

GETTING STARTED WITH BKEMV[®] (eculizumab-aeab)



BKEMV[®] (eculizumab-aeab) is a prescription medicine used to treat:

- ▶ people with paroxysmal nocturnal hemoglobinuria (PNH).
- ▶ people with atypical hemolytic uremic syndrome (aHUS).

BKEMV is not for use in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

- ▶ adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

It is not known if BKEMV is safe and effective in children with PNH.

Please see **full Important Safety Information** on pages 18-19.

FDA, Food and Drug Administration.

BKEMV is a prescription medicine that is administered through intravenous infusion.



ABOUT **YOUR DIAGNOSIS**

gMG

Generalized Myasthenia Gravis (gMG) affects the way your nerves communicate with your muscles, leading to muscle weakness, which grows worse after the muscle is used. It targets muscles in your eyes, face, neck, arms, and legs.

SYMPTOMS CAN INCLUDE:

- ▶ *Eyelid drooping and blurry or double vision*
- ▶ *Fatigue*
- ▶ *Mobility issues and muscle weakness*
- ▶ *Shortness of breath*
- ▶ *Difficulty chewing and swallowing*
- ▶ *Difficulty holding head up*
- ▶ *Speech impairment*
- ▶ *Cognitive impairment*

aHUS

Atypical Hemolytic Uremic Syndrome (aHUS), often caused by genetic mutations, happens when your immune system attacks the lining of tiny blood vessels within your body, leading to blood clots and reduced blood flow to your kidneys and other organs.

SYMPTOMS CAN INCLUDE:

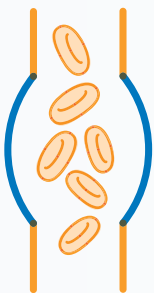
- ▶ *Anemia (lack of red blood cells)*
- ▶ *Kidney dysfunction*
- ▶ *Blood in your urine*
- ▶ *Swelling of the body*
- ▶ *Fatigue*
- ▶ *High blood pressure*
- ▶ *Shortness of breath*
- ▶ *Headaches and seizures*
- ▶ *Double vision*
- ▶ *Gastrointestinal bleeding*
- ▶ *Disease of the heart muscle*
- ▶ *Low platelets*

PNH

Paroxysmal Nocturnal Hemoglobinuria (PNH) is a rare blood disorder caused by a genetic mutation that affects your red blood cells and platelets.

Red blood cells: PNH causes your immune system to mistakenly attack and break down your red blood cells, leading to less oxygen being delivered to your tissues. It also causes the release of hemoglobin into your bloodstream, where it can cause damage to your body, especially your kidneys.

Platelets: PNH causes your platelets to function abnormally, making your blood clot more than it should.



SYMPTOMS CAN INCLUDE:

- ▶ *Fatigue*
- ▶ *Shortness of breath*
- ▶ *Kidney dysfunction*
- ▶ *Blood clots*
- ▶ *Abdominal pain*
- ▶ *Dark urine*
- ▶ *Chest pain*
- ▶ *Anemia (lack of red blood cells)*
- ▶ *Bone-marrow failure*

Important Safety Information

What is the most important information I should know about BKEMV?

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

- **BKEMV increases your chance of getting serious meningococcal infections caused by *Neisseria meningitidis* bacteria that may quickly become life-threatening or cause death if not recognized and treated early.**
 - You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of BKEMV.
 - If you have not been vaccinated and BKEMV must be started right away, you should receive the required vaccine(s) as soon as possible.

Please see **full Important Safety Information** on pages 18-19.

WHAT IS BKEMV?

**BKEMV IS A MEDICINE YOUR DOCTOR
MAY PRESCRIBE TO TREAT:**

gMG	aHUS	PNH
<p>Generalized myasthenia gravis (gMG)</p>	<p>Atypical hemolytic uremic syndrome (aHUS)</p>	<p>Paroxysmal nocturnal hemoglobinuria (PNH)</p>

BKEMV is a biosimilar to the biologic medicine SOLIRIS® (eculizumab).



Important Safety Information (*continued*)

- If you have not been vaccinated and BKEMV must be started right away, you should also receive antibiotics 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. **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 with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

WHAT ARE BIOLOGICS AND BIOSIMILARS?



Biologics are drugs that are produced using a living system, such as a microorganism, plant cell, or animal cell. Like biologics, all biosimilars are made from living sources.

A **biosimilar** is a biologic medicine that is a highly similar version of an already-approved biologic medicine (known as the reference product). The FDA requires that biosimilars show they are highly similar in both effectiveness and safety to their reference product through rigorous testing and clinical studies.



Compared to their reference products, biosimilars are:

- ▶ Given in the same way
- ▶ Expected to provide the same treatment benefit
- ▶ Expected to have the same potential side effects

Amgen biosimilar medicines have been prescribed to over 2 million patients globally



Learn the basics of biosimilars

FDA, Food and Drug Administration.

Important Safety Information (continued)

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last dose of BKEMV. Your risk of meningococcal infection may continue for several weeks after your last dose of BKEMV. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

Please see **full Important Safety Information** on pages 18-19.



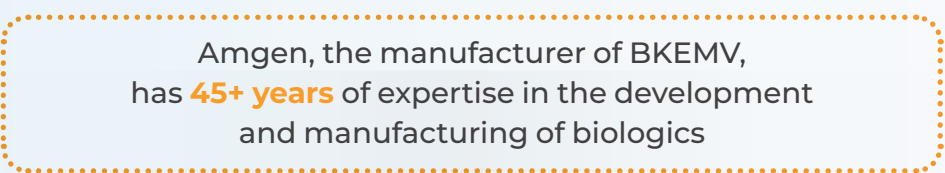
BKEMV IS THE FIRST FDA-APPROVED INTERCHANGEABLE ECULIZUMAB BIOSIMILAR TO SOLIRIS®

BKEMV is the first FDA-approved interchangeable eculizumab biosimilar for rare diseases PNH, aHUS and gMG and is proven to be highly similar to SOLIRIS®, with no clinically meaningful differences.



**BKEMV is
the first FDA-
approved biosimilar
for rare diseases
PNH, aHUS and
gMG**

**BKEMV is an
INTERCHANGEABLE
biosimilar
to SOLIRIS®**



Amgen, the manufacturer of BKEMV,
has **45+ years** of expertise in the development
and manufacturing of biologics

Talk to your doctor about whether BKEMV is right for you

aHUS, atypical hemolytic uremic syndrome; FDA, Food and Drug Administration; gMG, generalized myasthenia gravis; PNH, paroxysmal nocturnal hemoglobinuria.

Important Safety Information (continued)

BKEMV is only available through a program called the BKEMV Risk Evaluation and Mitigation Strategy (REMS). Before you can receive BKEMV, your healthcare provider must:

- enroll in the REMS program
- counsel you about the risk of serious meningococcal infections
- give you information about the signs and symptoms of serious meningococcal infection
- make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start BKEMV right away and you are not up to date on your vaccines
- give you a **Patient Safety Card** about your risk of meningococcal infection.

HOW TO TAKE BKEMV



BKEMV is given to you by a healthcare professional through an intravenous (IV) infusion.



What if my doctor switches me from SOLIRIS® to BKEMV?

BKEMV is as safe and effective as SOLIRIS®. It is given in the **same way**, with the same dose, and on the same schedule as SOLIRIS®.



Talk to your doctor about whether BKEMV is right for you.

If you are switching from SOLIRIS® to BKEMV, **there is no need for you to do another induction phase.**

Important Safety Information (continued)

BKEMV may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- If your child is treated with BKEMV, your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.
- Certain fungal infections (*Aspergillus*) may occur if you take BKEMV and have a weak immune system or a low white blood cell count.

Please see **full Important Safety Information** on pages 18-19.

THE SAME INFUSION SCHEDULE AS WITH SOLIRIS®



ADULTS WILL USUALLY RECEIVE A BKEMV INFUSION:



Every week for the first 5 weeks



Every 2 weeks thereafter

For children younger than 18 years of age with aHUS, the healthcare provider will decide at what dosing and how often they will receive BKEMV, based on their body weight.

Preparing for your infusion



Wear comfortable, **loose-fitting clothing**



Ask your doctor if you should eat, drink, or take any medications before arriving



Bring some things to help **pass the time** (like books, a tablet, or music)



Infusion time is ~ **35 minutes** for adults and **1 to 4 hours** for children.

- ▶ After each infusion, you should be monitored for at least 1 hour for infusion-related reactions.
- ▶ If you have an infusion-related reaction during your BKEMV infusion, your healthcare provider may decide to give BKEMV more slowly or stop your infusion.

For more information on dosage go to [BKEMV.com/dosing](https://www.bkemv.com/dosing)

Important Safety Information (*continued*)

Who should not receive BKEMV?

Do not receive BKEMV if you have a serious meningococcal infection when you are starting BKEMV.

WHAT TO KNOW WHEN STARTING BKEMV

BKEMV, like its reference biologic SOLIRIS®, is a medicine that affects your immune system. It may lower the ability of your immune system to fight infections.

BKEMV increases your chance of getting serious meningococcal infections, which can become life-threatening or cause death if not recognized and treated early. To minimize this risk:

You must 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 BKEMV must be started 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 boosters before starting BKEMV. Your healthcare provider will decide if you need additional meningococcal vaccines.*

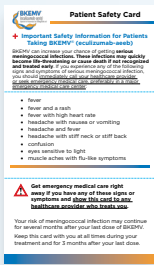
Important Safety Information (continued)

Before you receive BKEMV, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if BKEMV will harm your unborn baby or if it passes into your breast milk.

Please see **full Important Safety Information** on pages 18-19.

BKEMV PATIENT SAFETY CARD

As with the reference biologic SOLIRIS®, BKEMV is only available through a restricted program called Risk Evaluation and Mitigation Strategy (**REMS**). The goal of the BKEMV REMS is to mitigate the risk of serious meningococcal infections. Your healthcare provider will give you a patient safety card to carry with you during and after treatment.



PATIENT SAFETY CARD

Your healthcare provider will give you a **BKEMV REMS Patient Safety Card** detailing the risk of serious meningococcal infection.

You will need to **carry this BKEMV REMS Patient Safety Card with you at all times** while you are receiving BKEMV treatment and for 3 months after your last dose.

Because your risk of meningococcal infection may continue even after your last dose of BKEMV, it is important to **show this card to any healthcare provider who treats you**. This will help them diagnose and treat you quickly.

Important Safety Information (continued)

Who should not receive BKEMV? (continued)

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment. BKEMV and other medicines can affect each other causing side effects. Know the medications you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.



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.

If you lose your BKEMV REMS Patient Safety Card, go to [BKEMVREMS.com](https://www.bkemvrem.com) to download a new copy.

BEFORE YOUR TREATMENT WITH BKEMV

Before you receive BKEMV, tell your healthcare provider about all of your medical conditions, including if you:



- ▶ *Have an infection or fever*
- ▶ *Are pregnant or plan to become pregnant. It is not known if BKEMV will harm your unborn baby*
- ▶ *Are breastfeeding or plan to breastfeed. It is not known if BKEMV passes into your breast milk*

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BKEMV and other medicines can affect each other, causing side effects.



Know the medications you take and the vaccines you have received. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

DURING AND AFTER YOUR TREATMENT WITH BKEMV

It's important to note that meningococcal vaccines and antibiotics do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you experience any of the following signs and symptoms of a serious meningococcal infection during treatment:

SYMPTOMS CAN INCLUDE:

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

Review the [full Prescribing Information](#) and [Medication Guide](#) to learn more about potential side effects and symptoms.

SUPPORT THROUGHOUT YOUR PATIENT JOURNEY



Amgen By Your Side is a **patient-support program** designed specifically for patients like you, patients prescribed **BKEMV**.



CONNECT

You will be connected to one person dedicated to partner with you throughout your treatment experience.



COORDINATE

You will receive support on topics from insurance and financial support to coordinating appointments and more.



CHAMPION

Your dedicated partner will empower you—through education and resources—to be focused, motivated, and committed to maintaining your treatment goals.



Please see **full Important Safety Information** on pages 18-19.

PAL SUPPORT

After you have enrolled, you will be paired with a dedicated support partner called a **Patient Access Liaison (PAL)**.

PAL SUPPORT

Your PAL will serve as your partner to support and champion you while accomplishing your treatment goals. They will provide you with nonmedical, personalized support to help as you navigate your unique experience. Your PAL can educate and assist you with:



- ▶ *Learning about insurance coverage criteria and approval processes*
- ▶ *Understanding financial support options*
- ▶ *Understanding infusion appointment-related information*
- ▶ *Discussing what to expect at the start of treatment*
- ▶ *Receiving reminders to help stay on BKEMV as prescribed*
- ▶ *Discovering ways to connect with others, if interested (examples include being introduced to patient groups)*
- ▶ *Determining how treatment, as prescribed, can fit into your routine*
- ▶ *Providing information about additional resources or advocacy groups*

HOW TO ENROLL IN AMGEN BY YOUR SIDE

Once you and your doctor decide that BKEMV is right for you, you can enroll in **Amgen By Your Side**.

THERE IS NO COST TO ENROLL, AND YOU CAN ENROLL IN ONE OF 2 WAYS:

OPTION 1



Sign up through your doctor's office. They can start the enrollment on AmgenByYourSide.com and submit it for you. Your consent will be required.

OPTION 2



If you have a prescription for BKEMV, call 1-866-402-5622 to get connected. A Patient Access Liaison will help explain the enrollment options.

Once enrollment is complete, your Patient Access Liaison will be your dedicated partner to help as you get started and continue your treatment as prescribed by your doctor.

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



- May pay as little as \$0* out-of-pocket per month for each dose
- Can be applied to deductible, co-insurance, and co-payment*
- No income eligibility requirement

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

Self-enroll online at
AmgenSupportPlus.com/copay



Please see
**full Important
Safety Information**
on pages 18-19.



INDICATION AND IMPORTANT SAFETY INFORMATION

APPROVED USE

BKEMV® (eculizumab-aeeb) is a prescription medicine used to treat:

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IMPORTANT SAFETY INFORMATION

What is the most important information I should know about BKEMV?

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- You must complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of BKEMV.
- If you have not been vaccinated 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 BKEMV must be started right away, you should also receive antibiotics 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. **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 with high heart rate, headache and fever, confusion, muscle aches with flu-like symptoms, fever and rash, headache with nausea or vomiting, headache with a stiff neck or stiff back, or eyes sensitive to light.

Your healthcare provider will give you a Patient Safety Card about the risk of serious meningococcal infection. Carry it with you at all times during treatment and for 3 months after your last dose of BKEMV. Your risk of meningococcal infection may continue for several weeks after your last dose of BKEMV. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

BKEMV is only available through a program called the BKEMV Risk Evaluation and Mitigation Strategy (REMS). Before you can receive BKEMV, your healthcare provider must:

- enroll in the REMS program
- counsel you about the risk of serious meningococcal infections
- give you information about the signs and symptoms of serious meningococcal infection

Please click to see the BKEMV full [Prescribing Information](#), including [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (continued)

- make sure that you are vaccinated against serious infections caused by meningococcal bacteria, and that you receive antibiotics if you need to start BKEMV right away and you are not up to date on your vaccines
- give you a **Patient Safety Card** about your risk of meningococcal infection.

BKEMV may also increase the risk of other types of serious infections, including *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria gonorrhoeae*.

- If your child is treated with BKEMV, your child should receive vaccines against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib).
- Certain people may be at risk of serious infections with gonorrhea. Talk to your healthcare provider about whether you are at risk for gonorrhea infection, about gonorrhea prevention, and regular testing.
- Certain fungal infections (*Aspergillus*) may occur if you take BKEMV and have a weak immune system or a low white blood cell count.

Who should not receive BKEMV?

Do not receive BKEMV if you have a serious meningococcal infection when you are starting BKEMV.

Before you receive BKEMV, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if BKEMV will harm your unborn baby or if it passes into your breast milk.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment. BKEMV and other medicines can affect each other causing side effects. Know the medications you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

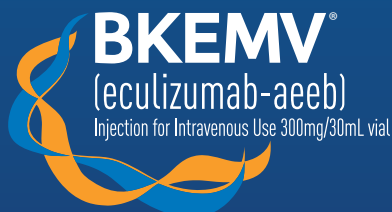
What are the possible side effects of BKEMV?

BKEMV can cause serious side effects, including serious infusion-related reactions. Tell your healthcare provider or nurse right away if you get any of these symptoms during your BKEMV infusion: headache, back pain, diarrhea, upper respiratory infection, urinary tract infections, fever, pain in your abdomen, pain or swelling of your nose or throat, common cold, cough, nausea, vomiting, chest pain, high blood pressure, low red blood cell count, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, swelling of legs or feet, muscle and joint pain, and feeling faint or passing out. If you have an infusion-related reaction to BKEMV, your healthcare provider may need to infuse BKEMV more slowly, or stop BKEMV.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of BKEMV. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at [1-800-FDA-1088](tel:1-800-FDA-1088).

Please click to see the BKEMV full [Prescribing Information](#), including [Medication Guide](#).



BKEMV® is a registered trademark of Amgen Inc.

SOLIRIS® is a registered trademark of Alexion Pharmaceuticals, Inc.

Please see **full Important Safety Information** on pages 18-19.

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