EMPAVELI® (pegcetacoplan) injection
TRIAL OFFER

HEALTHCARE PROVIDER FORM
Phone: 1-866-MY-APL-ASSIST | (1-866-692-7527)
Fax: 1-888-754-1285

ApellisAssist®

EMPAVELI Trial Offer Start Form

PROGRAM OVERVIEW

The EMPAVELI Trial Offer can provide 8 weeks of EMPAVELI at no cost to your eligible patients with PNH to determine whether EMPAVELI is an appropriate treatment for them.

There is no obligation for your patient to continue use of EMPAVELI after the program has been completed.

Patients may only enroll in the Trial Offer Program one time. Patients currently taking EMPAVELI or who have previously taken EMPAVELI are not eligible for the program.

Apellis Pharmaceuticals, Inc. reserves the right to change, modify, or discontinue this program at any time without notice.

GETTING STARTED

1. Visit EMPAVELIREMS.com to get certified in the EMPAVELI REMS before writing your first prescription. You will only need to register once. REMS certification is required to dispense EMPAVELI to your patient.
2. Review the REMS requirements with your patient.
3. Have your patient sign the Patient Authorizations section, section II, below.
4. Complete all remaining fields on pages 1-6.

I. Patient Information (to be completed by patient or patient caregiver/guardian)

First Name: _____ MI: ____

Last Name: _____

Date of Birth (mm/dd/yy): _____

Gender: ○ Male ○ Female ○ Prefer not to say

○ Other _____

Street Address: _____

City: _____ State: _____ ZIP Code: _____

Email: _____

Preferred Phone Number: _____

☐ Allow voicemail messages containing detailed medical information on this phone number

Alternative Phone Number: _____

☐ Allow voicemail messages containing detailed medical information on this phone number

Primary Language: ○ English ○ Spanish ○ Other _____

II. Patient Authorizations (to be completed by patient or patient caregiver/guardian)

Prior to completing the EMPAVELI Start Form, please share the Patient Authorizations section (page 7) with your patient and ask that they sign the authorizations below.

A. Authorization to Share Personal Health Information (see section A on page 7)

I have read and I understand the *Authorization to Share Personal Health Information* and agree to the terms.

Signature of patient: _____ Date: _____

OR **signature of patient caregiver/guardian:** _____ Date: _____

I authorize the disclosure of my personal health information to the following designated individual(s) (optional):

Caregiver (print name): _____ Relationship: _____

Caregiver email: _____ Phone: _____

B. Trial Offer Acknowledgment and Authorizations for Patient Support, Self-Administration Training and Education, and Marketing Communications (see section B on page 7)

☐ I have read and I understand the Trial Offer Acknowledgment and agree to the terms.

☐ I have read and I understand the Authorizations for Patient Support and Self-Administration Training and Education and agree to the terms.

☐ I have read and I understand the Authorization for Marketing Communications and agree to the terms.

Signature of patient or patient representative: _____ Date: _____

Please see Important Safety Information, including Boxed WARNING regarding risk of serious infections, on pages 9-10, full Prescribing Information, and Medication Guide.

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III. Insurance Information (to be completed by healthcare provider)

NOTE: You may attach a copy of both sides of the patient's insurance card(s) instead of, or in addition to, the below. **This information is only utilized if the patient continues past the trial offer period.**

☐ No insurance

A. Prescription Insurance

Insurance Name: _____

Policyholder Name (First, MI, Last), if other than the patient: _____

Policyholder Date of Birth: _____

Member ID Number: _____ Group Number: _____

Rx Bin Number: _____ Rx PCN Number: _____

Insurance Phone: _____

B. Medical Coverage

Insurance Name: _____

Policyholder Name (First, MI, Last) if other than the patient: _____

Policyholder Date of Birth: _____

Policy Number: _____ Group Number: _____

Insurance Phone: _____

IV. Clinical Information (to be completed by healthcare provider)

Primary Diagnosis

☐ Paroxysmal Nocturnal Hemoglobinuria (PNH) ICD-10 D59.5

Medical History

Known Drug Allergies: _____

_____

☐ No Known Drug Allergies

V. Current Medications (to be completed by healthcare provider)

Current PNH Therapy

☐ Soliris® (eculizumab) ☐ Ultomiris® (ravulizumab) ☐ Other: _____

Date of Last Infusion: _____

Other Current Medications: _____

_____

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Patient Name: _____ **Date of Birth:** _____

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VI. Prescriber Information (to be completed by healthcare provider)

Last Name: _____

First Name: _____ MI: ____

Office/Clinic/Facility Name: _____

NPI Number: _____

State License Number: _____

Practice Street Address: _____

City: _____ State: _____ ZIP Code: _____

Phone: _____

Fax: _____

Primary Office Contact

Office Contact Name: _____

Contact Phone Number: _____

Contact Email: _____

Preferred Method of Contact: ○ Phone ○ Email ○ Fax

Secondary Office Contact

Office Contact Name: _____

Contact Phone Number: _____

Contact Email: _____

Preferred Method of Contact: ○ Phone ○ Email ○ Fax

VII. Prescription for EMPAVELI® (pegcetacoplan) (to be completed by healthcare provider)

Rx: EMPAVELI 1080 mg/20 mL vial

This prescription will be filled by PANTHERx® Specialty Pharmacy.

Quantity: 4 week supply

SIG: Administer 1080 mg (20 mL) subcutaneously twice weekly as directed

☐ Other: _____

Refills #: ONE

Dispense administration device(s) and 1 month of ancillary supplies necessary to administer medication.

SHIP AS SOON AS AUTHORIZED - NO PRESCRIBER HOLD

☐ I have reviewed the EMPAVELI vaccination requirements, Vaccine Recommendations on page 8, and my patient's vaccination history and certify that my patient has been or will be vaccinated or will receive prophylactic antibiotic prior to beginning treatment with EMPAVELI and **PANTHERx is authorized to dispense as soon as possible.**

OR

HOLD SHIPMENT UNTIL VACCINATION IS CONFIRMED - CONTACT OFFICE PRIOR TO DISPENSE

☐ I have reviewed the EMPAVELI vaccination requirements, Vaccine Recommendations on page 8, and my patient's vaccination history and certify that my patient has been or will be vaccinated or will receive prophylactic antibiotic prior to beginning treatment with EMPAVELI. **I request that the EMPAVELI shipment should be held**, with additional follow-up to my office to confirm appropriate timing for dispense and allow for administration of missing vaccinations, prescribed herein or to an alternate provider.

Prescriber Signature (Stamps not accepted)

Dispense as written: _____ Date: _____

Substitution permissible: _____ Date: _____

VIII. Patient Vaccine History (to be completed by healthcare provider)

The ApellisAssist® program offers education and support specific to the vaccination requirements outlined in the EMPAVELI REMS. The EMPAVELI REMS requires the dispensing pharmacy to assess a patient's vaccination history by contacting the prescriber and documenting the findings prior to dispensing. Completing the patient's vaccination history will reduce the need for additional follow-up with your office to meet this pharmacy EMPAVELI REMS requirement.

In the Vaccination History box below, document the brand administered and administration date of each dose (if known) of the indicated vaccine.

☐ Check here if your patient will need vaccination support to help comply with REMS requirements. A dedicated ApellisAssist team member will follow up with you and/or your patient and provide more information.

Vaccination History

ACIP Recommendation for Patients With Complement Deficiency to Begin Treatment With EMPAVELI (Page 8)
Current ACIP recommendations available at: https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-medical-condition.html

Pneumococcal PCV21, PCV20, PCV15, PPSV23 & PCV13 ☐ History Unknown ☐ Vaccine Not Received	Brand administered: ☐ Capvaxive™ (PCV21) ☐ Prevnar 20® (PCV20) ☐ Vaxneuvance® (PCV 15) ☐ Pneumovax® (PPSV23) ☐ Prevnar 13® (PCV13) Dose #1 Date _____ Dose #2 Date _____ Dose #3 Date _____ Dose #4 Date _____
***Meningococcal Conjugate* (MenACWY)** ☐ History Unknown ☐ Vaccine Not Received	Brand administered: ☐ Menactra® (MenACWY-D) ☐ Menveo® (MenACWY-CRM) ☐ MenQuadfi® (MenACWY-TT) ☐ Penbraya™ (MenACWY-TT/MenB-FHbp) Dose #1 Date _____ Dose #2 Date _____ Booster Date _____
***Serogroup B Meningococcal* (MenB)** ☐ History Unknown ☐ Vaccine Not Received	Brand administered: ☐ Bexsero® (MenB-4C) ☐ Trumenba® (MenB-FHbp) ☐ Penbraya™ (MenACWY-TT/MenB-FHbp) Dose #1 Date _____ Dose #2 Date _____ Dose #3 Date _____ Booster Date _____

If prophylactic antibiotic was prescribed with EMPAVELI outside of this form, please indicate anticipated antibiotic start date.
Date: _____

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Patient Name: _____ **Date of Birth:** _____

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IX. Patient Vaccine Prescription(s) (to be completed by healthcare provider)

Submitting an order for vaccination(s) will reduce the need for additional follow-up with your office.

If you submit an order for vaccinations for your patient in the table below, ApellisAssist will coordinate the administration of vaccines directly with the patient based on the location and insurance coverage of the patient. ApellisAssist will also coordinate any provided prescription for prophylactic antibiotics with the patient's local pharmacy. Administer recommended vaccines if vaccination history is incomplete or unknown.

Vaccine Prescriptions (if necessary)

ACIP Recommendation for Patients With Complement Deficiency to Begin Treatment With EMPAVELI (Page 8)
Current ACIP recommendations available at: https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-medical-condition.html

Pneumococcal **PCV21, PCV20, PCV15, PPSV23 & PCV13**	☐ Capvaxive™ (PCV21) ☐ Prevnar 20® (PCV20) ☐ Vaxneuvance® (PCV 15) ☐ Pneumovax® (PPSV23) ☐ Prevnar 13® (PCV13) SIG: Administer intramuscularly as directed ☐ Other _____ Quantity x 1 Refills: _____
Meningococcal Conjugate **(MenACWY)**	☐ Menactra® (MenACWY-D) ☐ Menveo® (MenACWY-CRM) ☐ MenQuadfi® (MenACWY-TT) ☐ Penbraya™ (MenACWY-TT/MenB-FHbp) SIG: Administer intramuscularly as directed ☐ Other _____ Quantity x 1 Refills: _____
Serogroup B Meningococcal **(MenB)**	☐ Bexsero® (MenB-4C) ☐ Trumenba® (MenB-FHbp) ☐ Penbraya™ (MenACWY-TT/MenB-FHbp) SIG: Administer intramuscularly as directed ☐ Other _____ Quantity x 1 Refills: _____

Prescriber Signature (Stamps not accepted)

Dispense as written: _____ Date: _____

Substitution permissible: _____ Date: _____

Prescriber NPI: _____

X. Prescriber Authorization for Injection-Site Reaction Management Plan (Optional) (to be completed by healthcare provider)

Injection-site reactions (ISRs) are one of the most common side effects with EMPAVELI. ISRs are not the only adverse reactions (ARs a patient may experience with EMPAVELI. For a complete list of ARs associated with EMPAVELI, please refer to the full Prescribing Information.

The following are instructions you may have provided to your patients regarding treatment of common ISRs.

Should you choose to review these instructions with your patient, please select from the below options to indicate these are the instructions your patient should follow in the event of an ISR.

In the event of an AR, Care Educators follow Apellis protocols associated with AR reporting and instruct patients to call their doctors.

I (physician) authorize the following checked items for my patient regarding treatment for local ISRs:

- ☐ OTC analgesics, gentle massage, or warm compress for pain
- ☐ Cold compress for minor bruising and redness
- ☐ OTC antihistamine or topical steroid for itching
- ☐ Warm compress or gentle massage for swelling (5-10 min)
- ☐ OTC barrier film wipe for skin irritation (apply in a circular motion leaving the center untouched. Do not inject through the film)
- ☐ OTC silicone-based adhesive remover
- ☐ Other _____

Patients will be directed to call their doctor if a local reaction:

- Does not go away after 3 days
- Is severe: blisters, redness that is larger than 2 inches, or severe bruising, bleeding, pain, or itching
- Worsens after each injection; OR
- Other _____

XI. Prescriber Declaration and Authorization: HCP Signature Required

(to be completed by healthcare provider)

The purpose of this form is to permit Apellis Pharmaceuticals, Inc., its affiliates, representatives, agents, and contractors ("Apellis") to provide patient support and resources to eligible patients who have been prescribed an Apellis medication. The patient support and resources include, but are not limited to, providing: i) reimbursement and financial assistance information; ii) access to the Apellis medication; and iii) disease and medication-related educational resources and communications, including self-administration training by an Apellis Care Educator ("Patient Resources").

By signing below, I certify that:

i. The information contained in this form is complete and accurate to the best of my knowledge.

ii. I understand that the sole purpose of the EMPAVELI Trial Offer Program is to determine, with my patient, whether EMPAVELI is an appropriate treatment for them. I acknowledge that my patient has never been treated with EMPAVELI and he or she may only participate in the program one time.

iii. Any Patient Resource provided through Apellis on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use an Apellis medication or Patient Resource for anyone.

iv. My decision to prescribe an Apellis medication was based solely on my clinical determination and medical necessity. I understand that the EMPAVELI Trial Offer provides patients with an 8 week supply of EMPAVELI, a self-administration device, related ancillaries, and certain Patient Resources at no cost. I will not resell or seek reimbursement from any government program or third-party insurer for any Apellis medication, pump, ancillary, or Patient Resource provided by or through Apellis, regardless of whether or not my patient was prescribed an Apellis medication through the EMPAVELI Trial Offer.

v. I authorize Apellis to provide Patient Resources to my patient, including training by a Care Educator on administration of the medication. I understand that this does not include individual treatment or medical advice to my patient, and it does not replace or substitute the medical treatment and care provided by me as the patient's healthcare provider. I further certify that I have discussed this Care Educator training with my patient, and informed my patient of the risks associated with the medication and how to manage any potential side effects that may arise.

vi. I shall monitor my patient during and after the transition to EMPAVELI. Should my patient decide not to continue with EMPAVELI, I will advise and monitor my patient's transition off of EMPAVELI and to another therapy, if applicable.

☐ I have reviewed the optional ISR management plan in Section X. Prescriber Authorization for Injection-Site Reaction Management Plan and I authorize a Care Educator to train my patient on Injection Site Reaction (ISR) management plan per my designated instructions **as indicated in X. Prescriber Authorization for Injection-Site Reaction Management Plan.**

Prescriber Signature (Stamps not accepted)

Sign here: _____ Date: _____

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Patient Authorizations

Please read through sections A and B carefully. Signing this form will allow Apellis Pharmaceuticals, Inc. to provide you or your loved one with support and resources that may include, but are not limited to:

- Financial assistance for eligible patients and reimbursement information
- Helpful resources to help you stay on track
- Education about your medication
- Check-ins and training on how to self-administer your medication from an Apellis Care Educator

PATIENT AUTHORIZATIONS

A. Authorization to Share Personal Health Information

Please read this section carefully, and if you agree, **sign and date the Authorization to Share Personal Health Information (the "Authorization")** on page 1. You may keep a copy of this form for your records.

I authorize my healthcare team and staff, my pharmacies, and my insurance ("Health Care Providers and Insurers") to use and to share my personal health information, including information relating to my medical condition, treatment, care management, health insurance, and all information provided on any prescription form for EMPAVELI® (pegcetacoplan) **("My Information")** to Apellis Pharmaceuticals, Inc. and its affiliates, vendors, and other agents (collectively, "Apellis") for the purposes of receiving product support and resources from Apellis, including insurance verification and coverage; financial assistance; market research; internal data analyses; disease and medication-related educational resources and communications, including disease state education and training on administration of the medication by a Care Educator; and communicating with me by email or telephone about my medical condition, treatment, care management, and health insurance (the "Patient Support Program"). Once My Information has been shared with Apellis, I understand that it is outside of the control of my Health Care Providers and Insurers and it may no longer be required to be private under federal laws. However, I also understand that Apellis will protect My Information by sharing it only for the purposes needed to offer support. I understand and agree that the pharmacy that provides my EMPAVELI may receive payment from Apellis in exchange for giving My Information to Apellis.

I understand that I do not have to sign this Authorization. A decision by me not to sign this Authorization will not affect my ability to receive health insurance benefits or my ability to get my medications. However, if I do not sign this Authorization, I understand I will not be able to participate and receive services from this program. I understand that this Authorization expires ten years from the date signed below, or one year after the date of my last prescription, whichever is later. I may change my mind and cancel this Authorization at any time by calling 1-866-MY-APL-ASSIST (1-866-692-7527) or by notifying Apellis in writing at Attn: Privacy Office, Apellis Pharmaceuticals, Inc., 100 5th Avenue, Waltham, MA, 02451, or by emailing privacy@apellis.com. Cancellation of this Authorization will end further uses and sharing of My Information with Apellis and my participation in the Patient Support Program, but will not affect any uses or sharing of My Information based on this Authorization before cancellation. I understand I may request a signed copy of this Authorization.

B. Trial Offer Acknowledgment and Authorizations for Patient Support, Self-Administration Training and Education, and Marketing Communications

Trial Offer Acknowledgment

I understand that under the EMPAVELI Trial Offer program, an 8-week supply of EMPAVELI, a self-administration device, and related ancillaries will be provided to me at no cost for the duration of the EMPAVELI Trial Offer program and that I may not resell them or seek reimbursement for them from any government program or third-party insurer. I understand that I may only participate in the EMPAVELI Trial Offer program once. I understand that I may stop taking EMPAVELI at any time under the guidance of my physician and that there is no obligation to continue taking EMPAVELI at the conclusion of the trial period. If I stop taking EMPAVELI, I shall do so under the guidance and monitoring of my physician.

Authorization to Enroll in the ApellisAssist Patient Support Program

I authorize Apellis to collect My Information from me, my caregivers, and my Health Care Providers and Insurers, and to use and disclose My Information to provide product support and resources, including enrollment in the Patient Support Program. I also authorize Apellis to communicate with me by mail, phone, email and/or text message for the Patient Support Program.

Authorization to Receive Self-Administration Training and Education

I authorize Apellis to provide me with education and training on how to self-administer my medication by a Care Educator, and to provide me with helpful information and resources about EMPAVELI and PNH, including but not limited to educational materials on self-administration training, treatment routines, and storage solutions. I understand that this does not include medical advice and it does not replace or substitute the medical treatment and care I receive by my doctor. I further certify that I have discussed this with my doctor, and my doctor informed me of the potential risks and side effects associated with the medication and how to manage them if they occur. I also authorize the Care Educator to contact me by mail, phone, email, and/or text message for self-administration training and education purposes.

Authorization to Receive Marketing Communications

I authorize Apellis to communicate with me (by mail and/or email) for marketing purposes or to otherwise provide me with information about Apellis products, services, and programs or other topics of interest, to conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand and agree that any information I provide may be used by Apellis to help develop new products, services, and programs. I understand that the Authorizations will be in effect until such time as I opt-out of communications from Apellis.

I understand that I may revoke the Authorizations and choose not to receive information from Apellis by clicking the "unsubscribe" link provided in emails I receive from Apellis, calling Apellis at 1-866-MY-APL-ASSIST (1-866-692-7527), mailing a letter to Attn: Privacy Office, Apellis Pharmaceuticals, Inc., 100 5th Avenue, Waltham, MA, 02451, or emailing privacy@apellis.com.

ApellisAssist®

Patient Name: _____ Date of Birth: _____

Vaccine Recommendations

Below are the vaccination recommendations as of June 2024. The most current ACIP recommendations are available: https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-medical-condition.html

If you need vaccination support to help comply with REMS requirements, please call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527). A dedicated ApellisAssist team member will follow up with you and/or your patient and provide more information.

Administer recommended vaccines if vaccination history is incomplete or unknown.

Vaccine	ACIP Vaccination Recommendations
Pneumococcal **PCV21, PCV20, PCV15, PPSV23 & PCV13**	2024 Updated Recommendations for Vaccine-Naïve Adults and Unknown History: • 1 dose **PCV21** or **PCV20** OR • 1 dose **PCV15** followed by 1 dose **PPSV23** at least 8 weeks later *Previous PCV13/PPSV23 Recommendations:* • *1 dose PCV13 followed by 1 dose PPSV23 at least 8 weeks later* • *1 dose PPSV23 at least 5 years after previous PPSV23 dose* – *Age 65 years or older, administer 1 dose PPSV23 at least 5 years after most recent PPSV23 if 1st dose administered prior to age 65* *Note: only 1 dose PPSV23 recommended at age 65 years or older.*
Meningococcal Conjugate **(MenACWY)**	• **MenACWY (Menveo® or MenQuadfi®)** – 2 dose series at least 8 weeks apart • **MenACWY-TT/MenB-FHbp (Penbraya™)** – may be used as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day – *May also be used for additional* **MenACWY** *and* **MenB-FHbp (Trumenba®)** *doses (including booster doses) if both doses would be given on the same clinic day and at least 6 months have elapsed since the most recent* **Penbraya™** *dose* • Revaccinate every 5 years if risk remains
Serogroup B Meningococcal **(MenB)**	• **MenB-4C (Bexsero®)** and **MenB-FHbp (Trumenba®)** are not interchangeable (use same product for all doses in series). • **MenB-4C (Bexsero®)** and **MenACWY-TT/MenB-FHbp (Penbraya™)** are not interchangeable (use same product for all doses in series). • **MenB-4C (Bexsero®)** – 2-dose primary series at least 1 month apart OR • **MenB-FHBp (Trumenba®)** – 3-dose primary series at 0, 1-2, 6 months – *If dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a fourth dose should be administered at least 4 months after dose 3* • **MenACWY-TT/MenB-FHbp (Penbraya™)** – may be used as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day – *May also be used for additional* ***MenACWY and MenB-FHbp (Trumenba®)*** *doses (including booster doses) if both doses would be given on the same clinic day and at least 6 months have elapsed since the most recent* ***Penbraya™*** *dose* • 1 dose booster 1 year after primary series • Revaccinate every 2-3 years if risk remains
Note: Persons at an increased risk for meningococcal disease who receive a dose of MenACWY-TT/MenB-FHbp (Penbraya™) and are recommended to receive additional doses of MenACWY and MenB <6 months after a dose of pentavalent meningococcal vaccine should receive separate MenACWY and MenB-FHbp (Trumenba®) vaccines rather than MenACWY-TT/MenB-FHbp (Penbraya™).	

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

ApellisAssist®

Phone: 1-866-MY-APL-ASSIST | (1-866-692-7527)
Fax: 1-888-754-1285

INDICATION AND IMPORTANT SAFETY INFORMATION

What is EMPAVELI® (pegcetacoplan)?

EMPAVELI is a prescription medicine used to treat adults with a disease called paroxysmal nocturnal hemoglobinuria (PNH).

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

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

EMPAVELI increases your chance of getting serious infections caused by encapsulated bacteria such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type B. These serious infections may quickly become life-threatening or cause death if not recognized and treated early.

1. **You must complete or be up to date with the vaccines against *Streptococcus pneumoniae* and *Neisseria meningitidis* at least 2 weeks before your first dose of EMPAVELI.**
2. If you have not completed your vaccines and EMPAVELI must be started right away, you should receive the required vaccines as soon as possible.
3. If you have not been vaccinated and EMPAVELI must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
4. If you have been vaccinated against these bacteria in the past, you might need additional vaccines before starting EMPAVELI. Your healthcare provider will decide if you need additional vaccines.
5. Vaccines do not prevent all infections caused by encapsulated bacteria. **Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:**
   - fever with or without shivers or the chills
   - fever with chest pain and cough
   - fever with high heart rate
   - headache and a fever
   - confusion
   - clammy skin
   - fever and a rash
   - fever with breathlessness or fast breathing
   - headache with nausea or vomiting
   - headache with a stiff neck or stiff back
   - body aches with flu-like symptoms
   - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the risk of serious infections. Carry it with you at all times during treatment and for 2 months after your last EMPAVELI dose. Your risk of serious infections may continue for several weeks after your last dose of EMPAVELI. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

EMPAVELI is only available through a program called the EMPAVELI Risk Evaluation and Mitigation Strategy (REMS). Before you can take EMPAVELI, your healthcare provider must enroll in the EMPAVELI REMS program, counsel you about the risk of serious infections caused by certain bacteria, give you information about the symptoms of serious infections, make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that you receive antibiotics if you need to start EMPAVELI right away and you are not up to date on your vaccines, and give you a Patient Safety Card about your risk of serious infections.

Who should NOT take EMPAVELI?

Do not take EMPAVELI if you:

- are allergic to pegcetacoplan or any of the ingredients in EMPAVELI.
- have a serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type B when you are starting EMPAVELI treatment.

Please see full Prescribing Information, including Boxed WARNING regarding risk of serious infections, and Medication Guide for additional information.

Before you take EMPAVELI, 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. EMPAVELI may harm your unborn baby. Females who are able to become pregnant should have a pregnancy test before starting treatment with EMPAVELI and use an effective method of birth control during treatment with EMPAVELI and for 40 days after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if EMPAVELI passes into your breast milk. You should not breastfeed during treatment with EMPAVELI and for 40 days after the last dose.

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.

If you stop taking EMPAVELI, your healthcare provider will need to monitor you closely for at least 8 weeks after stopping EMPAVELI. Stopping treatment with EMPAVELI may cause a breakdown of red blood cells due to PNH.

Symptoms or problems that can happen due to red blood cell breakdown include:

- decreased hemoglobin level in your blood
- blood in your urine
- shortness of breath
- trouble swallowing
- tiredness
- pain in the stomach (abdomen)
- blood clots
- erectile dysfunction (ED)

What are the possible side effects of EMPAVELI?

EMPAVELI can cause serious side effects including allergic reactions. Allergic reactions can happen during your EMPAVELI infusion. Stop your EMPAVELI infusion and tell your healthcare provider or get emergency medical care right away if you get any of these symptoms during your EMPAVELI infusion:

- chest pain
- trouble breathing or shortness of breath
- swelling of your face, tongue, or throat
- feel faint or pass out

The most common side effects in people with PNH treated with EMPAVELI include injection-site reactions; infections; diarrhea; pain in the stomach (abdomen); respiratory tract infection; pain in the arms, hands, legs, or feet; low potassium in blood; tiredness; viral infection; cough; joint pain; dizziness; headache; and rash.

These are not all of the possible side effects of EMPAVELI. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including Boxed WARNING regarding risk of serious infections, and Medication Guide for additional information.

- Fax the completed EMPAVELI Trial Offer Start Form to 1-888-754-1285
- Call an ApellisAssist representative at 1-866-MY-APL-ASSIST (1-866-692-7527) from 8 AM-8 PM ET, Monday-Friday, to speak with a 24-hour on-call pharmacist
- For more information, visit EMPAVELI.com