**Sample Letter of Coverage Reauthorization**

**for EMPAVELI® (pegcetacoplan) for**

**C3G and Primary IC-MPGN**

***[Note: When preparing the actual letter, use your professional/physician letterhead and ensure it is signed by the prescriber.]***

**INTRODUCTION**

Routinely, payers will require a prior authorization for patients receiving specialty medications. After a specific time period, a patient will need reauthorization in order to reconfirm that their treatment is medically necessary and/or clinically beneficial. The payer’s clinical policy for a specialty drug will dictate the duration of treatment and the specified period of coverage.

Payers may request additional documentation from you to support reauthorizing the coverage of EMPAVELI. The reauthorization letter should include patient-specific information that includes supporting clinical evidence/documentation for continued medical necessity of the treatment.

This sample letter is for informational purposes only. Use of this information does not constitute medical or legal advice and does not guarantee coverage. It is not intended to be a substitute for, or an influence on, the independent clinical decision of the prescriber. Health plan requirements may vary. Please confirm the specific information required by your patient’s health plan to ensure you are providing accurate and complete information.

**Please see Important Safety Information on pages 4-6, and full** [**Prescribing Information**](https://pi.apellis.com/files/PI_Empaveli.pdf)**, including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and** [**Medication Guide**](https://pi.apellis.com/files/MedGuide_Empaveli.pdf)**.**

[Date]

[Payer Medical/Pharmacy Director/Contact Name]

[Payer Organization Name]

[Payer Street Address]

[Payer City, State, ZIP Code]

**ATTN: Reauthorization/Renewal**

**Re:** Coverage Reauthorization/Renewal for EMPAVELI® (pegcetacoplan) for [C3G or

Primary IC-MPGN]

**Patient:** [Patient First Name] [Patient Last Name]

**Patient Date of Birth:** [Patient Date of Birth]

**Policy ID/Group Number:** [Policy ID/Group Number]

**Diagnosis:** [ICD-10-CM Code] [Diagnosis]

Dear [Payer Medical/Pharmacy Director/Contact Name]:

I am [Physician Name, Credentials, Specialty, Hospital/Practice]. I am writing on behalf of my patient, [Patient Name], to request renewal of coverage for EMPAVELI® (pegcetacoplan) for the treatment of [diagnosis/condition]. This letter provides information about [Patient Name]’s medical history, experience on EMPAVELI, and a summary of the rationale supporting the continued use of EMPAVELI.

**Summary of Patient’s Medical History**

[You may be required to include the following:

* Patient’s diagnosis and date of diagnosis
* Basis for diagnosis (details about diagnostic workup, imaging, relevant medical history)]

**Summary of Patient’s Experience on EMPAVELI**

[You may be required to include the following:

* Date of initial and subsequent treatments
* Provider attestation for patient benefit
* Patient feedback/anecdotes while on treatment]

**Patient-Specific Rationale for Continued Treatment**

[Explain why you believe the continued administration of EMPAVELI is medically necessary for the maintenance treatment of this patient. This may include your clinical rationale for continuing this medication, as well as your professional opinion of the patient’s anticipated disease progression if treatment were to stop.]

[You may choose to include the specific criteria for renewal/reauthorization of coverage that the patient meets based on the patient’s health plan and their policy, along with other relevant details. This may include:

* Confirmation that the patient continues to meet initial payer criteria
* Documentation/clinical evidence of positive clinical response to EMPAVELI therapy (eg, reduction in proteinuria, improvement or stabilization of eGFR)
* Patient tolerability of treatment (eg, no evidence of unacceptable toxicity while on treatment)
* Confirmation that EMPAVELI will not be used in combination with another complement inhibitor (eg, FABHALTA®) for the treatment of C3G or primary IC-MPGN]

Based on my medical expertise and clinical assessment, I believe EMPAVELI continues to be medically appropriate and necessary for my patient. I respectfully request that you review the supporting documentation provided and renew coverage for this treatment.

Thank you for your prompt attention to this matter. Please contact my office at [telephone number] if I can provide you with any additional information.

Sincerely,

[Physician Name], [MD] or [DO]

[Participating Provider Number]

**Enclosures**

[The following is a suggested list of enclosures. Please confirm the specific information required by your patient’s health plan to ensure you are providing accurate and complete information.

* Documentation of prior payer approval for EMPAVELI through the initial review process
* Documentation confirming that the patient continues to meet initial payer criteria
* Clinical notes describing current and past medications
* Documentation of patient compliance with treatment plan
* EMPAVELI Prescribing Information]

**INDICATION**

EMPAVELI® (pegcetacoplan) 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.

**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.

**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](http://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.

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