SYFOVRE® (pegcetacoplan injection) 15 mg / 0.1 mL

Product Fact Sheet

SYFOVRE product information at a glance

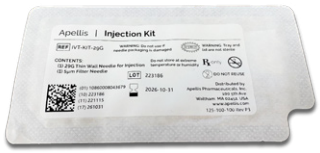
Indication: SYFOVRE® (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

SELECT SAFETY INFORMATION

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.

Please see additional Important Safety Information on the following page.

How Supplied[1]	A clear, colorless to light yellow aqueous solution.
Packaging[1]	Each SYFOVRE carton contains one single-dose glass vial.
Ancillary Supplies[1]	The following supplies are required to administer SYFOVRE: • One 5-micron filter needle **(included in the IVT Injection Kit)** • One 1-mL Luer-lock syringe with a 0.1 mL dose mark **(not included)** • One ½ inch; 29-gauge thin-wall injection needle with Luer-lock hub **(included in the IVT Injection Kit)** or 27-gauge needle with Luer-lock hub **(not included)** • Alcohol swab **(not included)**
Recommended Dosage[1]	15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once **every 25 to 60 days**.
Storage Requirements[1]	• Refrigerate between 2 °C to 8 °C (36 °F to 46 °F) • Store the vial in the original carton to protect from light • Do not use beyond the expiration date on the carton • Keep the vial in the original carton at room temperature for at least 15 minutes prior to injection, but no longer than 8 hours



Approval date[2]	2/17/23

	Nonexudative age-related macular degeneration (AMD)	Right eye	Left eye	Bilateral
ICD-10-CM Codes for GA[3]	Advanced atrophic **without** subfoveal involvement	H35.3113	H35.3123	H35.3133
	Advanced atrophic **with** subfoveal involvement	H35.3114	H35.3124	H35.3134

CPT Code[4]	**67028**: Intravitreal injection of a pharmacologic agent, separate procedure	
HCPCS Code[5]	**Permanent J-code**[a,b] **effective October 1, 2023**	**Site of care**
	J2781: Injection, pegcetacoplan, intravitreal, 1 mg Bill 15 units for each SYFOVRE injection	Physician office and hospital outpatient
NDC[1,6]	10-digit NDC: **73606-020-01**	11-digit NDC: **73606-0020-01**
Authorized Distributors	Specialty distributors for buy and bill: • AmerisourceBergen (Besse Medical) • Cardinal Health™ (Metro Medical™) • McKesson (Specialty Health and Plasma & Biologics) • CuraScript® SD • BioCare	Specialty pharmacies: • Accredo® Specialty Pharmacy • Optum Specialty Pharmacy • CenterWell Specialty Pharmacy™

Apellis does not recommend the use of any particular listed distributor or pharmacy.

The coding information in this document is provided for informational purposes only, is subject to change, and is not a substitute for independent clinical judgment when selecting diagnosis and reimbursement codes. Codes listed above may not be exhaustive of those required by payers.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision; NDC=National Drug Code.

[a] J2781 is a permanent, product-specific code assigned by Centers for Medicare & Medicaid Services (CMS). Bill 15 units for each SYFOVRE injection.

[b] Dose descriptor is assigned by CMS; please see full prescribing information for approved dosing.

Please see Important Safety Information on the following page and the full Prescribing Information.

SYFOVRE®
(pegcetacoplan injection)
15 mg / 0.1 mL

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 for more information.

References: 1. Syfovre. Prescribing information. Apellis Pharmaceuticals, Inc; 2024. **2.** NDA Approval 217171. US Food and Drug Administration. February 17, 2023. Accessed February 14, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217171Orig1s000ltr.pdf **3.** Lum F, Repka MX, Vicchrilli S. How to use the ICD-10 codes for age-related macular degeneration. *EyeNet Magazine*. 2017;9:61-62. **4.** Coding for injectable drugs. American Academy of Ophthalmology. Accessed February 14, 2025. https://www.aao.org/practice-management/coding/injectable-drugs **5.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. Centers for Medicare & Medicaid Services. Accessed February 14, 2025. https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-2-2023-drugs-and-biologicals.pdf **6.** Proposed rule on revising the national drug code format. US Food and Drug Administration. Updated September 7, 2022. Accessed February 14, 2025. https://www.fda.gov/drugs/drug-approvals-and-databases/proposed-rule-revising-national-drug-code-format

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