# Sample Letter for Coverage Denial Appeal 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]

## ATTN: Coverage Denial/Appeals

Re: Coverage for SYFOVRE® (pegcetacoplan injection) 15 mg/0.1 mL

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]

Claim reference number: [Claim or Reference Number] Claim submission date: [Submission Date]

Denial date: [Denial Date]

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

I am writing to request a review of a denial of coverage for SYFOVRE in treating [Patient Name] for [diagnosis/condition]. In a letter dated [date of denial letter], [Payer Name] stated that SYFOVRE is not covered because [insert denial reason from payer]. I have reviewed your letter and based on my medical expertise and clinical assessment of my patient, which I describe in greater detail below, I believe SYFOVRE is medically necessary for my patient and request that you reconsider this coverage decision.

[Patient Name]’s medical history and diagnosis are as follows:

[Describe the patient’s medical history, diagnosis, prognosis, and a summary of why you believe SYFOVRE is clinically appropriate and medically necessary for your patient.]

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

I respectfully request that you review the supporting documentation provided and consider overturning your coverage decision regarding SYFOVRE for [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.]

* Denial letter
* Full Prescribing Information
* Relevant clinical documentation