**Sample Letter of Coverage Reauthorization 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: Reauthorization/Renewal**

**Re:** Coverage Reauthorization/Renewal for SYFOVRE® (pegcetacoplan injection)

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

**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]
* Patient’s age

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

[You may be required to include the following]:

* Date of initial and subsequent treatments and eye(s) administered
* Provider attestation as to patient benefit
* Dosing frequency and whether you have discussed with the patient the potential for decreasing the frequency of administration
* Patient feedback/anecdotes while on treatment

**Patient-Specific Rationale for Continued Treatment**

[Explain why you believe the continued administration of SYFOVRE 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 patient continues to meet initial payer criteria
* The requested dose by the provider
* How patient has tolerated his/her SYFOVRE doses (discussion of no evidence of intolerable adverse events or drug toxicity that cannot be adequately treated if applicable for the patient)
* Confirmation that SYFOVRE will not be used with other intravitreal complement inhibitors

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

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.]

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