

# Access and Reimbursement Guide

A step-by-step guide to help support patient access to SYFOVRE

This guide is intended to provide information about access and reimbursement for SYFOVRE but is not meant in any way to provide a guarantee of coverage or reimbursement for any product or services. 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. 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.

ApellisAssist Here for your patients

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

Portal: ApellisAssistGA.com

Website: SyfovreECP.com

Fax: 888-405-6966

## **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.



# How to use this guide

In this guide, you will find an overview of access and reimbursement support services for SYFOVRE, including links to educational resources. Please click on the numbers below to learn more about each topic.

## Overview of the access and reimbursement process

### **Before injection**

- Learn about available access and reimbursement support offered by Apellis FRMs and the ApellisAssist<sup>®</sup> program
- Get to know your FRM (Field Reimbursement Manager)
- Get to know the ApellisAssist program



#### Enroll your patient in the ApellisAssist program • Once you decide SYFOVRE is right for your patient,

- enroll them online or via fax to start the benefits investigation process
- Register for the portal and submit your request online at ApellisAssistGA.com

#### OR

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



**Review insurance coverage information** Review the Summary of Benefits provided by the ApellisAssist program to determine insurance requirements.

**Obtain prior authorization (PA)** (if required) If the benefits investigation demonstrates that a PA is required, submit the PA and Letter of Medical Necessity (LMN) to the health plan.



A sample LMN can be downloaded at SyfovreECP.com

Understand patient financial assistance eligibility ApellisAssist will notify your office and patient of financial assistance eligibility.



#### Confirm product acquisition method Determine buy and bill or specialty pharmacy acquisition method and order the product.



The Product Ordering Guide can be downloaded at SyfovreECP.com

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

#### Endophthalmitis and Retinal Detachments

o 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.





#### **Appeal denied claims**

payment is received.

Submit the claim

accurate and complete.

If you receive a denied claim for a patient who is enrolled in the ApellisAssist program, then ApellisAssist and the FRM can work with you to help determine the denial reason and provide information about the steps you should take to appeal.



A sample **Appeals Letter** can be downloaded at SyfovreECP.com



**Prepare for PA reauthorization** (*if applicable*) ApellisAssist can help determine if your patient's health plan requires reauthorization for SYFOVRE.











## Access and reimbursement information about SYFOVRE

- Provide information about payer coverage, PA processes, and billing and coding
- Share regional payer trends and policy updates



## Product acquisition and procurement

- Explain policies and processes related to product acquisition
- Share contact details for our distribution network



### Patient support services education

- Walk through ApellisAssist patient support services and how to access support
- Share information about financial assistance options for eligible patients

# IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

### 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.





# Step 1 (cont'd): Get to know the ApellisAssist program



ApellisAssist is a program designed to help your patients along their treatment journey



We recognize that you are the expert in your patients' care. The ApellisAssist program is here to provide support by helping patients overcome potential access barriers to treatment.



# IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

### 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.





# **Step 2: Enroll your patient in the ApellisAssist program**



Once you decide SYFOVRE is right for your GA patient, enroll them in ApellisAssist support services in 1 of 2 ways<sup>a</sup>

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

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

### To successfully complete the Enrollment Form, please make sure:

All information is com	plete and accurate		
ENROLLMENT FORM Phone: 888-APE	LLIS (888-273-5547) • Fax: 888-405-6966 SYFOVRE		
lease ensure you and your patient complete all required infor Required Field	mation on the form and sign where indicated. (pegcetacoplan injection)		
Section 1. Support Request			
	pport services throughout the patient journey, but only when needed)		
Benefits Investigation Only Prior Authorization Assis	stance Co-pay Program (commercially insured patients) Patient Assistance Program (uninsured or underinsured patients)		
ection 2. Patient Information			
First Name:Middle	Initial:*Last Name:		
Gender: 🗖 Male 🔲 Female 🔲 Other:	*Date of Birth (MM/DD/YYYY)://		
Preferred Phone: Home Pl	hone 🔲 Mobile Phone Email:		
Address:City:	State: ZIP:		
Preferred Language: 🗌 English 📋 Spanish 🔲 Other:			
Section 3. Caregiver Information (optional) loes patient have a caregiver with whom they would like ApellisA	ssist to share information? 🗌 Yes 🗌 No (If yes, please complete this section)		
aregiver First Name:La	st Name:		
Preferred Phone: Home Phone Mobile Phone Email:			
/hat is the caregiver's relationship to the patient? 🔲 Legal Gu	uardian 🔲 Spouse 🔲 Sibling 🔲 Other:		
rimary Insurance ( I f copy of card is attached, check here) Payer Name and Payer ID:	Secondary Insurance ( I If copy of card is attached, check here) *Payer Name and Payer ID: Phone:		
Phone: Policyholder Name:	Policyholder Name:		
Policyholder Name.	Policyholder DOB:		
Policy Number:	*PolicyNumber:		
Employer/Group Number:	Employer/Group Number:		
Optional Section) Pharmacy (PBM) Name: BM Group ID: PBM BIN/PCN:	PBM Phone Number:		
How many people live in the patient's household? Total annual household income (including salary/wages; S Less than \$150,000 G Greater than \$150,000	ompleted for Patient Assistance Program requests only) — foocial Security income: disability income: any other income): it may also ask for proof of income at any time for audit/verification.		
	ad and agree to		
Section 10.1 Authorization Section 1	10.2 Authorization to Section 10.3 Authorization		
Section 10.1 Authorization Section 1 to Share Personal Enroll in A	10.2 Authorization to ApellisAssist Patient to Receive Marketing		
Section 10.1 Authorization Section 1 to Share Personal Enroll in A	10.2 Authorization to Section 10.3 Authorization		
Section 10.1 Authorization Section 1 to Share Personal Enroll in A	10.2 Authorization to ApellisAssist Patient         Section 10.3 Authorization to Receive Marketing           Program (required)         Communications (optional)		
Section 10.1 Authorization Section 1 to Share Personal Enroll in A	10.2 Authorization to ApellisAssist Patient to Receive Marketing		
Section 10.1 Authorization Section 1 to Share Personal Enrollin / Health Information (required) Support	10.2 Authorization to ApellisAssist Patient Program (required)		



patient to https://hipaaconsent.com/

## What happens next?

The ApellisAssist program will provide your office with a status update on your patient's enrollment within 1 business day. The ApellisAssist team will check the patient's insurance coverage for SYFOVRE, identify any initial coverage requirements, and assess eligibility for financial assistance.

<sup>a</sup>Any patient enrollment submitted to ApellisAssist may be viewed in the ApellisAssist portal no matter how the enrollment was submitted (portal, tablet-based technology, or fax). Providers must establish an account within the ApellisAssist portal to view patient enrollment statuses and to submit enrollments via the ApellisAssist portal.

# IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

### 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.







# **Step 3: Review insurance coverage information**

## Review the Summary of Benefits provided by the ApellisAssist program to determine insurance requirements

If your office requested that ApellisAssist complete the patient's benefits investigation, then you will receive a Summary of Benefits within 1 business day (upon receipt of the completed enrollment form).

Patient Name:	DOB: Patient HUB ID:		
Primary Medical Insurance:			
Insurance Phone Number:	ID#:		
Payer Type:	Plan Type:		
Group#:	Effective Date:		
Is SYFOVRE Covered: Yes No	Benefits: In Network Out of Network		
Individual Deductible/Amount Met:	/		
Individual Out of Pocket/Amount Met: /			
Patient Drug Cost Share:			
Office Visit Copay/Co-Insurance:			
Admin Copay/Co-Insurance:			
Prior Authorization Required: Yes No Prior Authorization Submission Details:	See prior authorization details below		
Prior Authorization Submission Details: Secondary Medical Insurance:			
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number:	ID#:		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type:			
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#:	ID#: Plan Type:		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No	ID#: Plan Type: Effective Date:		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No Individual Deductible/Amount Met:	ID#: Plan Type: Effective Date:		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No Individual Deductible/Amount Met: Individual Out of Pocket/Amount Met:	ID#: Plan Type: Effective Date: Benefits: In Network Out of Network /		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No Individual Deductible/Amount Met: Individual Out of Pocket/Amount Met:	ID#: Plan Type: Effective Date: Benefits: In Network Out of Network /		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No Individual Deductible/Amount Met: Individual Out of Pocket/Amount Met: Patient Drug Cost Share:	ID#: Plan Type: Effective Date: Benefits: In Network Out of Network /		
Prior Authorization Required: Yes No Prior Authorization Submission Details: Secondary Medical Insurance: Insurance Phone Number: Payer Type: Group#: Is SYFOVRE Covered: Yes No Individual Deductible/Amount Met: Individual Out of Pocket/Amount Met: Patient Drug Cost Share: Office Visit Copay/Co-Insurance:	ID#: Plan Type: Effective Date: Benefits: In Network Out of Network /		

# A Summary of Benefits includes:

- Coverage details
- PA requirements (if applicable)
- Patient out-of-pocket costs

The practice should review the Summary of Benefits to determine if a PA is required or if the patient may need financial assistance from Apellis.

## IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

- 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.





# **Step 4: Obtain prior authorization** (if required)

# The ApellisAssist program and your FRM can help guide you through the PA process

Payers may require a PA describing your patient's medical history and the reasons why SYFOVRE has been prescribed. Various health plans have different requirements. It is important to check with your patient's health plan to ensure you are using the correct form and supplying all the required information. To avoid delays, it is prudent to include a **Letter of Medical Necessity** to support the PA submission.

# **PA checklist**

### Helpful reminders for the PA process

- Confirm PA requirements and how the PA should be submitted (eg, fax, phone, or online)
- Oetermine if the health plan has a specific form that must be used and if it is available online
- Check the health plan's policy for treating GA with SYFOVRE to ensure medical documentation addresses specific policy requirements
- ✓ Use the appropriate billing codes
  - The **Billing and Coding Guide** can be downloaded at **SyfovreECP.com**

All PA forms must be filled out and submitted by a patient's healthcare provider based on their clinical judgment and assessment of the patient's case.

Letter of Medical Necessity (some payers may require this)

- Be specific in your request (ie, requesting approval of the PA to support the prescribed medication)
- Highlight the clinical assessments that demonstrate the patient need and that the patient meets the health plan medical policy criteria for treatment with SYFOVRE
- ⊘ Include a copy of the health plan medical policy, if available
- ⊘ Include the physician's contact information



A sample LMN can be downloaded at SyfovreECP.com

## IMPORTANT SAFETY INFORMATION (cont'd)

### **ADVERSE REACTIONS**

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





# **Step 4 (cont'd): Obtain prior authorization** (if required)

## Follow up!

- ⊘ Call to make sure the PA request was received
- Keep a record of your phone calls: who you talked to, when, and what was agreed to or discussed
- Occument the PA approval number and duration (with written confirmation, if possible)
- ⊘ Include the PA reference number on the claim form, if possible

# What happens next?

- If the PA is approved, be sure to document the PA approval number/date in the patient's record and make note of the expiration date
- 2 If the PA is denied, you can file an appeal. The ApellisAssist program can support you and provide information about how your office can properly file this paperwork. The following PA denial appeal checklist may be helpful as you're preparing an appeal:
  - Review the denial letter to understand the reason for the denial and note any deadlines for next steps
  - Ocompile supporting medical information, documentation, and clinical assessments
  - Submit the first appeal per the health plan's process and requirements
  - ✓ If rejected, submit a second appeal that responds to the health plan's concerns, questions, or requirements
  - ✓ Many health plans' appeal policies allow up to 2 levels of internal appeal for PA denials. You may have the right to request an external appeal, which can include a review by an independent expert not affiliated with the health plan or an external review board. Be sure to note any deadlines for these additional appeals

## **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.





# **Step 5: Understand patient financial** assistance eligibility

Financial assistance options are available for SYFOVRE patients who are enrolled in the ApellisAssist program and meet eligibility requirements.

ApellisAssist will notify your office and patient of financial assistance eligibility.

## Financial Assistance Programs include:



### Patient Assistance Program<sup>a</sup>

A program for patients who are uninsured (no insurance), underinsured (limited or no pharmacy/medical benefit), or functionally uninsured (denied coverage by their insurance)



### Co-pay Assistance<sup>b,c</sup>

A program for commercially insured patients that assists with co-pay and co-insurance expenses

<sup>a</sup>Program eligibility criteria, including annual household income limits, apply.

<sup>b</sup>The SYFOVRE Co-pay Program is for eligible patients who are enrolled in the ApellisAssist program, are commercially insured, and are not covered under government insurance programs such as Medicare, Medicaid, VA/DoD, or TRICARE. Apellis reserves the right to modify or terminate the program at any time without notice.

<sup>c</sup>The program assists only with the cost of SYFOVRE and its administration (injection) up to the program maximum. It does not assist with the cost of other administrations, medicines, procedures, or office visits. Eligible patients residing in Massachusetts or Rhode Island can only receive assistance with the cost of SYFOVRE but not the cost of its administration. Patients receiving assistance through another program or foundation, free trial, or other similar offer or program, are not eligible for the program.

# Step 6: Confirm product acquisition method



SYFOVRE is typically acquired via buy and bill, which means your office buys product from your specialty distributor, administers the product, and then bills the payer.

Alternatively, in some cases, SYFOVRE may be acquired via a specialty pharmacy.

More information on distributors and methods of acquisition can be found in the SYFOVRE **Product Ordering Guide** located at **SyfovreECP.com** 

# IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

### • Endophthalmitis and Retinal Detachments

o 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.







# Step 7: Submit the claim

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Billing information, including codes and tips on completing forms accurately and completely, is available in the SYFOVRE **Billing and Coding Guide** located at **SyfovreECP.com** 

Note that coding information provided in the **Billing and Coding Guide** is for informational purposes only and is subject to change.

- Codes may not apply to all patients or all payers. Providers should use their own independent and clinical judgment when selecting coding information
- Practices should contact the patient's health plan for specific information on coverage, coding, and reimbursement policies

# **Step 8: Understand and manage reimbursement**



It is important to understand the processes related to reimbursement for your practice. To do this, you can:

- Determine the reimbursement rate based on the plan contract and published fee schedules
- Establish a reconciliation process to ensure all inventory is captured in the billing process
- Track claims to ensure appropriate payment is received

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

### 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.





# **Step 9: Appeal denied claims**

# The ApellisAssist program and your FRM can help guide you through the appeals process

If the claim is denied, follow the appeals process, which may involve a series of steps. Various health plans have different processes, and it is important to check with your patient's plan to confirm their requirements.

# **Appeal checklist**

- Review the denial letter to understand the reason for the denial and note any deadlines for next steps
- Compile supporting medical information, documentation, and clinical assessments
- Submit the first appeal per the health plan's process and requirements
- ✓ If rejected, submit a second appeal that responds to the health plan's concerns, questions, or requirements

All forms must be filled out and submitted by a patient's healthcare provider based on their clinical judgment and assessment of the patient's case.

Many health plans' appeal policies allow up to 2 levels of internal appeal for claim denials. You may have the right to request an external appeal, which can include a review by an independent expert not affiliated with the health plan or an external review board. Note any deadlines for these additional appeals

A sample Appeals Letter can be downloaded at SyfovreECP.com

# Step 10: Prepare for PA reauthorization (if applicable)

# The ApellisAssist program is available to help determine payer reauthorization requirements and criteria

- Depending on your patient's health plan medical policy, reauthorization for SYFOVRE may be required after 6–12 months of treatment. ApellisAssist is available to help determine payer reauthorization requirements and criteria (eg, upon PA expiration or yearly), which may be subject to change without notice
- Consider making a note in your patient's medical record to initiate the reauthorization process early enough to maintain continuity of treatment

# IMPORTANT SAFETY INFORMATION (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

- 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.









## INDICATION

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

### **IMPORTANT SAFETY INFORMATION**

### CONTRAINDICATIONS

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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 ≥5%) are ocular discomfort, neovascular age-related macular degeneration, vitreous floaters, conjunctival hemorrhage.

### Please see full <u>Prescribing Information</u> for more information.

