



Whether your patients are starting on BKEMV or switching from SOLIRIS®, here are some

KEY STEPS TO GET THEM STARTED



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

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

Please see below for additional Important Safety Information, including BOXED Warning.



BKEMV is an FDA-approved interchangeable biosimilar to SOLIRIS¹⁻³

BKEMV is given in the **same way**, with the same dose, and on the same schedule as SOLIRIS.^{1,4}

LEARN MORE ABOUT BKEMV



What Your Patients Should Know About BKEMV

- ✓ BKEMV is an **FDA-approved biosimilar to SOLIRIS** for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), and generalized myasthenia gravis (gMG) in adult patients.¹
- ✓ BKEMV demonstrated **highly similar safety and efficacy to SOLIRIS** in PNH patients who were stable on SOLIRIS and switched to BKEMV.^{1,5*}
- ✓ Your patients can expect **highly similar safety and effectiveness** to SOLIRIS over their course of treatment⁶

	Same for both BKEMV and SOLIRIS ^{1,4}
Infusion schedule	✓
Dosing	✓
Required vaccinations [†]	✓

*In a randomized, double-blind, multicenter, active-controlled, two-period crossover study of BKEMV vs SOLIRIS in subjects with PNH (N = 42).

[†]Comply with the most current ACIP recommendations for vaccinations against meningococcal bacteria in patients receiving a complement inhibitor.^{1,4}

PATIENTS SWITCHING FROM SOLIRIS **DO NOT NEED TO REPEAT** THE INDUCTION PHASE^{1,5}



Patient Vaccination Requirements

As with SOLIRIS, patients must complete or update their meningococcal vaccines at least 2 weeks before their first dose.^{1,4}

If the patient is not up to date with vaccines and BKEMV must be started right away, patients should receive meningococcal vaccines as soon as possible and also receive prophylactic antibiotics for as long as deemed appropriate.¹



Get BKEMV REMS Certified

To prescribe or dispense BKEMV, a Risk Evaluation and Mitigation Strategy (REMS) certification is required. REMS is a program required by the FDA to help ensure that the benefits of a drug outweigh its risks.^{1,4}

Each eculizumab has its own REMS program. BKEMV is available only through the BKEMV REMS, a restricted distribution program because of the risk of serious meningococcal infections.¹

Visit BKEMV.com to learn more



Additional support and resources are available at BKEMV.com

Please see Important Safety Information below and click here for the [full Prescribing Information](#), including Medication Guide for BKEMV.



Accessing Patient Support

You Can Assist Your Patients With Enrolling in Amgen By Your Side

Amgen By Your Side is a support program for patients prescribed BKEMV.

The Amgen By Your Side Team is led by a Patient Access Liaison (PAL). The PAL is a dedicated support partner who helps investigate, explain, and educate on the steps in the treatment experience. They are your patient's point of contact and champion while your patient is accomplishing their treatment goals.



Patients will communicate with the same assigned PAL each time they reach out for assistance.



Amgen SupportPlus Co-Pay Program

The Amgen SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.†

Visit [Amgen SupportPlus Co-Pay Program](#) or call (866) 264-2778 for more information.

†Eligibility criteria and program maximums apply. See [AmgenSupportPlus.com/copay](#) for full Terms and Conditions.



Enroll Your Patients



Important Safety Information (continued)

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.
- Patients receiving ecuzumab 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.

Ecuzumab 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 ecuzumab 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 ecuzumab 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.

ACIP = Advisory Committee on Immunization Practices.

SOLIRIS is a registered trademark of Alexion Pharmaceuticals, Inc.

References: 1. BKEMV® (eculizumab-aeeb) Prescribing Information, Amgen. 2. US Food and Drug Administration. FDA approves first interchangeable biosimilar for two rare diseases. [www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-two-rare-diseases](#). Accessed November 5, 2025. 3. US Food and Drug Administration. Biological license application approval letter for BKEMV (eculizumab-aeeb) injection. May 2024. [www.fda.gov/drugs/biosimilars/biosimilar-product-information](#). Accessed November 5, 2025. 4. SOLIRIS® (eculizumab) Prescribing Information, Alexion. 2025. 5. Kulasekararaj A, Lanza F, Arvanitakis A, et al. Comparative clinical efficacy and safety of biosimilar ABP 959 and ecuzumab reference product in patients with paroxysmal nocturnal hemoglobinuria. *Am J Hematol*. 2024;99:2108-2117. 6. US Food and Drug Administration. 9 things to know about biosimilars and interchangeable biosimilars. [www.fda.gov/drugs/things-know-about/9-things-know-about-biosimilars-and-interchangeable-biosimilars](#). Accessed November 5, 2025.

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 ecuzumab products treatment has not been established. Therefore, treatment with ecuzumab products should not alter anticoagulant management.

Infusion-Related Reactions

Administration of ecuzumab 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 ecuzumab. 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 (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea
- the aHUS single arm prospective trials (≥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 (≥10%) in adult patients is musculoskeletal pain

Drug Interactions

- Concomitant use of ecuzumab 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 ecuzumab product concentrations and requires a supplemental dose of BKEMV.
- Concomitant use of ecuzumab products with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of ecuzumab products. Closely monitor for reduced effectiveness of BKEMV.

Please click here for [full Prescribing Information](#) and [Medication Guide](#) for BKEMV.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](#), or call 1-800-FDA-1088.