**Sample Letter of Appeal for a Prior Authorization (PA) Denial 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**

When a payer denies a prior authorization request for EMPAVELI, your patient has the right to appeal the decision. If your patient wishes to appeal, you and your staff may assist by submitting an appeal letter and the requisite supporting documentation to overturn the decision.

Payers may request additional documentation from you to support coverage of EMPAVELI when the initial approval has been denied. The letter of appeal should explain why EMPAVELI is medically necessary and/or clinically appropriate for the specific patient. The appeal letter should include patient-specific information, address the reason(s) for the denial, and be signed by the prescriber.

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 3-5, 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: Prior Authorization Denials/Appeals**

**Re:** PA Denial 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]

**PA Reference Number:** [Reference Number]

**PA Submission Date:** [Submission Date]

**PA Denial Date:** [Denial Date]

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

I am writing to formally appeal the Prior Authorization (PA) denial of EMPAVELI® (pegcetacoplan) for my patient, [Patient Name], for [diagnosis/condition]. In a letter dated [date of PA denial letter], [Payer Name] stated that the PA for EMPAVELI was denied because [insert denial reason from payer].

The clinical assessment of my patient, which I describe in greater detail below, supports that EMPAVELI is medically necessary for my patient, and I formally request that you reconsider this decision.

**Summary of Patient’s Medical History**

[Describe the patient’s medical history, diagnosis, and prognosis. Attach relevant documentation that supports this information, such as:

* Confirmation of patient’s age
* Record of biopsy confirming C3G or primary IC-MPGN
* Recent lab results (eg, uPCR, serum C3 level)
* Recent assessment of patient renal function (eg, eGFR)
* List of all current and previous treatments for C3G or primary IC-MPGN and confirmation that patient has not achieved adequate results from current or prior therapy]

**Patient-Specific Rationale for Treatment**

[Provide a summary of why you believe EMPAVELI is clinically appropriate and medically necessary for your patient.

Make sure you clearly address the reason(s) for denial and consider including the specific PA criteria that the patient meets based on the patient’s health plan. Include clinical support for prescribing EMPAVELI, such as clinical trial data found in the EMPAVELI Prescribing Information. Provide your professional opinion of the patient’s likely prognosis or disease progression without EMPAVELI.]

[If you are writing this on behalf of a patient who was previously enrolled in the Expanded Access Program (EAP) or Compassionate Use Program (CU), please be sure to include this information for the payer’s awareness.]

Based on the information provided above, the use of EMPAVELI is medically appropriate and necessary for [Patient Name]. I have enclosed a copy of the full Prescribing Information for EMPAVELI.

I respectfully request that you review the supporting documentation provided and please approve coverage of EMPAVELI for the patient, [Patient Name]. Thank you for your prompt attention to this matter. I look forward to your reconsideration. 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.

* PA denial letter
* Relevant clinical documentation
* 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.**

**IMPORTANT SAFETY INFORMATION**

**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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