EMPAVELI® (pegcetacoplan) injection, for subcutaneous use

Company: Apellis Pharmaceuticals, Inc
Product name: EMPAVELI
Generic name: pegcetacoplan

Indication: EMPAVELI is indicated for the treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria[1]

Product specifications

How supplied[1]	EMPAVELI injection is a clear, colorless to slightly yellowish aqueous solution for subcutaneous infusion supplied as 1080 mg/20 mL (54 mg/mL) solution in 20 mL single-dose vials
Packaging[1]	A carton containing 8 individually packaged 20 mL single-dose vials (4-week supply)
Storage[1]	Refrigerate vials at 36 °F to 46 °F (2 °C to 8 °C) in the original carton
Distribution	PANTHERx and other REMS-certified pharmacies will dispense EMPAVELI, along with ancillary supplies, to the patient. Patients using the EMPAVELI Injector will receive a single-use, disposable, on-body injector supplied in boxes of 8 to align with twice-weekly dosing. Patients using an infusion pump will receive 1 infusion pump with the first shipment
Equipment and ancillary supplies	○ **EMPAVELI Injector[2]** ○ **Ancillaries: sterile 20 mL syringe, needleless transfer device, and alcohol wipes[2]** ○ **Sharps container[2]** ○ Commercially available infusion pump[3] ○ Ancillaries: needle set, compatible syringe, infusion tubing, vial adapter, alcohol wipes, gauze, and tape[3] ○ Sharps container[3]
REMS[1]	Prescribers and pharmacies must enroll in the EMPAVELI REMS program
NDC number[1]	73606-010-01

ICD-10-CM codes for C3G and primary IC-MPGN are listed on the next page.

ApellisAssist®

Here for your patients

The ApellisAssist program is designed to help your patients along their treatment journey.
ApellisAssist can be reached at 1-866-MY-APL-ASSIST (1-866-692-7527) from 8 AM-8 PM ET, Monday–Friday.

INDICATION

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

EMPAVELI, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, unless the risks of delaying therapy with EMPAVELI outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving EMPAVELI are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the EMPAVELI REMS.

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

Please see Important Safety Information on pages 3-4, full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

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1080 mg/20 mL solution

ICD-10-CM codes for C3G[4]

Code	Description
N00.A	Acute nephritic syndrome with C3GN
N00.6	Acute nephritic syndrome with DDD
N01.A	Rapidly progressive nephritic syndrome with C3GN
N01.6	Rapidly progressive nephritic syndrome with DDD
N02.A	Recurrent and persistent hematuria with C3GN
N02.6	Recurrent and persistent hematuria with DDD
N03.A	Chronic nephritic syndrome with C3GN
N03.6	Chronic nephritic syndrome with DDD
N04.A	Nephrotic syndrome with C3GN
N04.6	Nephrotic syndrome with DDD
N05.A	Unspecified nephritic syndrome with C3GN
N05.6	Unspecified nephritic syndrome with DDD
N06.A	Isolated proteinuria with C3GN
N06.6	Isolated proteinuria with DDD
N07.A	Hereditary nephropathy, not elsewhere classified with C3GN
N07.6	Hereditary nephropathy, not elsewhere classified with DDD

ICD-10-CM codes for primary IC-MPGN

Current ICD-10-CM codes[4]

Code	Description
N00.5	Acute nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N01.5	Rapidly progressive nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N02.5	Recurrent and persistent hematuria with diffuse mesangiocapillary glomerulonephritis
N03.5	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N04.5	Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis
N05.5	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N06.5	Isolated proteinuria with diffuse mesangiocapillary glomerulonephritis
N07.5	Hereditary nephropathy, not elsewhere classified with diffuse mesangiocapillary glomerulonephritis

New ICD-10-CM codes effective October 1, 2025[5]

Code	Description
N00.B1	Acute nephritic syndrome with idiopathic IC-MPGN
N04.B1	Nephrotic syndrome with idiopathic IC-MPGN

The coding information in this document is provided for informational purposes only, is subject to change, and is not a substitute for independent clinical judgment when selecting diagnosis codes. Codes listed here are not a guarantee of coverage or reimbursement. Coverage and reimbursement may vary significantly by health plan, patient, and setting of care. Please check with your patient's health plan to ensure you are providing accurate and complete information.

C3GN=C3 glomerulonephritis; DDD=dense deposit disease; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IC-MPGN= immune-complex membranoproliferative glomerulonephritis; NDC=National Drug Code; REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B

Please see Important Safety Information on pages 3-4, full Prescribing Information, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and Medication Guide.

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IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

EMPAVELI, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, unless the risks of delaying therapy with EMPAVELI outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving EMPAVELI are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the EMPAVELI REMS.

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type B

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

EMPAVELI, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* (caused by any serogroup, including non-groupable strains), and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of EMPAVELI treatment is contraindicated in patients with unresolved serious infection caused by encapsulated bacteria.

Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to administration of the first dose of EMPAVELI, according to the most current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent EMPAVELI therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. The benefits and risks of treatment with EMPAVELI, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI is available only through a restricted program under a REMS.

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

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

EMPAVELI REMS

EMPAVELI is available only through a restricted program under a REMS called EMPAVELI REMS, because of the risk of serious infections caused by encapsulated bacteria. Notable requirements of the EMPAVELI REMS include the following:

Under the EMPAVELI REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria, provide patients with the REMS educational materials, ensure patients are vaccinated against encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, prescribe antibacterial drug prophylaxis if patients' vaccine status is not up to date and treatment must be started urgently, and provide instructions to always carry the Patient Safety Card both during treatment, as well as for 2 months following last dose of EMPAVELI. Pharmacies that dispense EMPAVELI must be certified in the EMPAVELI REMS and must verify prescribers are certified.

Further information is available at www.empavelirems.com or 1-888-343-7073.

Infusion-Related Reactions

Systemic hypersensitivity reactions (eg, facial swelling, rash, urticaria, pyrexia) have occurred in patients treated with EMPAVELI, which may resolve after treatment with antihistamines. Cases of anaphylaxis leading to treatment discontinuation have been reported. 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.

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

Most common adverse reactions in adult and pediatric patients 12 years of age and older with C3G or primary IC-MPGN (incidence ≥10%) were infusion-site reactions, pyrexia, nasopharyngitis, influenza, cough, and nausea.

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.

References: 1. EMPAVELI. Prescribing information. Apellis Pharmaceuticals, Inc; 2025. **2.** EMPAVELI Injector. Instructions for use. Apellis Pharmaceuticals, Inc; 2025. **3.** EMPAVELI. Instructions for use. Apellis Pharmaceuticals, Inc; 2025. **4.** Centers for Medicare & Medicaid Services. ICD-10 codes. CMS.gov. Updated July 10, 2025. Accessed July 16, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes **5.** Centers for Disease Control and Prevention. ICD-10 Coordination and Maintenance Committee Meeting. September 10-11, 2024.

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