



# Amgen By Your Side

is a support program for patients prescribed **BKEMV<sup>®</sup>** (eculizumab-aeab)

Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as you prescribe.



**Patient Support**



**Financial Assistance**



**Infusion Logistics Assistance**



**Insurance Benefits Investigation**



**Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form. Patient consent will be required.**

OPTIONS AVAILABLE AT:



[amgenbyside.com/bkemv/hcp](https://amgenbyside.com/bkemv/hcp)



# Our mission is to connect, coordinate, and champion your patient at important steps along the way:



## Connect

Your patient will be connected to one person dedicated to partnering with them throughout their treatment experience

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## Coordinate

Your patient will receive educational support on insurance, financial assistance options, important appointment-related information, and more

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## Champion

Your patient's dedicated partner will strive to empower them to be confident self-advocates committed to maintaining their treatment goals

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When you are ready to prescribe:

# Support access to treatment for your patients

The Amgen By Your Side team is here to assist your patients along the way

## Amgen By Your Side offers patient-focused support:



### Patient Support

- Provide dedicated, one-on-one support for your patients
- Work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment



### Insurance Benefits Investigation

- Provide education to you and your staff about product coding and billing
- Educate you and your staff about insurance processes, including specific payor requirements and examples



### Financial Assistance

- Educate patients on the results of their benefits investigation and review their insurance coverage
- Help patients understand potential out-of-pocket costs and financial assistance options



### Infusion Logistics Assistance

- Provide site of care options for you and your patients, if needed

# Meet the Amgen By Your Side team

Initiate your patient's enrollment in Amgen By Your Side by submitting the Patient Enrollment Form at [amgenbyside.com/bkemy/hcp](https://amgenbyside.com/bkemy/hcp). Your patient must complete enrollment to access our patient-focused services and resources.



## Patient Access Liaison (PAL)

The PAL provides dedicated, one-on-one support for your patient.

- They work directly with individual patients to answer nonmedical, logistical questions and provide support upon enrollment
- Additionally, the PAL educates on navigating insurance processes and accessing treatment
- The PAL has the expertise and tools to support the patient by educating on patient benefits, prior authorization requirements, payor policies, and coding and claim submissions



## Site of Care Team

The Site of Care Team evaluates site of care interest in infusing Amgen rare disease therapies, with the goal of expanding infusion center options for patients.

- The team educates sites of care on coding, billing, and payor access and provides product education



## Case Manager

Case Managers work on behalf of the patient and interact with the doctor's office to obtain accurate insurance information and to inform the office on insurance criteria for the submission of a prior authorization.

In addition, a Case Manager:

- May reach out to the doctor's office after a prescriber initiates enrollment and inquire about missing information on the enrollment form
- Has the expertise and knowledge to educate the doctor's office on payor policies and insurance criteria for access to Amgen products

The team at Amgen By Your Side is available by phone at 1-866-402-5622

## Amgen Co-Pay Programs

Eligible patients with commercial insurance may pay as little as \$0 out-of-pocket for each dose or cycle and receive up to \$1,000 per calendar year for out-of-pocket costs for in-office administration through the Amgen SupportPlus Co-Pay Program.\*



PALs can speak with patients prescribed BKEMV about the insurance approval process and help them understand coverage options

\*Eligibility criteria and program maximums apply. See full terms and conditions at [amgensupportplus.com/copay](https://amgensupportplus.com/copay). Patients who are residents of Massachusetts or Rhode Island are not eligible for administration support.



## Support access to BKEMV for your patients with Amgen By Your Side

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Options available at: [amgenbyside.com/bkemv/hcp](https://amgenbyside.com/bkemv/hcp)



### Questions?

Contact the Amgen By Your Side team

Phone:  
1-866-402-5622



## Indications

BKEMV® (eculizumab-aeeb) 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

**Eculizumab 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.**
- **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.**

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

### 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 reinstitution 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.

