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

Resource Guide

BKEMV (eculizumab-aeeb) is a biosimilar to SOLIRIS® (eculizumab) backed by Amgen expertise[1]

Reimbursement Disclaimer

This resource intended as a reference for coding and billing for product and associated services. It is not intended to be directive. Amgen does not guarantee coverage or reimbursement with the codes in this guide. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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).

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious** and **life-threatening or fatal meningococcal infections.**

AMGEN

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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.**

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

HOW SUPPLIED / STORAGE AND HANDLING[1]

HOW SUPPLIED[1]

BKEMV (eculizumab-aeeb) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution supplied as one 300 mg/30 mL (10 mg/mL) single-dose vial per carton (NDC 55513-180-01).

STORAGE AND HANDLING[1]

- Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use.
- Store in original carton at controlled room temperature (not more than 25°C (77°F)) for only a single period up to 7 days.
- Do not use beyond the expiration date stamped on the carton.

Refer to Prescribing Information on the stability and storage of diluted solutions of BKEMV.

DO NOT FREEZE OR SHAKE.

Important Safety Information (cont'd)

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS (cont'd)

- **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.

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DOSING AND ADMINISTRATION[1]

RISK EVALUATION AND MITIGATION STRATEGY (REMS) INFORMATION

Healthcare providers must be certified in the BKEMV Risk Evaluation and Mitigation Strategy (REMS) to prescribe BKEMV.

BKEMV is available only through a restricted program under a REMS because of the risk of serious meningococcal infections. The goal of the BKEMV REMS is to mitigate the risk of serious meningococcal infections.

All eculizumab products have the same REMS requirements per the FDA. All healthcare providers, patients, healthcare settings, pharmacies, and wholesalers-distributors involved with BKEMV must comply with the BKEMV REMS requirements.

Call BKEMV REMS Coordinating Center at 1-866-718-6927 Monday to Friday 8:00 am – 8:00 pm ET, or visit **BKEMVREMS.com** for more information.

ADMINISTRATION[1]

Administer only as an intravenous (IV) infusion. *Do not administer as an intravenous push or bolus*.

- Administer over 35 minutes in adults and 1 to 4 hours in pediatric patients via gravity feed, a syringe-type pump, or an infusion pump. Admixed solutions of BKEMV are stable for 64 hours at 2°C to 8°C (36°F to 46°F) or 24 hours at room temperature.
- If adverse reaction occurs: Infusion may be slowed or stopped. If slowed, total infusion time should not exceed two hours in adults.
- Monitor for at least 1 hour following infusion for signs or symptoms of an infusion-related reaction.

Amgen By Your Side offers a wide array of patient-focused services to support your patients throughout the journey.

LEARN MORE ON PAGE 13.

Important Safety Information (cont'd)

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

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DOSING AND ADMINISTRATION[1] (cont'd)

RECOMMENDED DOSAGE REGIMENS

PNH — FOR PATIENTS 18 YEARS OF AGE AND OLDER

- 600 mg weekly for the first 4 weeks, followed by
- 900 mg for the fifth dose 1 week later, then
- 900 mg every 2 weeks thereafter.

aHUS — FOR PATIENTS 18 YEARS OF AGE AND OLDER

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

aHUS — FOR PATIENTS YOUNGER THAN 18 YEARS OF AGE (based on body weight)

Body Weight	Induction	Maintenance
40 kg and over	900 mg weekly for the first 4 weeks	1200 mg at week 5; then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly for the first 2 weeks	900 mg at week 3; then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly for the first 2 weeks	600 mg at week 3; then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg single dose at week 1	300 mg at week 2; then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg single dose at week 1	300 mg at week 2; then 300 mg every 3 weeks

gMG - FOR ADULT PATIENTS

- 900 mg weekly for the first 4 weeks, followed by
- 1200 mg for the fifth dose 1 week later, then
- 1200 mg every 2 weeks thereafter.

Induction phase is not repeated when patients switch from SOLIRIS® to BKEMV.[1,2]

Administer BKEMV at the recommended dosage regimen time points, or within two days of these time points.

Dose Adjustment in Case of Plasmapheresis, Plasma Exchange, Fresh Frozen Plasma Infusion or IVIg.

For adult and pediatric patients with aHUS, and adult patients with gMG, supplemental dosing of BKEMV is required in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion.

Please see the full dosing information in the PI for full information.

PNH = paroxysmal nocturnal hemoglobinuria; aHUS = atypical hemolytic uremic syndrome; gMG = generalized myasthenia gravis.

Important Safety Information (cont'd)

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.

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

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

CODING

CODING INFORMATION

NDC	**55513-180-01:** Single-dose vial of 300 mg of BKEMV in 30 mL (10 mg/mL)
11-DIGIT NDC*	**55513-0180-01**
HCPCS CODE	**Q5152:** Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
MODIFIERS	**JZ:** Zero drug amount discarded/not administered to any patient
	JW: Drug amount discarded/not administered to any patient
	RE: Furnished in full compliance with FDA-mandated Risk Evaluation and Mitigation Strategy (REMS)
REVENUE CODES†	**Medicare: 0636** (Drugs requiring detailed coding) **Other payers: 0250** (General pharmacy) or **0636**, if required by a given payer

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

NDC = National Drug Code; HCPCS = Healthcare Common Procedure Coding System; CPT= Current Procedural Terminology; FAR/DFARS = Federal Acquisition Regulation/Defense Federal Acquisition Regulation Supplement; ICD-10-PCS = International Classification of Diseases, Tenth Revision, Procedure Coding System.

*The NDC has been "zero-filled" to create an 11-digit code that meets HIPAA format standards.

†Revenue codes are only required on the CMS-1450 claim form.

Important Safety Information (cont'd)

Other Infections (cont'd)

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.

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CODING (cont'd)

CODING INFORMATION

CPT	**96365:** Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	+ 96366: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
	96413: Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug
	+ 96415: Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to primary procedure)
ICD-10-PCS (hospital inpatient only)	**3E033GR:** Introduction of other therapeutic monoclonal antibody into peripheral vein, percutaneous approach
	3E043GR: Introduction of other therapeutic monoclonal antibody into central vein, percutaneous approach

The CPT® codes listed above may be appropriate product administration codes. Providers should check with individual payers and consult CPT® coding guidelines to determine the appropriate administration codes.

Important Safety Information (cont'd)

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.

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CODING (cont'd)

PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)

ICD-10-CM	**D59.5:** Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]

ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)

ICD-10-CM	**D59.30:** Hemolytic-uremic syndrome, unspecified
	D59.32: Hereditary hemolytic uremic syndrome • Atypical hemolytic uremic syndrome with an identified genetic cause
	D59.39: Other hemolytic uremic syndrome • Atypical (nongenetic) hemolytic uremic syndrome • Secondary hemolytic uremic syndrome

GENERALIZED MYASTHENIA GRAVIS (gMG)

ICD-10-CM	**G70.00:** Myasthenia gravis without (acute) exacerbation
	G70.01: Myasthenia gravis with (acute) exacerbation

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and always select the most appropriate diagnosis code(s) with the highest level of specificity to describe a patient's actual condition.

ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

Important Safety Information (cont'd)

Monitoring Disease Manifestations after BKEMV Discontinuation (cont'd)

Treatment Discontinuation for aHUS: (cont'd)

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.

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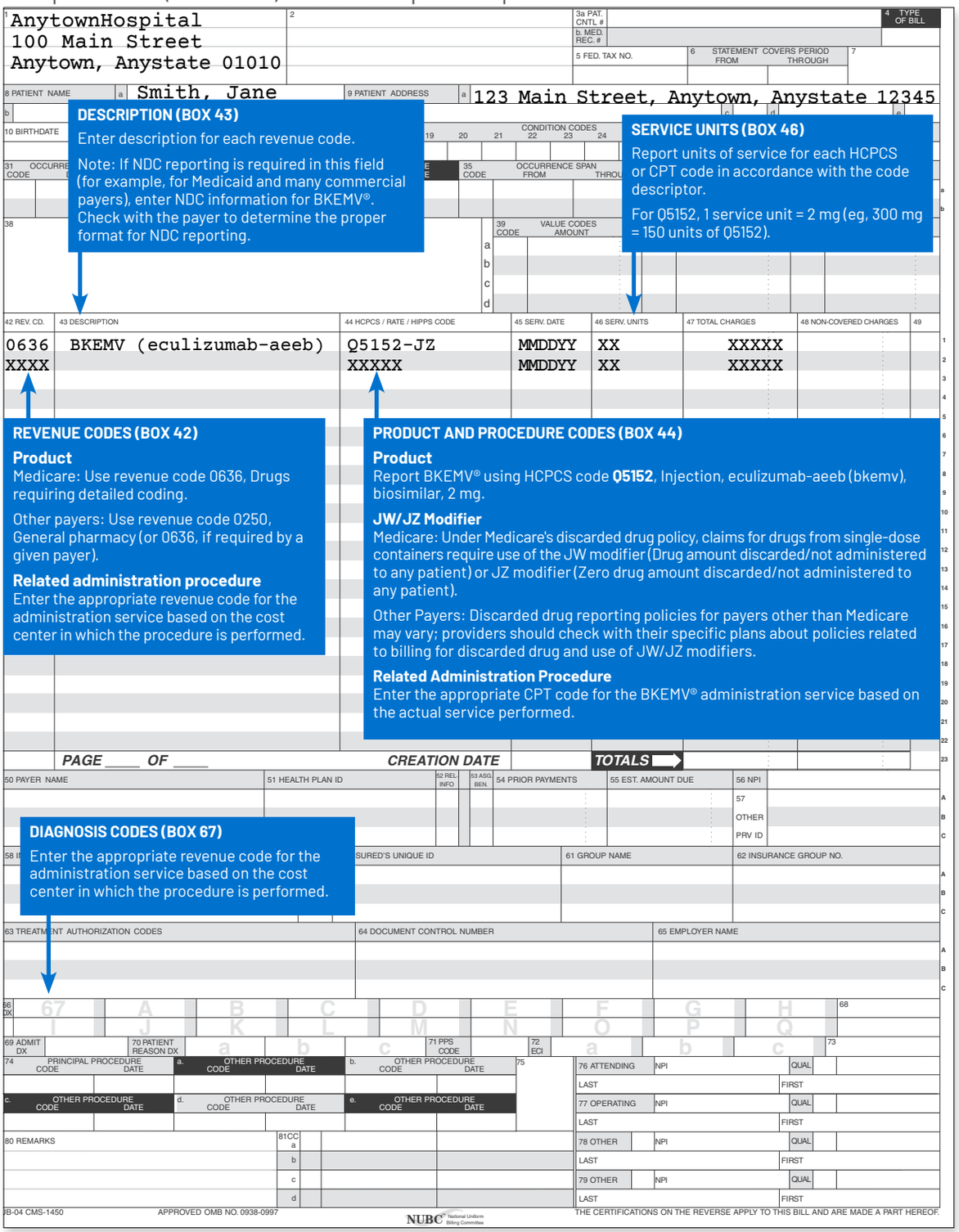
The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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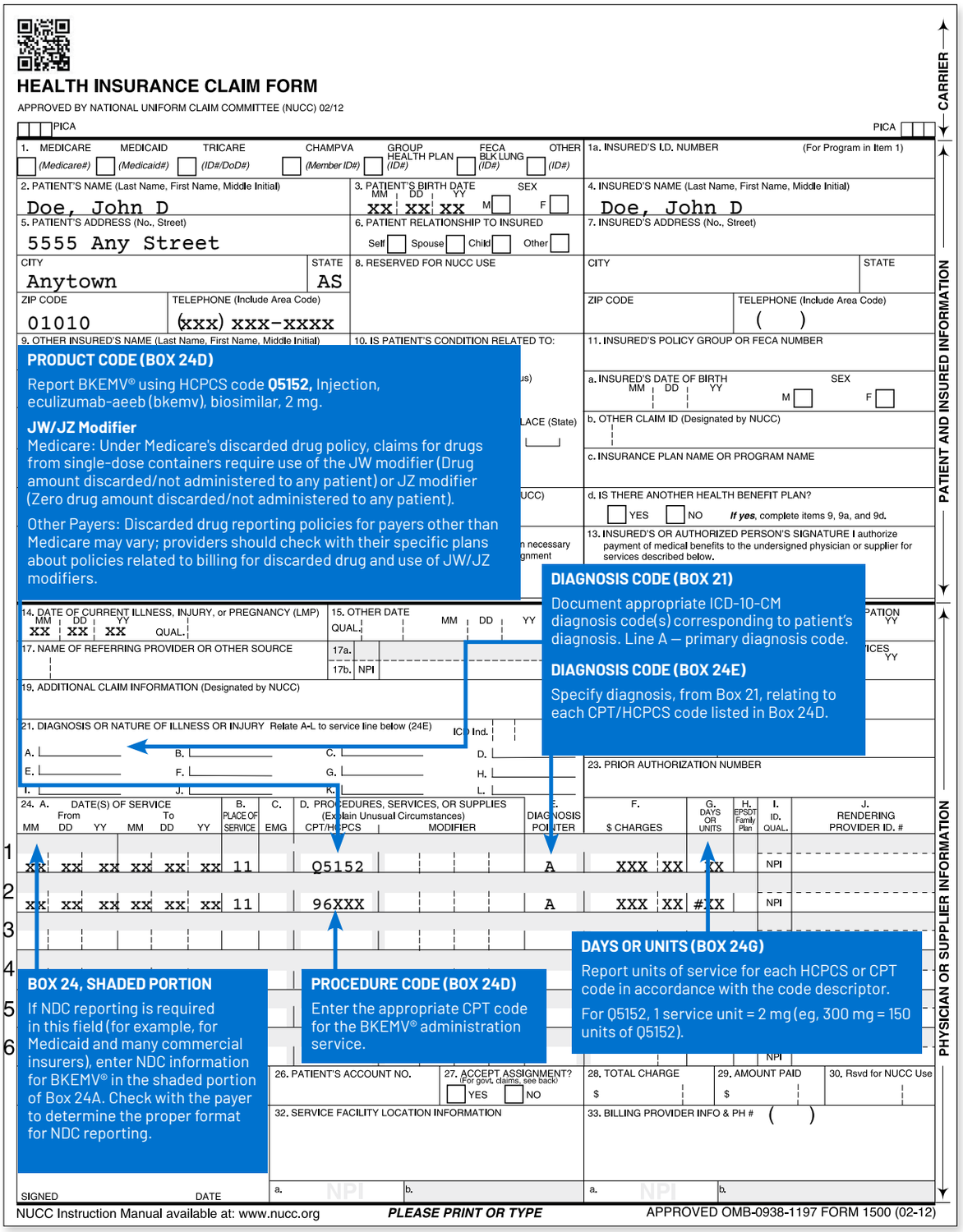
The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



PRODUCT CODE (BOX 24D)

Report BKEMV® using HCPCS code **Q5152,** Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg.

JW/JZ Modifier

Medicare: Under Medicare's discarded drug policy, claims for drugs from single-dose containers require use of the JW modifier (Drug amount discarded/not administered to any patient) or JZ modifier (Zero drug amount discarded/not administered to any patient).

Other Payers: Discarded drug reporting policies for payers other than Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of JW/JZ modifiers.

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

BOX 24, SHADED PORTION

If NDC reporting is required in this field (for example, for Medicaid and many commercial insurers), enter NDC information for BKEMV® in the shaded portion of Box 24A. Check with the payer to determine the proper format for NDC reporting.

PROCEDURE CODE (BOX 24D)

Enter the appropriate CPT code for the BKEMV® administration service.

DAYS OR UNITS (BOX 24G)

Report units of service for each HCPCS or CPT code in accordance with the code descriptor.

For Q5152, 1 service unit = 2 mg (eg, 300 mg = 150 units of Q5152).

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BKEMV PRODUCT FACT SHEET

INDICATIONS[1]

BKEMV is a complement inhibitor indicated for:

- 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).

PRODUCT INFORMATION

NDC	Description	Quantity
55513-180-01	300 mg of BKEMV in 30 mL (10 mg/mL)	One single-dose vial per carton

STORAGE AND HANDLING REQUIREMENTS

Store BKEMV vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. BKEMV vials may be stored in the original carton at controlled room temperature (not more than 25°C (77°F)) for only a single period up to 7 days. Do not use beyond the expiration date stamped on the carton. Refer to Prescribing Information for information on the stability and storage of diluted solutions of BKEMV. DO NOT FREEZE. DO NOT SHAKE.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.

amgen.com

BKEMV.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

MEDICAL INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Call Amgen By Your Side at 866-402-5622 Monday to Friday 8:00 am to 5:00 pm CST, or visit https://www.bkemv.com/support-and-resources. You may also contact us at BKEMVABYS@amgen.com.

Important Safety Information (cont'd)

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.

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

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ORDERING INFORMATION

To order BKEMV, please refer to the list of Specialty Distributors below. BKEMV is available in a single-dose vial.

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

PRODUCT INFORMATION

Product Description	NDC	Q-Code	Billing Unit
300 mg/30 mL (10 mg/mL) single-dose vial	55513-0180-01	Q5152	150 billing units*

*1 billing unit = 2 mg

SPECIALTY DISTRIBUTOR LIST

Contact Information	BKEMV 300 mg/30 mL (10 mg/mL) single-dose vial item #
ASD Healthcare Ph: 800.837.5403 asdhealthcare.com	10298506
Besse Medical Ph: 800.543.2111 besse.com	10298505
BioCare Specialty Distribution Ph: 800.304.3064 biocare-us.com	1001271
Cardinal Health Specialty Hosp/Multi. Specialty Ph: 855.855.0708 PCP Ph: 877.451.3972 cardinalhealth.com	5972377
M&D Specialty Distribution Ph: 800.710.6100 mdspecialtydist.com	50436
CuraScript Specialty Distribution Ph: 877.599.7748 curascriptsd.com	10006549
McKesson Plasma & Biologics Ph: 877.625.2566 mckesson.com	3024585
McKesson Specialty Health Ph: 415.983.8300 mckesson.com	5019896
Oncology Supply Ph: 800.633.7555 oncologysupply.com	10298455

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

SUPPORT SERVICES

Amgen By Your Side is a support program for patients prescribed BKEMV.
Our dedicated team is your patient's partner, committed to providing non-medical support to help patients as they start and continue on treatment as you prescribe.

OUR MISSION IS TO CONNECT, COORDINATE, AND CHAMPION YOUR PATIENT AT THE IMPORTANT STEPS ALONG THE WAY:

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

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

Champion
Your patient's dedicated partner will empower them to be confident self-advocates for maintaining treatment goals

PATIENT ACCESS LIAISON*

The non-medical 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. The PAL can educate and assist your patient in:

- Learning about their insurance coverage criteria and approval process.
- Understanding financial assistance options.
- Understanding infusion appointment-related information.
- Discussing what to expect at the start of treatment.
- Determining how treatment can fit into their routine.
- Receiving reminders to help stay on treatment as directed.
- Discovering ways to connect with others, if interested.
- Connecting patients to external resources or advocacy groups that may provide additional support.

TO ENROLL, DOWNLOAD THE PATIENT ENROLLMENT FORM AT HTTPS://WWW.BKEMV.COM/SUPPORT-AND-RESOURCES

*The Patient Access Liaison is not part of a patient's treatment team and does not provide medical advice or administer medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

AMGEN Support+ | Co-Pay Program

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

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

Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay

†Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions. Patients who are residents of Massachusetts or Rhode Island are not eligible for administration support.

Call Amgen By Your Side at 866-402-5622
Monday to Friday 8:00 am to 5:00 pm CST, or visit https://www.bkemv.com/support-and-resources.

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.**

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IMPORTANT SAFETY INFORMATION

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- **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.

Please see continued Important Safety Information on the next page.

IMPORTANT SAFETY INFORMATION (cont'd)

Monitoring Disease Manifestations after BKEMV Discontinuation (cont'd)

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 (≥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 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.

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

References: 1. BKEMV (eculizumab-aeeb) Prescribing Information, Amgen. **2.** Kulasekararaj A, Lanza F, Arvanitakis A, et al. Comparative clinical efficacy and safety of biosimilar ABP 959 and eculizumab reference product in patients with paroxysmal nocturnal hemoglobinuria. *Am J Hematol*. 2024;99(11):2108-2117.

Reimbursement Disclaimer

This resource is intended as a reference for coding and billing for product and associated services. It is not intended to be directive. Amgen does not guarantee coverage or reimbursement with the codes in this guide. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see **full Important Safety Information** on pages 14 and 15 and **full Prescribing Information** including **Boxed WARNING regarding serious** and **life-threatening or fatal meningococcal infections.**

Please visit www.BKEMV.com for additional information and resources.

Call 1-800-77-AMGEN (1-800-772-6436) if you have questions about the preparation and administration of BKEMV.

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