

BKEMV REMS Readiness checklist* for prescribing Healthcare Providers (HCPs)



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. Each eculizumab has its own REMS program.

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

1. Patients are required to be vaccinated against meningococcal infections prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations
2. Prescribers need to be aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation

PRESCRIBING HCP REQUIREMENTS

BKEMV REMS program certification is required to prescribe BKEMV. Follow the steps below to fulfill the BKEMV REMS program requirements.

1 BECOME REMS CERTIFIED (one-time step with 1 form)

- Review BKEMV prescribing and risk information in the *Healthcare Provider Safety Brochure*, *Patient Safety Card*, and *Patient Guide*
- Complete and submit the *Prescriber Enrollment Form* at BKEMVREMS.com

2 COUNSEL PATIENTS

- Review the *BKEMV REMS Patient Safety Card* and *Patient Guide* with your patients
- Instruct patients to carry their Patient Safety Card at all times and for 3 months after their last dose of BKEMV, showing it to any healthcare provider involved in their care
- Confirm the patient meets meningococcal vaccination requirements prior to the next BKEMV infusion
 - Assess the patient for unresolved meningococcal infection
 - For patients with unresolved serious meningococcal infection, do 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

For REMS support, contact the BKEMV REMS Coordinating Center

available Monday to Friday, 8:00 am to 8:00 pm ET

- Phone: 1-866-718-6927
- Email: Amgen@BKEMVREMS.com
- Fax: 1-866-718-8244

Amgen is committed to supporting your practice throughout your REMS enrollment

At all times: Report adverse events suggestive of meningococcal infections to Amgen Inc. by phone at 1-800-772-6436 (1-800-77-AMGEN)

*For complete list of BKEMV REMS requirements, visit BKEMVREMS.com.

BKEMV REMS PROCESS OVERVIEW



In order to prescribe, dispense, and distribute BKEMV to patients, HCPs, healthcare settings, pharmacies, wholesalers, and distributors must comply with all requirements of the BKEMV REMS



- **HCP** becomes BKEMV REMS certified to prescribe BKEMV
- **HCP** prescribes BKEMV and sends prescription to pharmacy



- **HCS/pharmacy** designates an authorized representative (AR) who becomes REMS certified
- **AR adds staff** to their profile on BKEMVREMS.com (staff to help implement REMS)
- **AR** sets up procedures and training to meet BKEMV REMS requirements
- **HCS/pharmacy** places BKEMV order to wholesaler/distributor



Wholesaler/distributor verifies that HCS/pharmacy is BKEMV REMS certified

If YES, ships with BKEMV order

If NO, contacts HCS/pharmacy to become BKEMV REMS certified



For each dispense:

- HCS/pharmacy AR or AR's staff inputs prescribing HCP's NPI on BKEMVREMS.com portal to generate REMS Dispense Authorization (RDA)
- HCS/pharmacy sends BKEMV to infusion site
- Within 1 day from each dispense, AR or AR's staff to input/confirm all necessary patient-, prescription-, and vaccination-related information on BKEMVREMS.com for each RDA
- Comply with audits carried out by Amgen Inc. (or a third party acting on behalf of Amgen Inc.) to ensure all REMS requirements are met per FDA requirements

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HCS = healthcare setting.

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