EMPAVELI™
(pegcetacoplan) injection
1080 mg/20 mL solution

Frequently asked questions (FAQs)

INDICATION

EMPAVELI is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

Meningococcal infections may occur in patients treated with EMPAVELI and may become rapidly life-threatening or fatal if not recognized and treated early. Use of EMPAVELI may predispose individuals to serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria.
- Vaccinate patients at least 2 weeks prior to administering the first dose of EMPAVELI unless the risks of delaying therapy with EMPAVELI outweigh the risk of developing a serious infection.
- Vaccination reduces, but does not eliminate, the risk of serious infections. Monitor patients for early signs of serious infections and evaluate immediately if infection is suspected.

EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the EMPAVELI REMS, prescribers must enroll in the program.

Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 8-9, and full Prescribing Information and Medication Guide.

Initiating a patient on EMPAVELI

Q | Will my patient continue taking C5 inhibition while starting treatment with EMPAVELI?

- **Eculizumab:** If switching from eculizumab, your patient will continue to take their current dose of eculizumab in addition to a twice-weekly subcutaneous dose of 1080 mg EMPAVELI for the first 4 weeks. After 4 weeks, your patient will discontinue their C5 inhibitor and continue with EMPAVELI monotherapy.[1]
- **Ravulizumab:** If switching from ravulizumab, your patient will initiate EMPAVELI no more than 4 weeks after the last dose of ravulizumab.[1]

Q | When does my patient stop treatment with C5 inhibition and continue only on EMPAVELI?

- **Eculizumab:** If switching from eculizumab, your patient will stop treatment with their C5 inhibitor after 4 weeks and continue on with EMPAVELI monotherapy.[1]
- **Ravulizumab:** If switching from ravulizumab, your patient will initiate EMPAVELI no more than 4 weeks after the last dose of ravulizumab.[1]

Q | Is the concomitant therapy period required? What is the purpose of this?

Yes, the concomitant therapy period is required. The purpose of this period is to help reduce the risk of hemolysis with abrupt treatment discontinuation.[1]

- **Eculizumab:** If switching from eculizumab, your patient will continue to take their current dose of eculizumab in addition to a twice-weekly subcutaneous dose of 1080 mg EMPAVELI for the first 4 weeks. After 4 weeks, your patient will discontinue their C5 inhibitor and continue with EMPAVELI monotherapy.[1]
- **Ravulizumab:** If switching from ravulizumab, your patient will initiate EMPAVELI no more than 4 weeks after the last dose of ravulizumab.[1]

Q | How do I start a patient who is new to treatment for PNH on EMPAVELI?

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib).[1] For this reason, you must enroll in the EMPAVELI REMS program before starting your patient on EMPAVELI.[1]

To reduce the risk of infection, all patients must be:

- Vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation of EMPAVELI therapy according to current Advisory Committee on Immunization Practices (ACIP) guidelines *[see Warnings and Precautions (5.1)]*.[1]
- Provided with 2 weeks of antibacterial drug prophylaxis if EMPAVELI must be initiated immediately and patients were vaccinated less than 2 weeks before starting therapy with EMPAVELI.[1]

PNH=paroxysmal nocturnal hemoglobinuria.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- Not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism
- Unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae*

Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 8-9, and full Prescribing Information and Medication Guide.

Initiating a patient on EMPAVELI (cont'd)

Q | How do I start a patient who is taking a C5 inhibitor on EMPAVELI?

Once you've enrolled in the EMPAVELI REMS program, ensure all patients are vaccinated against encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib) according to the most current ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies. Provide 2 weeks of antibacterial drug prophylaxis to patients if EMPAVELI must be initiated immediately and vaccines are administered less than 2 weeks before starting therapy with EMPAVELI.[1]

Q | What is the starting dose of EMPAVELI for patients with PNH?

The recommended dose of EMPAVELI is 1080 mg by subcutaneous infusion twice weekly via a commercially available infusion pump with a reservoir of at least 20 mL. EMPAVELI is intended for use under the guidance of a healthcare professional. After proper training in subcutaneous infusion, a patient may self-administer, or the patient's caregiver may administer EMPAVELI, if a healthcare provider determines that it is appropriate.[1]

EMPAVELI data-related questions

Q | What is C3-loading? What is the clinical significance of C3-loading?

C3-loading is the coating of PNH RBCs with C3 fragments, which can be caused by continued activation of the complement cascade. C3-loading can trigger PNH RBC destruction via hemolysis, which may result in a continued transfusion requirement in a proportion of patients.[2]

Q | Why were the PEGASUS primary efficacy endpoint data, change from baseline to Week 16 in Hb level, censored for transfusions?

Primary endpoint analysis of the PEGASUS data is censored for transfusion. Transfusions could confound the results, so data after the first transfusion for all patients were not included in the primary analysis. Post-transfusion data were omitted once they had a transfusion and their data was modeled out for the remainder of the 16-week randomized control period.[3,4]

Q | Why were the PEGASUS key secondary endpoints tested in a hierarchical manner?

As there were multiple secondary endpoints in the PEGASUS study, key secondary endpoints were tested in a hierarchical manner according to their clinical importance. If an endpoint did not meet noninferiority, all subsequent endpoints were not statistically tested.[3,4]

ACIP=Advisory Committee on Immunization Practices; Hb=hemoglobin; RBC=red blood cell.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib). To reduce the risk of infection, all patients must be vaccinated against these bacteria according to the most current ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI.

Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 8-9, and full Prescribing Information and Medication Guide.

EMPAVELI data-related questions (cont'd)

Q | Did the PEGASUS study include only anemic patients with a history of transfusions?

A history of transfusions was not an eligibility requirement for enrollment in the PEGASUS study. Eligibility requirements for the PEGASUS study included patients with PNH who had been treated with a stable dose of eculizumab for at least the previous 3 months and had Hb levels <10.5 g/dL. Patients were stratified based on the number of transfusions within the 12 months prior (<4 or ≥4).[1] Of the total study population, 25% of patients received 0 transfusions within the last 12 months.[5]

Q | How is transfusion avoidance different from transfusion independence?

Transfusion avoidance and transfusion independence are synonymous. In PEGASUS, transfusion avoidance was defined as the proportion of subjects who did not require a transfusion during the study during the 16-week randomized control period.[5]

Q | Why didn't LDH meet noninferiority?

Based on observations of post-treatment LDH levels and statistical analysis rules, noninferiority was not met in change from baseline at Week 16 in LDH. Specifically, the upper bound of the 95% confidence interval for the difference between EMPAVELI and eculizumab treatment groups was not less than the prespecified noninferiority margin of 20 U/L.[3,4]

EMPAVELI safety

Q | What were the serious adverse reactions?

Serious adverse events were reported in 7 (17%) patients with PNH receiving EMPAVELI. The most common serious adverse reaction in patients treated with EMPAVELI was infections (5%).[1]

Q | What were the most common adverse reactions?

The most common adverse reactions (≥10%) with EMPAVELI were injection-site reactions, infections, diarrhea, abdominal pain, respiratory tract infection, viral infection, and fatigue.[1]

Q | Why does EMPAVELI have a REMS program?

The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B (Hib). For this reason, EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), prescribers must enroll in the program.[1]

LDH=lactate dehydrogenase.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria (cont'd)

For patients without known history of vaccination, administer required vaccines at least 2 weeks prior to receiving the first dose of EMPAVELI. If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis.

Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 8-9, and full Prescribing Information and Medication Guide.

EMPAVELI safety (cont'd)

Q | How do I enroll in REMS?

You can enroll in the REMS program by visiting empavelirems.com before writing your first prescription. You will only need to enroll once. Additionally, you must also counsel patients about the risk of serious infections, provide the patients with the REMS educational materials, and ensure patients are vaccinated against encapsulated bacteria.[1]

Patient support and self-infusion training

Q | Are my patients eligible for the support available through ApellisAssist™?

In order to receive all of the training/services and resources offered through ApellisAssist, your patient must first opt in by completing the EMPAVELI Start Form.

Q | What support/resources are available to help my patients learn how to self-infuse EMPAVELI?

Apellis is committed to ensuring patients are informed and supported as they start and continue therapy with EMPAVELI. Every patient will be assigned a Care Coordinator through our specialty pharmacy, PANTHERx Rare, and an Apellis Care Educator. The Care Educator provides self-infusion training, education, and ongoing product support. In addition to infusion training support, we offer a variety of helpful resources for patients getting started on EMPAVELI through ApellisAssist, including:

- **The CareKit by Apellis™** includes infusion supplies, educational resources, and wellness items they can select to make the treatment experience more comfortable
- **HOME SUITE HOME** provides patients with My Infusion Studio, a storage container to help patients organize their treatment supplies at home in a seamless, organized way

ACCOMPANYING RESOURCES: The **Patient Self-Infusion Guide** and the **Self-Infusion Video**
Along with HOME SUITE HOME and the CareKit by Apellis, the Patient Self-Infusion Guide and the Self-Infusion Video are both informative resources to help patients learn how to self-infuse.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria (cont'd)

Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI REMS

Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers must enroll in the program and must counsel patients about the risk of serious infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated against encapsulated bacteria. Enrollment and additional information are available by telephone: 1-888-343-7073 or at www.empavelirems.com.

Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 8-9, and full Prescribing Information and Medication Guide.

Patient support and self-infusion training (cont'd)

Q | Will patients be trained to self-infuse EMPAVELI?

Prior to self-administration, a qualified healthcare professional should provide the patient with instructions and training for subcutaneous infusion. If a patient enrolls in the ApellisAssist program, additional resources will be available including self-infusion training by a Care Educator, an infusion training video, email support, and the My Infusion Tracker™ app.

ACCOMPANYING RESOURCES: The **Patient Self-Infusion Guide** and the **Self-Infusion Video** are both educational resources that help support patients as they learn how to self-infuse.

Q | What if my patient is struggling to self-infuse EMPAVELI?

The Apellis Care Educator can provide assistance to patients struggling to self-infuse EMPAVELI through in-person or virtual administration training. The Care Educator is a compassionate care partner with a nursing background who supports patients along their treatment journey.

ACCOMPANYING RESOURCES: The **Patient Self-Infusion Guide** and the **Self-Infusion Video** Along with the help of the Care Educator, the Patient Self-Infusion Guide and the Self-Infusion Video are both informative resources for patients who are struggling to self-infuse EMPAVELI.

Access and reimbursement

Q | Are my patients eligible for financial support programs?

The Care Coordinator, a member of the Apellis Care Team, may be able to help your patients find out if they are eligible for financial support and other logistical, financial, and insurance assistance as needed.

Q | What if my patients have insurance questions?

Patients enrolled in ApellisAssist will have access to a dedicated Care Coordinator through our specialty pharmacy, PANTHERx Rare. The Care Coordinator will explain insurance benefits and coverage options, review financial assistance programs for eligible patients, and help coordinate shipment of product and infusion supplies.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Systemic hypersensitivity reactions (e.g., facial swelling, rash, urticaria) have occurred in patients treated with EMPAVELI. One patient (less than 1% in clinical studies) experienced a serious allergic reaction which resolved after treatment with antihistamines. If a severe hypersensitivity reaction (including anaphylaxis) occurs, discontinue EMPAVELI infusion immediately, institute appropriate treatment, per standard of care, and monitor until signs and symptoms are resolved.

Monitoring PNH Manifestations after Discontinuation of EMPAVELI

After discontinuing treatment with EMPAVELI, closely monitor for signs and symptoms of hemolysis, identified by elevated LDH levels along with sudden decrease in PNH clone size or hemoglobin, or reappearance of symptoms such as fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (including thrombosis), dysphagia, or erectile dysfunction. Monitor any patient who discontinues EMPAVELI for at least 8 weeks to detect hemolysis and other reactions. If hemolysis, including elevated LDH, occurs after discontinuation of EMPAVELI, consider restarting treatment with EMPAVELI.

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Access and reimbursement (cont'd)

Q | What is the Apellis Co-Pay Program?

The Apellis Co-Pay Program for patients with commercial insurance is available to help cover your patients' co-pay and co-insurance costs. Your patient can enroll in ApellisAssist today to see if they are eligible for this program.*†

Q | What if patients have no insurance or limited coverage?

These patients may be eligible for the Apellis Patient Assistance Program (PAP) that can provide EMPAVELI at no cost. To qualify, your patient must:

- Be diagnosed with PNH in accordance with the approved EMPAVELI indication
- Be enrolled in ApellisAssist
- Have no insurance or be underinsured
- Have a prescription for EMPAVELI
- Currently live in the US or a US territory
- Meet financial eligibility criteria

Q | Are there specific codes for billing and coding EMPAVELI?

The following codes may be relevant for billing and coding for EMPAVELI:

- NDC: 74606-010-01
- ICD-10-CM: D59.5

*The Apellis Co-Pay Program is for eligible patients who are enrolled in the ApellisAssist program, who are commercially insured, and who are not covered under government insurance programs such as Medicare, Medicaid, VA/DOD, or TRICARE.

†Program terms are subject to change.

ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Interference with Laboratory Tests

There may be interference between silica reagents in coagulation panels and EMPAVELI that results in artificially prolonged activated partial thromboplastin time (aPTT); therefore, avoid the use of silica reagents in coagulation panels.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥10% of patients) with EMPAVELI vs. eculizumab were injection-site reactions (39% v. 5%), infections (29% v. 26%), diarrhea (22% v. 3%), abdominal pain (20% v. 10%), respiratory tract infection (15% v. 13%), viral infection (12% v. 8%), and fatigue (12% v. 23%).

USE IN SPECIFIC POPULATIONS

Females of Reproductive Potential

EMPAVELI may cause embryo-fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential prior to treatment with EMPAVELI. Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.

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CONTRAINDICATIONS

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- Not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism
- Unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae*

WARNINGS AND PRECAUTIONS

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References: 1. EMPAVELI [prescribing information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; 2021. **2.** McKinley CE, Richards SJ, Munir T, et al. Extravascular hemolysis due to C3-loading in patients with PNH treated with eculizumab: defining the clinical syndrome. *Blood*. 2017;130(suppl 1):3471. **3.** Hillmen P, Szer J, Weitz I, et al. Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. *N Engl J Med*. 2021;384:1028-1037. **4.** Hillmen P, Szer J, Weitz I, et al. Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. *N Engl J Med*. 2021;384(suppl):1-16. **5.** Data on file. Apellis Pharmaceuticals, Inc., Waltham, MA.

Apellis