
Image is an actor portrayal.

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

Starting patients on EMPAVELI

INDICATION

EMPAVELI™ (pegcetacoplan) 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 9-10, and full Prescribing Information and Medication Guide.

Start your patients on EMPAVELI in 3 steps

Here's what to do when you're ready to prescribe:

Enroll in the EMPAVELI REMS

Visit EMPAVELIREMS.com to enroll in the EMPAVELI Risk Evaluation and Mitigation Strategy (REMS) program before writing your first prescription. You will only need to enroll once.

- Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers and pharmacies must enroll in the program
- Prescribers 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. See more information about the EMPAVELI REMS at EMPAVELIREMS.com

Complete the EMPAVELI Start Form

Download the EMPAVELI Start Form at EMPAVELIhcp.com/support.
The EMPAVELI Start Form contains the actual prescription for EMPAVELI.

- Complete the EMPAVELI Start Form in its entirety
- Review the REMS requirements with your patient
- Have them sign the Patient Authorizations on page 1 of the EMPAVELI Start Form
- Review the Patient Authorizations sections on page 4 of the EMPAVELI Start Form with your patient

Fax the EMPAVELI Start Form

Fax the completed EMPAVELI Start Form to ApellisAssist™ at **1-888-754-1285**.

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 9-10, and full Prescribing Information and Medication Guide.

A closer look at the EMPAVELI REMS Program

What Is the EMPAVELI REMS?

This **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is a safety program required by the Food and Drug Administration (FDA) to ensure the potential benefits of EMPAVELI outweigh its risks.

Because of the risk of serious infections, EMPAVELI is available only through a restricted program under a REMS. Under the EMPAVELI REMS, prescribers and pharmacies must enroll in the program.

Prescribers 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.

What do healthcare providers need to do to prescribe EMPAVELI?

To enable prescribing:

Prescribers of EMPAVELI must be enrolled in the REMS to prescribe. To enroll, prescribers must complete the following steps:

step1 Review the EMPAVELI Prescribing Information

step2 Review the Healthcare Provider Brochure

step3 Review the Patient Safety Guide

step4 Review the Patient Safety Card

step5 Complete and submit the Prescriber Enrollment Form to the EMPAVELI REMS at EMPAVELIREMS.com

Prescribers will be notified within 2 business days when their enrollment in the EMPAVELI REMS is complete and they can prescribe EMPAVELI

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 9-10, and full Prescribing Information and Medication Guide.

Things to remember throughout treatment

Before initiating a patient's treatment:

- Assess the patient's vaccination status for the following: *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* Type B (Hib), and immunize patient if needed according to the current ACIP recommendations for vaccinations against encapsulated bacteria in patients with altered immunocompetence associated with complement deficiencies
- If immediate therapy with EMPAVELI is indicated, administer required vaccine as soon as possible and provide patients with 2 weeks of antibacterial drug prophylaxis
- Counsel the patient on:
  - the requirement to vaccinate patients against encapsulated bacteria
  - How to recognize and respond to signs and symptoms of serious bacterial infection, using the **Patient Safety Guide** and **Patient Safety Card**
- Provide the patient with the **Patient Safety Guide** and **Patient Safety Card**

During a patient's treatment:

- Assess patients for early signs and symptoms of serious infection and treat patients immediately if an infection is suspected
- Consider discontinuation of EMPAVELI in patients who are undergoing treatment for serious bacterial infection
- Revaccinate patients in accordance with ACIP recommendations for patients with altered immunocompetence associated with complement deficiencies

At all times:

Report cases of serious bacterial infection, including the patient's clinical outcomes, to Apellis Pharmaceuticals, Inc. by calling 1-833-866-3346. To report an adverse event, visit MedWatch at www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088

Comply with the requirements of the EMPAVELI REMS to maintain certification to prescribe

Comply with requests from the EMPAVELI REMS and its agents or contractors to support the administration of the EMPAVELI REMS

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (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.

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.

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ApellisAssist™ Here for your patients

ApellisAssist is a program designed to help your patients along their treatment journey

ApellisAssist provides your patients with a comprehensive support system throughout their treatment, including:

- FINANCIAL ASSISTANCE FOR ELIGIBLE PATIENTS
- INSURANCE SUPPORT
- SELF-INFUSION TRAINING
- EMPAVELI AND PNH EDUCATION

The Care Team, comprised of the **Care Coordinator** through our specialty pharmacy, PANTHERx Rare, and an Apellis **Care Educator**, will support patients as they prepare to start treatment with EMPAVELI™ (pegcetacoplan). Together, they'll make decisions tailored to your patients' preferences, such as:

- Their preference of in-person or telehealth self-infusion training
- Their preference of communication style
- Their desired frequency of calls or text reminders

Care Coordinator

A dedicated coordinator who will work with patients one-on-one to help:

- Explain their insurance benefits and coverage options
- Review available financial assistance programs
- Manage their product and infusion supply shipments

Care Educator

A compassionate care partner with a nursing background who will help:

- Provide in-person or virtual training and education on how your patients can self-infuse EMPAVELI
- Address any questions about EMPAVELI or PNH

Financial assistance

After your patient is enrolled in ApellisAssist, they may be eligible for one of the following programs. Learn more on the next page

PNH=paroxysmal nocturnal hemoglobinuria.

ApellisAssist is your partner in navigating payment and insurance

Your patients may be eligible for one of the programs below.

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.*†

Patients can sign up for ApellisAssist when you prescribe EMPAVELI™ (pegcetacoplan).

Have your patients sign the Authorizations for Patient Support on the EMPAVELI Start Form to enroll in ApellisAssist.

Patient Assistance Program

Patients with no insurance or limited coverage 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 paroxysmal nocturnal hemoglobinuria (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

ApellisAssist™ **can be reached at**

1-866-MY-APL-ASSIST (1-866-692-7527)
FROM 8 AM–8 PM ET, MONDAY–FRIDAY

ApellisAssist can also connect your patients to a PANTHERx Rare pharmacist who is on call 24 hours per day.

*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.

Multiple options help patients learn how to self-infuse with confidence

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.

Patients can learn about self-infusion through your guidance

A Care Educator can provide step-by-step self-infusion training and support over time. Learn more about Care Educators on page 5

A step-by-step guide for self-infusion is available in the EMPAVELI Instructions for Use

Patients have access to a variety of educational materials to learn more about EMPAVELI™ (pegcetacoplan), including:

- Patient Self-Infusion Guide
- Travel Brochure
- Support When Starting EMPAVELI Guide
- Patient Brochure
- HOME SUITE HOME videos on EMPAVELI.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

EMPAVELI REMS

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Please see Important Safety Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, on pages 9-10, and full Prescribing Information and Medication Guide.

Support that's a step above

Apellis is committed to ensuring patients are informed and supported as they start and continue therapy with EMPAVELI. Once a patient enrolls in ApellisAssist, they will have access to the resources below that can help integrate treatment into their lives.

CareKit by Apellis™

This resource was designed with input from real patients with PNH, who offered thoughtful suggestions about what items were key for making them feel most comfortable when starting a new treatment.

This kit includes infusion supplies, educational resources, and wellness items patients can select to make the most of their treatment experience.

HOME SUITE HOME

Self-infusing EMPAVELI may be new to patients, so making them feel as comfortable as possible is key. This resource helps patients organically integrate the process of self-infusion into their daily lives, providing them with:

- **My Infusion Studio**—A storage container to help patients organize their treatment supplies at home in a seamless, organized way
- **Refrigerator Storage**—Secure refrigerator storage with lock option for EMPAVELI vials
- **HSH TV**—Videos featuring interior designer Genevieve Gorder sharing tips and tricks for integrating EMPAVELI treatment into patients' homes and daily lives

Ongoing support communications

All patients who sign up will receive useful information about PNH, treatment with EMPAVELI, and ongoing treatment support for EMPAVELI. Communications will include topics such as:

- Self-infusion training and education
- Practical tips and tools for setting up an at-home treatment routine
- Details on programs offered by Apellis Community Liaisons

My Infusion Tracker™ App

This app was developed with patients and their caregivers in mind, so they can stay connected to and on top of their treatment with EMPAVELI. The app provides features such as a treatment calendar, self-infusion support tools, infusion resources, FAQs, and integrated assistance with an Apellis Care Educator or Caregiver.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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- **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.**

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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.

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.

Please see full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

EMPAVELI™
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1080 mg/20 mL solution

Start your patients on EMPAVELI

Apellis is committed to ensuring patients are informed and supported as they start and continue therapy with EMPAVELI.

Patients can learn about self-infusion from you, their Care Educator, and through training materials

ApellisAssist™

Patient support is available through ApellisAssist to help get patients started on EMPAVELI

EMPAVELI billing codes | **NDC Number:** 74606-010-01 **ICD-10 Code:** D59.5

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

Visit www.EMPAVELIhcp.com to download the EMPAVELI Start Form and to learn more about starting your patients on EMPAVELI

Reference: EMPAVELI [prescribing information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; 2021.

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Apellis