

Tips for completing a prior authorization request



Use the following tips, checklists, and sample letters to help you through the prior authorization process.

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.

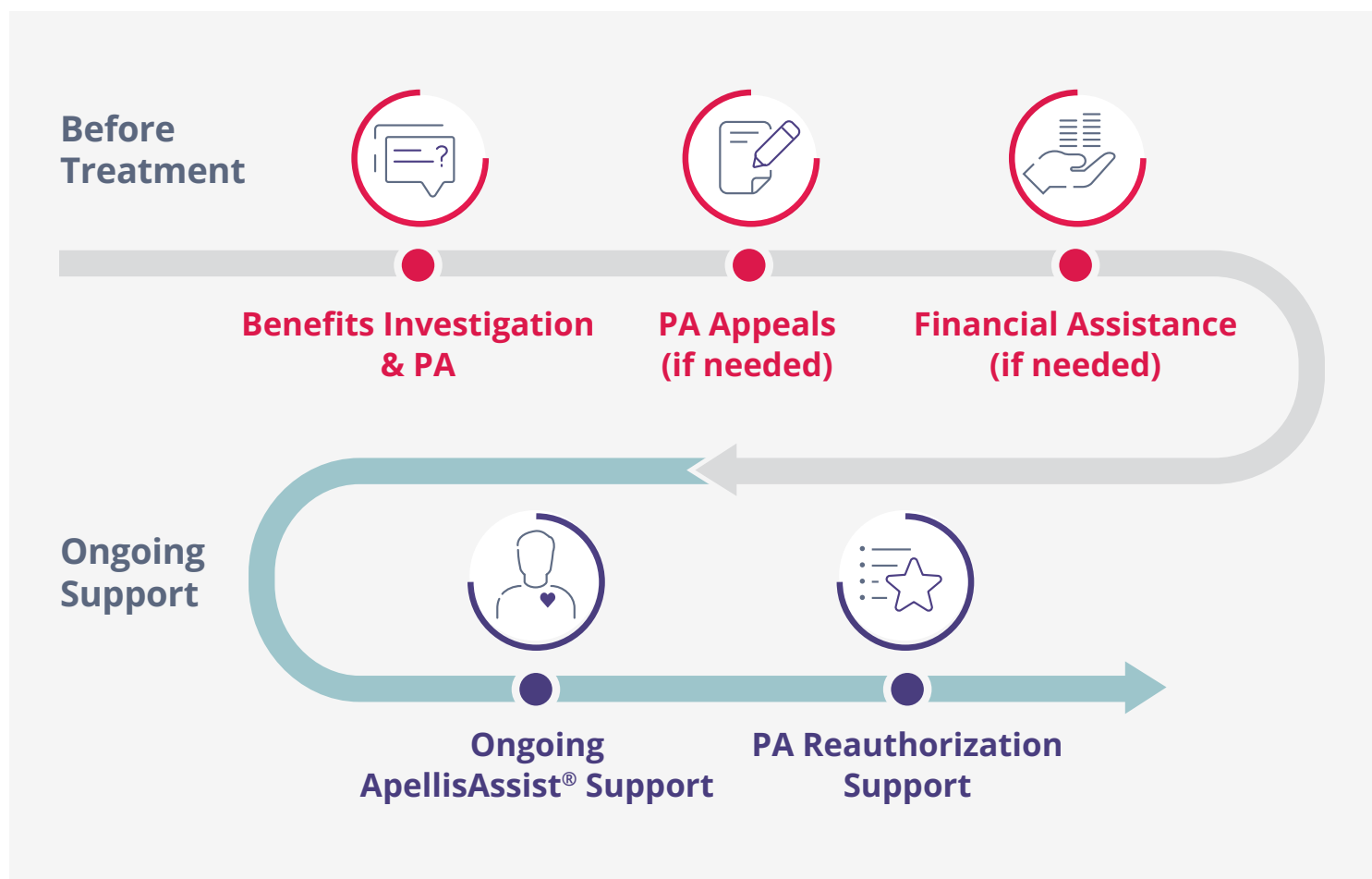
- Complete or update vaccination for encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, unless the risks of delaying therapy with EMPAVELI outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations 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.

Please see full Important Safety Information on [pages 6-7](#) and full [Prescribing Information](#), including Boxed WARNING regarding serious infections caused by encapsulated bacteria, and [Medication Guide](#).

What is prior authorization?

Prior authorization (PA) is a process that requires healthcare providers (HCPs) to obtain approval from a patient's health plan before it will cover the cost of a particular drug or service. A health plan may require evidence that supports the prescriber's decision and explains the potential consequences of the patient not receiving the prescribed drug or service during the PA process.



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Tips for PA submission for EMPAVELI

If a patient's health plan requires a PA for EMPAVELI, review the specific forms and criteria required by the health plan to ensure that the PA request is as complete as possible.



If you have any questions on a payer-specific policy, **contact your Apellis Field Access Manager.**

1. **Once you submit the EMPAVELI Start Form to ApellisAssist, your Care Coordinator will initiate a Benefits Investigation. If a PA is required, it is recommended to include the following clinical information:**



eGFR levels



Proteinuria and/or uPCR levels



Kidney biopsy pathology report



Other therapies tried and failed (eg, ACE inhibitors or ARBs)



Any additional relevant clinical records that support treatment with EMPAVELI, including but not limited to:

- ✓ Kidney transplant (date if applicable)
- ✓ Concurrent medications
- ✓ Serum C3 levels



The clinical information above can be submitted at any time via fax to **1-888-754-1285**

ACE = Angiotensin-Converting Enzyme; ARB = Angiotensin Receptor Blocker; eGFR = estimated Glomerular Filtration Rate; uPCR = urine Protein-Creatinine Ratio.

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Tips for PA submission for EMPAVELI

2. Upon receipt of required clinical information:

ApellisAssist can compile the PA on [CoverMyMeds](#) (when possible) and share the key code with your office. You can then:



LOGIN TO [CoverMyMeds](#) and review the information for accuracy



SUBMIT the PA to the payer

If CoverMyMeds is not an option due to payer restrictions, you may need to complete the PA directly with the payer. ApellisAssist and your Field Access Manager can still assist with the navigation of this process.



CONFIRM plan-specific PA requirements and how the PA should be submitted (eg, fax, phone, online)

- ✓ **FILL OUT** the plan-specific PA form (if applicable)
- ✓ **ATTACH** relevant clinical documentation (listed on prior page)
- ✓ **COMPLETE** a *Letter of Medical Necessity*
 - Highlight the clinical assessments that demonstrate the patient need for treatment with EMPAVELI



Access the sample *Letter of Medical Necessity* at empavelihcp.com/c3g/resources

3. Check the accuracy of all information to ensure patient and prescriber details are complete and correct.

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What happens next?

1. **If PA is approved, be sure to document the PA approval number and date in the patient's record and make note of the expiration date.**

ApellisAssist will reach out to your office 20 days prior to the PA expiration to assist with submission of a new PA.

2. **If PA is denied, you can file an appeal.**

ApellisAssist and your Field Access Manager can support you on how to properly file the appeal. The following PA denial checklist may be helpful as you're preparing an appeal:

 Access the sample *Letter of Appeal* at empavelihcp.com/c3g/resources

-  **REVIEW** the denial letter to understand the reason for the denial and note any deadlines for next steps
-  **COMPILE** supporting medical information, documentation, and clinical assessments
-  **SUBMIT** the first appeal per the health plan's process and requirements
-  **COMPLETE** a *Letter of Appeal*
 - Explain why EMPAVELI is medically necessary for the patient and why the payer's initial decision should be overturned

If rejected, you may be able to submit a second level appeal or request a peer-to-peer review

Many health plans' appeal policies allow up to 2 levels of internal appeal for PA denials. You may have the right to request an external appeal, which can include a review by an independent expert not affiliated with the health plan or an external review board. Be sure to note any deadlines for these additional appeals.

If a prior authorization denial is upheld, **ApellisAssist can help** determine patient eligibility for financial assistance

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- 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.

Please see full [Prescribing Information](#), including **Boxed WARNING** regarding serious infections caused by encapsulated bacteria, and [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Serious Infections Caused by Encapsulated Bacteria (cont'd)

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 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 $\geq 10\%$) 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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Your Apellis **Field Access Manager** can help support patient access

A Field Access Manager helps to optimize patient access to EMPAVELI by:

- Working directly with your office to address patient-specific access issues
- Providing education and resources on ApellisAssist support programs
- Proactively analyzing access and prior authorization requirements, and addressing challenges



**Reach out to your local Field Access Manager for
any support regarding PAs with your patients.**

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