# Sample Letter of Medical Necessity for SYFOVRE® (pegcetacoplan injection) 15 mg/0.1 mL

## 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.

***Note: When preparing the actual letter, use your professional/physician letterhead.***

# INDICATION

SYFOVRE® (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

# IMPORTANT SAFETY INFORMATION

# CONTRAINDICATIONS

## SYFOVRE is contraindicated in patients with ocular or periocular infections, in patients with active intraocular inflammation, and in patients with hypersensitivity to pegcetacoplan or any of the excipients in SYFOVRE. Systemic hypersensitivity reactions (e.g., anaphylaxis, rash, urticaria) have occurred.

# WARNINGS AND PRECAUTIONS

## Endophthalmitis and Retinal Detachments

* + Intravitreal injections, including those with SYFOVRE, may be associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering SYFOVRE to minimize the risk of endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
* **Retinal Vasculitis and/or Retinal Vascular Occlusion**
	+ Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of SYFOVRE. Cases may occur with the first dose of SYFOVRE and may result in severe vision loss. Discontinue treatment with SYFOVRE in patients who develop these events. Patients should be instructed to report any change in vision without delay.

## Neovascular AMD

* + In clinical trials, use of SYFOVRE was associated with increased rates of neovascular (wet) AMD or choroidal neovascularization (12% when administered monthly, 7% when administered every other month and 3% in the control group) by Month 24. Patients receiving SYFOVRE should be monitored for signs of neovascular AMD. In case anti-Vascular Endothelial Growth Factor (anti-VEGF) is required, it should be given separately from SYFOVRE administration.

## Intraocular Inflammation

* + In clinical trials, use of SYFOVRE was associated with episodes of intraocular inflammation including: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare. After inflammation resolves, patients may resume treatment with SYFOVRE.

## Increased Intraocular Pressure

* + Acute increase in IOP may occur within minutes of any intravitreal injection, including with SYFOVRE. Perfusion of the optic nerve head should be monitored following the injection and managed as needed.

# ADVERSE REACTIONS

* Most common adverse reactions (incidence ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

## Please see full [Prescribing Information](https://pi.apellis.com/files/PI_SYFOVRE.pdf) for more information.

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[Date]

[Payer Medical/Pharmacy Director/Contact Name] [Payer Organization Name]

[Payer Street Address] [Payer City, State, ZIP Code]

RE: [Patient Name]

Date of Birth: [Patient’s DOB]

Policy ID/Group Number: [Policy ID/Group Number] Policy Holder: [Policy Holder’s Name]

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 document the medical necessity of SYFOVRE® (pegcetacoplan injection) 15 mg/0.1 mL for the treatment of [diagnosis/condition]. This letter provides information about [Patient Name]’s medical history, diagnosis, prognosis, and a summary of the rationale supporting the use of SYFOVRE for this patient.

## Summary of Patient’s Medical History

[You may be required to include the following]:

* Patient’s diagnosis of GA and date of diagnosis by [name of referring physician]
* Basis for diagnosis [details about diagnostic workup, relevant medical history]
* Patient’s current condition [current state, signs of disease progression that led to you prescribing SYFOVRE]

## Patient-Specific Rationale for Treatment

[Explain why SYFOVRE is medically necessary for this patient. This may include your treatment rationale as well as your professional opinion of the patient’s anticipated prognosis or disease progression without treatment.]

[Provider may choose to include the specific criteria for coverage that the patient meets based on the patient’s health plan and their policy, along with other relevant details.]

Based upon [Patient Name]’s clinical condition and a review of the supporting documentation, I am confident you will agree that SYFOVRE is medically necessary for this patient. Please contact my office at [telephone number] if I can provide you with any additional information. I look forward to receiving your timely response and approval of this authorization.

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.]

* Full Prescribing Information
* Relevant clinical documentation