BKEMV™ REMS

Healthcare Provider Safety Brochure

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

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.
- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor antibody positive.

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.

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