEMV™ (eculizumab-aeeb)

BKEMV can increase your chance of getting **serious meningococcal infections. These infections may quickly become life-threatening or cause death if not recognized and treated early.** If you experience any of the following signs and symptoms of serious meningococcal infection, you should immediately call your healthcare provider or seek emergency medical care, preferably in a major emergency medical care center:

- fever
- fever and a rash
- fever with high heart rate
- headache with nausea or vomiting
- headache and fever
- headache with stiff neck or stiff back
- confusion
- eyes sensitive to light
- muscle aches with flu-like symptoms

Get emergency medical care right away if you have any of these signs or symptoms and show this card to any healthcare provider who treats you.

Your risk of meningococcal infection may continue for several months after your last dose of BKEMV.

Keep this card with you at all times during your treatment and for 3 months after your last dose.

Patient Safety Card

Information for the Treating Healthcare Provider

This patient has been prescribed BKEMV (eculizumab-aeeb) therapy, which increases the patient's susceptibility to meningococcal infections (*Neisseria meningitidis*) or other general infections.

- Meningococcal infections may become rapidly life-threatening or fatal if not recognized and treated early.
- **Closely monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected. Promptly treat known infections.**
- Contact prescribing healthcare provider who prescribed BKEMV (listed below) as soon as possible if the patient has signs and symptoms of serious meningococcal infection.

For more information about BKEMV, please refer to the Prescribing Information. Report adverse events suggestive of serious meningococcal infections at 1-800-772-6436 (1-800-77-AMGEN).

Patients receiving BKEMV should carry this card at all times during your treatment and for 3 months after your last dose of treatment. Show this card to any healthcare provider involved in your health care.

Patient Name

Prescriber Name

Prescriber Telephone Number

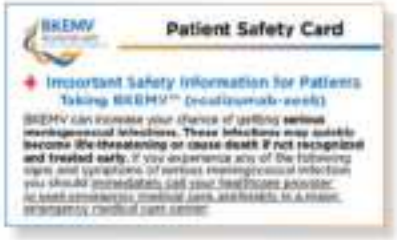
Phone: 1-866-718-6927 | Fax: 1-866-718-8244 | www.BKEMVREMS.com

Revised: [illegible]8/2024

Patient Safety Card

You will receive a **Patient Safety Card** from your healthcare provider. This card covers the risk of serious meningococcal infection while taking BKEMV.

- Carry this card at all times during your treatment and for 3 months after your last BKEMV dose.
- Your risk of serious meningococcal infections may continue for several months after your last dose of BKEMV.
- **Show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.**
- Get treatment right away for any signs and symptoms of a meningococcal infection even if you do not have your card on you.


Patient Safety Card

Important Safety Information for Patients Taking BKEMV™ (eculizumab-aeeb)

BKEMV can increase your chance of getting **serious meningococcal infections. These infections may quickly become life-threatening or cause death if not recognized and treated early.** If you experience any of the following signs and symptoms of serious meningococcal infection you should immediately call your healthcare provider or seek emergency medical care, preferably in a vaccine emergency medical care center.

What is the BKEMV REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. When there is a REMS, drug companies, healthcare providers, healthcare settings, and pharmacies must take extra steps to make sure the benefits of using the drug are greater than the risks.

BKEMV has a REMS because BKEMV can increase your chance of getting serious meningococcal infections. Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.

AMGEN

Phone: 1-866-718-6243 | Fax: 1-866-718-6244 | www.BKEMVREMS.com

Reference ID: 5388039

BKEMV™ REMS

Patient Guide

BKEMV® (eculizumab-aeeb) Injection for Intravenous Use 300mg/30mL vial

What You Need to Know About BKEMV™ (eculizumab-aeeb)

What is BKEMV?

BKEMV (eculizumab-aeeb) is a prescription medicine used to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

What are the Serious Risks of BKEMV?

BKEMV is a medicine that affects your immune system. It can lower the ability of your immune system to fight infections.

BKEMV increases your chance of getting serious and life-threatening meningococcal infections.

Meningococcal infections may quickly become life-threatening or cause death if not recognized and treated early.

Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious meningococcal infection:

- Fever
- Fever and a rash
- Fever with high heart rate
- Headache with nausea or vomiting
- Headache and fever
- Headache with stiff neck or stiff back
- Confusion
- Eyes sensitive to light
- Muscle aches with flu-like symptoms

Getting Your Meningococcal Vaccines

- Complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of BKEMV.
- If you have not completed your meningococcal vaccines and BKEMV must be started right away, you should receive the required vaccine(s) as soon as possible.
- If you have not been vaccinated and you must take BKEMV right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
- If you had a meningococcal vaccine in the past, you might need additional vaccines before starting BKEMV. Your healthcare provider will decide if you need additional meningococcal vaccines.
- Meningococcal vaccines do not prevent all meningococcal infections.
- Keep your vaccination records in a safe place and notify your healthcare provider that you have been vaccinated.
- **Your healthcare provider and the certified healthcare setting or pharmacy may contact you to verify your vaccination records before your medicine is provided for you.**

AMGEN®

BKEMV™
(eculizumab-aeeb)

Reference ID: 5388039

BKEMV™ REMS

What is the BKEMV REMS?

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

What is the Goal of the BKEMV REMS?

The goal of the BKEMV REMS is to mitigate the risk of serious meningococcal infections.

1. Patients are vaccinated against meningococcal infections caused by *Neisseria meningitidis* serogroups A, C, W, Y, and B prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving complement inhibitors and receive antibacterial drug prophylaxis if needed.
2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

What does BKEMV treat?

Indications

BKEMV 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.

Limitation of Use

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

Prescribers

BKEMV is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS).

Healthcare providers who prescribe BKEMV must be certified in the BKEMV REMS.

Prescriber Certification

Healthcare Settings and Pharmacies

BKEMV is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS).

Healthcare settings and pharmacies who dispense BKEMV must be certified in the BKEMV REMS.

Healthcare Setting and Pharmacy Certification

Patient Counseling

Prescribers must:

- Counsel the patients using the **Patient Safety Card** and **Patient Guide**. Provide these materials to your patients.
  - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:
    - The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least 2 weeks prior to receiving the first dose of BKEMV or receive antibacterial drug prophylaxis if BKEMV must be initiated immediately, and they have not previously been vaccinated.
    - Additional vaccines may be necessary during treatment with BKEMV.
    - Meningococcal vaccines do not prevent all meningococcal infections.
  - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the signs and symptoms which, if experienced, should prompt the patient to seek immediate medical care.
- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care
  - Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

Reporting Adverse Events

Report adverse events suggestive of meningococcal infections, including the patient's clinical outcomes, immediately to Amgen Inc. at 1-800-772-6436 (1-800-77-AMGEN).

You are encouraged to report other adverse reactions of BKEMV to Amgen Inc. at 1-800-772-6436 (1-800-77-AMGEN) or FDA at or www.fda.gov/medwatch or call 1-800-FDA-1088.

Resources for Prescribers

- Prescriber Enrollment Form
- Healthcare Provider Safety Brochure
- Patient Safety Card
- Spanish Patient Safety Card
- Patient Guide
- Spanish Patient Guide

Download All Prescriber Resources

Resources for Healthcare Settings and Pharmacies

- Healthcare Setting and Pharmacy Enrollment Form
- Healthcare Provider Safety Brochure

Download All Healthcare Setting and Pharmacy Resources

Have Questions?

Contact the BKEMV REMS by calling 1-866-718-6927

Prescribers

Program Requirements for Prescribers

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

Healthcare providers (HCPs) who prescribe BKEMV must be specially certified.

Prescriber Certification

Enrollment in the BKEMV REMS allows HCPs to be able to prescribe BKEMV. Certification in the BKEMV REMS includes the following steps:

Step 1: Review the following: BKEMV Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**

Step 2: Enroll in the BKEMV REMS. Complete and submit the **Prescriber Enrollment Form**

- online
- by fax at 1-866-718-8244
- by scanning and emailing to Amgen@BKEMVREMS.com

Patient Counseling

Prescribers must:

- Counsel the patients using the **Patient Safety Card** and **Patient Guide**. Provide these materials to your patients.
  - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:
    - The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least 2 weeks prior to receiving the first dose of BKEMV or receive antibacterial drug prophylaxis if BKEMV must be initiated immediately, and they have not previously been vaccinated.
    - Additional vaccines may be necessary during treatment with BKEMV.
    - Meningococcal vaccines do not prevent all meningococcal infections.
  - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the signs and symptoms which, if experienced, should prompt the patient to seek immediate medical care.
- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care
  - Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

Reporting Adverse Events

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Resources for Prescribers

- Prescriber Enrollment Form
- Healthcare Provider Safety Brochure
- Patient Safety Card
- Patient Guide
- Spanish Patient Safety Card
- Spanish Patient Guide

Download All Prescriber Resources

BKEMV™ REMS
Prescriber Enrollment Form

Instructions

To become certified in the BKEMV REMS and prescribe BKEMV, prescribers must:

1) Review the BKEMV Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2) Enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.

You may complete this form:

- online
- by fax at 1-866-718-8244
- by scanning and emailing to Amgen@BKEMVREMS.com

The BKEMV REMS will verify completion of the **Prescriber Enrollment Form** and provide confirmation of certification via email within 2 business days after certification in the REMS.

(Fields marked with * are REQUIRED)

Prescriber Agreement

By completing, signing, and submitting this form, I acknowledge and agree that:

- I have read and understand the BKEMV Prescribing Information (PI), **Healthcare Provider Safety Brochure**, and **Patient Safety Card**, and **Patient Guide**.
- I understand the:
  - Risk of serious meningococcal infections associated with BKEMV.
  - Early signs and symptoms of meningococcal infections and the need for immediate medical evaluation.
- I will enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.

Before treatment initiation, I must:

- Assess the patient for unresolved meningococcal infection.
- For patients with an unresolved serious meningococcal infection: NOT initiate BKEMV.
- Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient about using the **Patient Safety Card** and **Patient Guide**. Provide a copy of these materials to the patient.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

During treatment, I must:

- Assess the patient for early signs and symptoms of meningococcal infections and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.

At all times, I must:

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Amgen Inc. by phone at 1-800-772-6436.

I understand that if I do not maintain compliance with the requirements of the BKEMV REMS, I will no longer be able to prescribe BKEMV.

I understand that BKEMV REMS and its agents or contractors may contact me to support the administration of the BKEMV REMS.

Prescriber Information

*National Provider Identifier (NPI):

Continue

BKEMV™ REMS
Prescriber Enrollment Form

Instructions

To become certified in the BKEMV REMS and prescribe BKEMV, prescribers must:

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- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient about using the **Patient Safety Card** and **Patient Guide**. Provide a copy of these materials to the patient.
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I understand that BKEMV REMS and its agents or contractors may contact me to support the administration of the BKEMV REMS.

Prescriber Information

*National Provider Identifier (NPI):
1234567890

*First Name: John
MI:
*Last Name: Smith

*Clinic/Practice Name:

*Address Line 1: 123 Main Street
Address Line 2:

*City: Philadelphia
*State: PA
*Zip Code: 99999

*Email:
*Phone:
Ext:
*Fax:

*Credentials (please select one)
○ MD ○ DO ○ APRN* ○ PA ○ PharmD

*Medical Specialty (please select one)
○ Hematology/Oncology ○ Immunology ○ Internal medicine ○ Nephrology ○ Neurology ○ Rheumatology ○ Other (please specify)

* Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM).

Clear Signature

Please use your mouse or stylus to sign below

Clear | Cancel | Submit

BKEMV™ REMS
Prescriber Enrollment Form

Instructions

To become certified in the BKEMV REMS and prescribe BKEMV, prescribers must:

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(Fields marked with * are REQUIRED)

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- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start BKEMV urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient about using the **Patient Safety Card** and **Patient Guide**. Provide a copy of these materials to the patient.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

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At all times, I must:

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Amgen Inc. by phone at 1-800-772-6436.

I understand that if I do not maintain compliance with the requirements of the BKEMV REMS, I will no longer be able to prescribe BKEMV.

I understand that BKEMV REMS and its agents or contractors may contact me to support the administration of the BKEMV REMS.

Prescriber Information

*National Provider Identifier (NPI):
1234567890

*First Name: John
MI:
*Last Name: Smith

*Clinic/Practice Name:

*Address Line 1: 123 Main Street
Address Line 2:

*City: Philadelphia
*State: PA
*Zip Code: 99999

*Email:
*Phone:
Ext:
*Fax:

*Credentials (please select one)
○ MD ○ DO ○ APRN* ○ PA ○ PharmD

*Medical Specialty (please select one)
○ Hematology/Oncology ○ Immunology ○ Internal medicine ○ Nephrology ○ Neurology ○ Rheumatology ◉ **Other (please specify)**

* Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM).

*Medical Specialty Other
Other

Clear Signature

Please use your mouse or stylus to sign below

Clear | Cancel | Submit

BKEMV™ REMS
Prescriber Enrollment Form

Thank you for submitting your information to certify in the BKEMV REMS.

A confirmation of this submission has been sent to the email address provided.

If you do not receive the email within the next few hours, or would like to update your enrollment information at any time, please contact the BKEMV REMS at 1-866-718-6927.

Resources for Patients

- Patient Safety Card
- Patient Guide
- Spanish Patient Safety Card
- Spanish Patient Guide

Download All Patient Resources

Healthcare Settings and Pharmacies

Requirements for Healthcare Settings and Pharmacies

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

To become certified in the BKEMV REMS and dispense BKEMV, the healthcare setting or pharmacy that dispenses BKEMV must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy.

Healthcare Settings and Pharmacies Certification

For a healthcare setting and pharmacy to become certified, the Authorized Representative must complete the following steps:

Step 1: Review the **Healthcare Provider Safety Brochure**

Step 2: Enroll in the BKEMV REMS by completing and submitting the **Healthcare Setting and Pharmacy Enrollment Form** to the BKEMV REMS

- by fax at 1-866-718-8244
- by scanning and emailing to Amgen@BKEMVREMS.com

Reporting Adverse Events

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Resources for Healthcare Settings and Pharmacies

- Healthcare Provider Safety Brochure
- Healthcare Setting and Pharmacy Enrollment Form

Download All Healthcare Setting and Pharmacy Resources

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

TANYA M WROBLEWSKI
05/28/2024 04:09:41 PM