Thank you for your form submission, which has been captured on the following date: _____

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® (pegcetacoplan) Nephrology Trial Offer Program Start Form

PROGRAM OVERVIEW

The EMPAVELI Trial Offer Program can provide 8 weeks of EMPAVELI at no cost to your eligible patients with C3G/primary IC-MPGN 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 the patient or caregiver sign the Patient Consents section, section II, below.
4. Complete all remaining fields on pages 1-6.

I. Patient Information (to be completed by patient or patient's caregiver)

First Name: _____ MI: ____

Last Name: _____

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

Sex: ◯ Male ◯ Female

Street Address: _____

City: _____ State: _____ ZIP Code: _____

Email: _____

Preferred Phone: _____

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

Alternative Phone: _____

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

Primary Language: ◯ English ◯ Spanish ◯ Other: _____

II. Patient Consents (to be completed by patient or patient's caregiver)

Prior to completing the EMPAVELI Start Form, please share the Enrollment and Privacy Terms (page 7) with your patient or their caregiver and have them complete sections A, B, and C below.

A. HIPAA Authorization (see section A on page 7)

By signing this form, I attest that I have read and agree to the HIPAA Authorization on page 7, section A. I understand I am entitled to a copy of this signed authorization.

Signature of patient or caregiver: _____ **Date:** _____

B. Trial Offer Program Acknowledgment (see section B on page 7)

☐ I have read and I understand the Trial Offer Program Acknowledgment on page 7, section B, and agree to the terms.

C. Consent to Enroll in Patient Support through ApellisAssist® and Receive Self-Administration Training and Education (see section B on page 7)

I have read and I understand the Patient Support and Self-Administration Training and Education enrollment terms on page 7, section B and agree to the terms.

Signature of patient or caregiver: _____ **Date:** _____

D. Marketing Consent (optional)

☐ I consent to receive marketing communications from Apellis Pharmaceuticals, Inc., about its programs, products, services, and research opportunities. I understand I can opt-out anytime and review Apellis's privacy practices at https://apellis.com/privacy-policy/

III. Caregiver Information (Optional)

Caregiver First Name: _____ Last Name: _____

Preferred Phone: _____ Email: _____

What is the caregiver's relationship to the patient? ◯ Parent/Legal Guardian ◯ Spouse ◯ Other: _____

ApellisAssist®

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

HEALTHCARE PROVIDER FORM

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IV. 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.

☐ **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: _____

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

See page 9 for list of possible diagnosis codes.

Primary Diagnosis

☐ C3G: ICD-10 diagnosis code: _____

☐ Primary IC-MPGN: ICD-10 diagnosis code: _____

☐ Other: _____

Transplant History

Has the patient had a kidney transplant? ◯ Yes ◯ No

Date of most recent kidney transplant: _____ (month/year)

Medical History

☐ No Known Drug Allergies Known Drug Allergies: _____

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

Current Therapy

☐ FABHALTA® (iptacopan) ☐ C5 inhibitors ☐ Immunosuppressants ☐ Rituximab

Other Current Medications: _____

VII. 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: _____

Contact Email: _____

Preferred Method of Contact: ◯ Phone ◯ Email ◯ Fax

Secondary Office Contact

Office Contact Name: _____

Contact Phone: _____

Contact Email: _____

Preferred Method of Contact: ◯ Phone ◯ Email ◯ Fax

ApellisAssist®

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

HEALTHCARE PROVIDER FORM

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

VIII. 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.

Patient weight (for pediatric patients between 12 and less than 18 years of age): _____ ◯ kg ◯ lbs Anticipated Start Date: _____

Directions for patients to infuse subcutaneously (please check one of the four boxes below):		
◯	Adult patients (18 years and older) or Pediatric patients (12 years of age and older) ≥ 50 kg	Infuse 1080 mg (20 mL) subcutaneously twice weekly as directed
◯	Pediatric patients (12 years of age and older) 35 to < 50 kg	First dose: Infuse 648 mg (12 mL) subcutaneously as directed Second dose: Infuse 810 mg (15 mL) subcutaneously as directed Maintenance dose: Infuse 810 mg (15 mL) subcutaneously twice weekly as directed
◯	Pediatric patients (12 years of age and older) < 35 kg	First dose: Infuse 540 mg (10 mL) subcutaneously as directed Second dose: Infuse 540 mg (10 mL) subcutaneously as directed Maintenance dose: Infuse 648 mg (12 mL) subcutaneously twice weekly as directed
◯	Other	First dose: Infuse _____ mg subcutaneously as directed Second dose: Infuse _____ mg subcutaneously as directed Maintenance dose: Infuse _____ mg subcutaneously as directed thereafter SIG: _____

Vials: ◯ 8 or ◯ _____

Quantity: Dispense quantity sufficient for a 4-week supply

Refills: One

Dispense administration device(s) and 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: _____

ApellisAssist®

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

HEALTHCARE PROVIDER FORM

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

IX. 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) Please enter all relevant dose dates below: 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) Please enter all relevant dose dates below: 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) Please enter all relevant dose dates below: 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: _____

X. 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: _____

XI. 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: _____

XII. 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. 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. My decision to prescribe an Apellis medication was based solely on my clinical determination and medical necessity, and I will not seek reimbursement for any medication or Patient Resource provided by or through Apellis from any government program or third-party insurer.

iii. 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.

☐ I have reviewed the optional ISR management plan in section XI. 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 XI. **Prescriber Authorization for Injection-Site Reaction Management Plan.**

Prescriber Signature (stamps not accepted)

Sign here: _____ Date: _____

Patient / Caregiver Enrollment and Consent Terms

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 / CAREGIVER CONSENTS

A. HIPAA Authorization

Please read this section carefully, and if you agree, sign and date the HIPAA Authorization (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 protected 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 protected under the Health Insurance Portability and Accountability Act (HIPAA). 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 in the Patient Support 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. Program Enrollment and Consent Terms

Trial Offer Program Acknowledgment

I understand that under the EMPAVELI Trial Offer Program, an 8-week supply of EMPAVELI, self-administration device(s), 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.

Consent to Enroll in Patient Support Program, ApellisAssist

I consent to enroll in Patient Support through ApellisAssist, to receive product support and resources, and to be contacted by mail, phone, email, and/or text message for Patient Support Program purposes.

Consent 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 disease education resources, 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.

Privacy Statement

Apellis Pharmaceuticals, Inc., will use the personal information provided on this form and through your healthcare providers, such as medical condition, treatment, care management, and health insurance, to provide the patient product support and resources requested by you. These services may include insurance verification and financial assistance and disease and medication-related educational resources and communications (the "Patient Support Program"). Apellis will also use de-identified information to conduct internal data analyses. You may cancel enrollment at any time by contacting Apellis using the information provided on this form. The personal information collected on this form, which may include health information, is needed to fulfill your requested enrollment. For more information on Apellis's privacy practices, including additional privacy rights under state law, please visit https://apellis.com/privacy-policy/.

ApellisAssist®

Vaccine Recommendations

Below are the vaccination recommendations as of May 2025. The most current ACIP recommendations are available at: 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**	2025 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®)** – 3-dose primary series at 0, 1-2, 6 months • **MenB-FHBp (Trumenba®)** – 3-dose primary series at 0, 1-2, 6 months • **For both MenB-4C (Bexsero®) and MenB-FHbp (Trumenba®):** – *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 4th 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™).

Indication	Diagnosis Description	Diagnosis Code
C3G	Acute nephritic syndrome with C3 glomerulonephritis	N00.A
	Acute nephritic syndrome with dense deposit disease	N00.6
	Chronic nephritic syndrome with C3 glomerulonephritis	N03.A
	Chronic nephritic syndrome with dense deposit disease	N03.6
	Hereditary nephropathy, not elsewhere classified with C3 glomerulonephritis	N07.A
	Hereditary nephropathy, not elsewhere classified with dense deposit disease	N07.6
	Isolated proteinuria with C3 glomerulonephritis	N06.A
	Isolated proteinuria with dense deposit disease	N06.6
	Nephrotic syndrome with C3 glomerulonephritis	N04.A
	Nephrotic syndrome with dense deposit disease	N04.6
	Rapidly progressive nephritic syndrome with C3 glomerulonephritis	N01.A
	Rapidly progressive nephritic syndrome with dense deposit disease	N01.6
	Recurrent and persistent hematuria with C3 glomerulonephritis	N02.A
	Recurrent and persistent hematuria with dense deposit disease	N02.6
	Unspecified nephritic syndrome with C3 glomerulonephritis	N05.A
	Unspecified nephritic syndrome with dense deposit disease	N05.6
IC-MPGN	Acute nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	N00.5
	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	N03.5
	Hereditary nephropathy, not elsewhere classified with diffuse mesangiocapillary glomerulonephritis	N07.5
	Isolated proteinuria with diffuse mesangiocapillary glomerulonephritis	N06.5
	Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis	N04.5
	Rapidly progressive nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	N01.5
	Recurrent and persistent hematuria with diffuse mesangiocapillary glomerulonephritis	N02.5
	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis	N05.5

INDICATIONS 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).
- adults and children 12 years of age and older with a kidney disease called complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce levels of protein in the urine (proteinuria).

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.

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 have PNH and 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 and can be life-threatening. Stop your EMPAVELI infusion and 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
- wheezing
- swelling of your face, tongue, or throat
- feel dizzy or faint or pass out
- fast heart rate
- nausea or vomiting
- feel confused or anxious
- skin reactions, including rash, hives, and itching

The most common side effects in adults 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.

The most common side effects in adults and children 12 years of age and older with C3G or primary IC-MPGN treated with EMPAVELI include injection-site reactions, fever, common cold, flu, cough, and nausea.

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 Program Start Form to 1-888-754-1285
- Call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527) from 8 AM-8 PM ET, Monday-Friday, to speak with a Care Coordinator
- For more information, visit EMPAVELIHCP.com