




SYFOVRE[®]
(pegcetacoplan injection)
15mg / 0.1mL

EFFECTIVE OCTOBER 1, 2023

Permanent J-code for SYFOVRE: **J2781**

Billing and Coding Guide

 Phone: 888-APELLIS (888-273-5547) 8 AM-8 PM ET, Monday-Friday

 Portal: ApellisAssistGA.com

 Website: SyfovreECP.com

 Fax: 888-405-6966

The coding information in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice.

This guide is intended to provide general information for submitting claims to payers for reimbursement. In no way should this information be considered a guarantee of coverage or reimbursement for any product or service. Coding and coverage policies change periodically, often without warning. The responsibility to determine coverage and reimbursement parameters and appropriate coding for a particular patient or procedure is always the responsibility of the provider. The codes listed herein may not apply to all patients or to all payers. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient. Practices should contact the applicable payer for more information on a payer's coverage, coding, and reimbursement policies.

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, and in patients with active intraocular inflammation

Please see additional Important Safety Information throughout and full [Prescribing Information](#).

Apellis

Coding Information

The following codes may be appropriate when billing for SYFOVRE and its related services.

Several terms are used in Geographic Atrophy (GA) to indicate lesion location relative to the fovea

H35.31X3:
WITHOUT SUBFOVEAL INVOLVEMENT

- ⊖ **no** involvement of the fovea
- ⊖ **extra**foveal lesions
- ⊖ **nonsub**foveal lesions
- ⊖ **without** subfoveal lesions

H35.31X4:
WITH SUBFOVEAL INVOLVEMENT

- ⊕ **with** involvement of the fovea
- ⊕ **foveal** lesions
- ⊕ **subfoveal** lesions
- ⊕ **with** subfoveal lesions

The ICD-10-CM codes below are designated for GA¹

| Geographic Atrophy ICD-10-CM Codes ¹ Used for diagnosis coding | | | | |
|---|--|-----------|----------|-----------|
| Nonexudative age-related macular degeneration (AMD) | | Right eye | Left eye | Bilateral |
| GA | Advanced atrophic without subfoveal involvement | H35.3113 | H35.3123 | H35.3133 |
| | Advanced atrophic with subfoveal involvement | H35.3114 | H35.3124 | H35.3134 |

Drug Administration CPT Code^{2a}
Used to report medical procedures and services

| CPT code | Description |
|----------|---|
| 67028 | Intravitreal injection of a pharmacologic agent, separate procedure |

This may not be reflective of all CPT codes that may be used for SYFOVRE.

Modifiers Used in conjunction with the CPT Code at left to provide further information about the procedure or service

| Modifier | Description |
|----------|-------------|
| -LT | Left eye |
| -RT | Right eye |
| -50 | Bilateral |

This is not an exhaustive list of modifiers, and requirements may vary by payer.

CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

^aCPT codes, descriptions, and material are ©2023 American Medical Association. All rights reserved.

IMPORTANT SAFETY INFORMATION

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.



Please see additional Important Safety Information throughout and full Prescribing Information.



Coding Information (cont'd)

The following codes may be appropriate when billing for SYFOVRE and its related services.

| HCPCS Code ³ Used for drugs administered by a medical professional | | |
|---|--|--|
| Permanent J-code | CMS long descriptor ^a | Site of care |
| J2781 effective October 1, 2023 | Injection, pegcetacoplan, intravitreal, 1 mg | Physician office and hospital outpatient |

J2781 is a permanent, product-specific code assigned by CMS. **Bill 15 units for each SYFOVRE injection.**

^aDose descriptor is assigned by CMS; please see full prescribing information for approved dosing.

The JZ modifier is required starting July 1, 2023.⁴ Please check with your patient's health plan for specific requirements.

| National Drug Code (NDC) ^{5,6} Used by the FDA as an identifier for drugs | |
|---|---|
| 10-digit NDC for SYFOVRE Many NDCs listed on drug packaging are in a 10-digit format | 11-digit NDC for SYFOVRE The 11-digit NDC is derived from the 10-digit code. Many payers require the use of the 11-digit code |
| 73606-020-01 | 73606-0020-01 |

| Dosage form and strength |
|---|
| Intravitreal injection: 15 mg (0.1 mL of 150 mg/mL solution), clear, colorless to light yellow aqueous solution in a single-dose vial |

| Revenue Codes ⁷ For hospital outpatient use only | |
|---|---------------------------------|
| Revenue code | Description |
| 0636 | Drugs requiring detailed coding |
| 0510 | Clinic visit, general |

This is not an exhaustive list of revenue codes, and requirements may vary by payer.

CMS=Centers for Medicare and Medicaid Services; HCPCS=Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

• 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.



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Sample CMS-1500 Claim Form: Physician Office

Below is a sample CMS-1500 form for SYFOVRE claim submissions.

The sample claim form provided below is for illustrative purposes only. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

Box 21:
Enter the appropriate ICD-10-CM code corresponding to the patient's diagnosis.

Box 23:
If available, report the Prior Authorization number here.

Shaded area below box 24A:
The payer may require the N4 qualifier immediately preceding the 11-digit NDC, the unit of measurement qualifier, and unit quantity.

Box 24B:
Enter the place of service for physician offices.

Box 24D:
Include all appropriate CPT codes, modifiers, and HCPCS codes. The JZ modifier is required starting July 1, 2023.⁴

Box 24E:
Specify the diagnosis letter from Box 21 relating to each CPT/HCPCS code listed in Box 24D.

Box 24G:
Enter the number of units for each CPT/HCPCS code. When using the permanent J-code, bill 15 units for each SYFOVRE injection. Check with each payer for their specific coding requirements.

NOTE: Payers may vary in their specific billing and coding requirements. Please check with your patient's health plan to ensure you are providing accurate and complete information.

The JZ modifier is required starting July 1, 2023.⁴

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

• 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.



Please see additional Important Safety Information throughout and full Prescribing Information.

Sample CMS-1450 (UB-04) Claim Form: Hospital Outpatient

Below is a sample CMS-1450 (UB-04) form for SYFOVRE claim submissions.

The sample claim form provided below is for illustrative purposes only. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

| | | | | | | |
|---|--|--|--|---|-----------------|---|
| 1 Hospital Name Street Address City, State, Zip | | 2 Pay-to Name Pay-to Address Pay-to City, State, Zip | | 3a PAT CITY # | 3b MED REC # | 4 TYPE OF BILL |
| 8 PATIENT NAME a Patient ID | | 9 PATIENT ADDRESS a | | 6 STATEMENT COVERS PERIOD FROM THROUGH | | |
| 10 BIRTHDATE 11 SEX 12 DATE | | 13 ADMISSION 13 HR 14 TYPE 15 SRC | | 16 DHR | | 17 STAT |
| 18 19 20 21 | | 22 23 24 25 26 27 28 | | 29 ACCT STATE | | 30 |
| 31 OCCURRENCE DATE 32 CODE | | 33 OCCURRENCE DATE 34 CODE | | 35 OCCURRENCE DATE 36 CODE | | 37 |
| 38 | | 39 VALUE CODES AMOUNT | | 40 VALUE CODES AMOUNT | | 41 VALUE CODES AMOUNT |
| 42 REV CD | | 43 DESCRIPTION | | 44 HCPCS / RATE / HPSV CODE | | 45 SERV DATE |
| 46 | | 47 | | 48 | | 49 |
| 0636 | | Drugs requiring detailed coding [N473606002001ML0.1] | | J2781-JZ | | 15 |
| 0510 | | Clinic Visit (General) | | 67028-RT | | 1 |
| PAGE OF | | CREATION DATE | | TOTALS | | |
| 50 PAYER NAME | | 51 HEALTH PLAN ID | | 52 REL PRIO | | 53 ADD PRIO |
| 54 PRIOR PAYMENTS | | 55 EST. AMOUNT DUE | | 56 NPI | | 57 OTHER PRV ID |
| 58 INSURED'S NAME | | 59 FREL | | 60 INSURED'S UNIQUE ID | | 61 GROUP NAME |
| 62 INSURANCE GROUP NO. | | 63 TREATMENT AUTHORIZATION CODES | | 64 DOCUMENT CONTROL NUMBER | | 65 EMPLOYER NAME |
| 66 | | 67 | | 68 | | 69 |
| H353113 | | A B C D E F G H I J K L M N O P Q R S T U V W X Y Z | | A B C D E F G H I J K L M N O P Q R S T U V W X Y Z | | A B C D E F G H I J K L M N O P Q R S T U V W X Y Z |
| 69 ADMIT DATE | | 70 PATIENT REASON FOR ADMIT | | 71 PPS CODE | | JZ ICD |
| 72 PRINCIPAL PROCEDURE CODE DATE | | 73 OTHER PROCEDURE CODE DATE | | 74 OTHER PROCEDURE CODE DATE | | 75 |
| 76 ATTENDING LAST FIRST | | 77 OPERATING LAST FIRST | | 78 OTHER LAST FIRST | | 79 OTHER LAST FIRST |
| 80 REMARKS | | 81CCI a | | 82 | | 83 |

Box 42

Box 43

Box 44

Box 46

J2781: Permanent J-code for SYFOVRE effective October 1, 2023

JZ modifier required effective July 1, 2023, to attest that no amount of drug was discarded and eligible for payment

Box 42:
Enter the appropriate revenue code corresponding to the HCPCS code and CPT code in Box 44.

Box 43:
Enter a detailed drug description, including the N4 qualifier immediately preceding the 11-digit NDC, the unit of measurement qualifier, and unit quantity.

Box 44:
Enter the appropriate HCPCS code for SYFOVRE as required by the payer, as well as the JZ modifier (required effective July 1, 2023). Also include the CPT code representing procedure performed, as well as the appropriate modifier.

Box 46:
Enter the number of HCPCS units administered. When using the permanent J-code, bill 15 units for each SYFOVRE injection. Check with each payer for their specific coding requirements.

Box 63

Box 67

Box 63:
If available, report the Treatment Authorization codes here.

Box 67:
Enter the appropriate ICD-10-CM code corresponding to the patient's diagnosis.

NOTE: Payers may vary in their specific billing and coding requirements. Please check with your patient's health plan to ensure you are providing accurate and complete information. The JZ modifier is required starting July 1, 2023.⁴

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (CONTINUED)

- 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.



Please see additional Important Safety Information throughout and full Prescribing Information.



Tips for completing claim forms:



Use the most appropriate ICD-10-CM and CPT codes associated with each patient's diagnosis and care



When using the permanent J-code J2781, bill 15 units for each SYFOVRE injection



Contact the payer prior to submitting the claim to confirm the payer's method for submission and if supporting documentation is required



Ensure the appropriate documentation that supports the information on the claim form is in the patient's medical record in case the payer requests it



Verify the claim for accuracy and file it as soon as possible, within each payer's filing time limits



Check your contract, or contact provider services at the payer to determine reimbursement

Questions? Please reach out to your Apellis Field Reimbursement Manager or the ApellisAssist® program

ApellisAssist® Here for your patients

The ApellisAssist program can provide assistance on a range of topics, including insurance coverage requirements, claim submission policies and procedures, and billing and coding questions.

To enroll your patients in ApellisAssist

Register for the portal and submit your request online at ApellisAssistGA.com



Download the Enrollment Form from SyfovreECP.com and fax the completed form to **888-405-6966**



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• 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 $\geq 5\%$) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

Please see full [Prescribing Information](#) for more information.

References: 1. Lum F, Repka MX, Vicchilli S. How to use the ICD-10 codes for age-related macular degeneration. *EyeNet Magazine*. 2017;9:61–62. 2. Coding for injectable drugs. American Academy of Ophthalmology. Accessed July 18, 2023. <https://www.aao.org/practice-management/coding/injectable-drugs> 3. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding recommendations. Centers for Medicare & Medicaid Services. Accessed August 14, 2023. <https://www.cms.gov/files/document/2023-hcpcs-application-summary-quarter-2-2023-drugs-and-biologicals.pdf> 4. Medicare program. Discarded drugs and biologicals – JW modifier and JZ modifier policy. Frequently asked questions. Centers for Medicare & Medicaid Services (CMS). Accessed July 21, 2023. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf> 5. Syfovre. Prescribing information. Apellis Pharmaceuticals, Inc.; 2023. 6. Proposed rule on revising the national drug code format. US Food and Drug Administration. Updated December 27, 2022. Accessed July 18, 2023. <https://www.fda.gov/drugs/drug-approvals-and-databases/proposed-rule-revising-national-drug-code-format> 7. Revenue codes. Noridian Healthcare Solutions. Updated June 28, 2022. Accessed July 18, 2023. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>