

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, and in patients with active intraocular inflammation

Please see additional Important Safety Information throughout and the full <u>Prescribing Information</u>.



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[®] 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.



After injection

Submit the claim



accurate and complete. The Billing and Coding Guide can be

downloaded at SyfovreECP.com



Understand and manage reimbursement Understand reimbursement processes for your practice. Track claims and ensure appropriate payment is received.



Appeal denied claims

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.





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







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



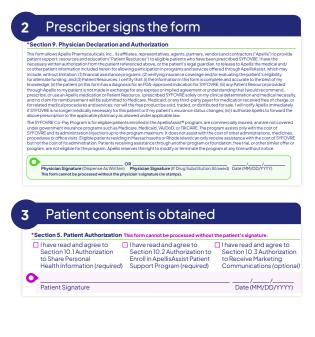
Once you decide SYFOVRE is right for your GA patient, enroll them in ApellisAssist support services in 1 of 2 ways^a

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:

1 All information is complete and accurate					
Please ensure you and your patient complete all required informat Required Field					
Section 1. Support Request Check here for all available services (Checking 'all' allows for suppo OR choose individual services below:	rt services throughout the patient journey, but only when needed)				
Benefits Investigation Only	ce Co-pay Program (commercially insured patients) Patient Assistance Program (uninsured or underinsured patients)				
Section 2. Patient Information					
First Name:Middle Initia	al:*Last Name:				
Gender: 🗌 Male 🔲 Female 🔲 Other:	*Date of Birth (MM/DD/YYYY)://				
Preferred Phone: Home Phone	e Mobile Phone Email:				
Address:City:	State: ZIP:				
Preferred Language: 🗌 English 📋 Spanish 🔲 Other:					
Section 3. Caregiver Information (optional) Does patient have a caregiver with whom they would like ApellisAssis	t to share information? 🗌 Yes 🗌 No (If yes, please complete this section)				
Caregiver First Name: Last N	ame:				
referred Phone: Home Phone					
Vhat is the caregiver's relationship to the patient? 🗌 Legal Guard					
Primary Insurance (] If copy of card is attached, check here) Payer Name and Payer ID:	Secondary Insurance (If copy of card is attached, check here) *Payer Name and Payer ID:				
Phone:	Phone:				
Policyholder Name:	Policyholder Name:				
Policyholder DOB:	Policyholder DOB:				
Policy Number:	*Policy Number:				
Employer/Group Number:	Employer/Group Number:				
Optional Section) Pharmacy (PBM) Name: 'BM Group ID: PBM BIN/PCN:	PBM Phone Number:				
Section 4.1 Financial Information (Must be com How many people live in the patient's household?	pleted for Patient Assistance Program requests only) al Security income; disability income; any other income): ay also ask for proof of income at any time for audit/verification.				
Section 5. Patient Authorization This form cannot	be processed without the patient's signature.				
	2 Authorization to Section 10.3 Authorization ellisAssist Patient to Receive Marketing				
	//				
Patient Signature	Date (MM/DD/YYYY)				
Please see Indication and Important Safety Information on	page 6 and the full Prescribing Information. Page 1 of 6				



To obtain electronic consent, direct your 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 I 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.

^aAny 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.



Please see additional Important Safety Information throughout and the full <u>Prescribing Information</u>.





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:					
Payer Type:				Plan Type:	
ID#:	Group#:		Effective Date:		
Secondary Medical Insurance	e:				
Insurance Phone Number:					
Payer Type:			Plan Type:		
ID#:	Group#:		Effective Date:		
SYFOVRE Billing Code:		Administra	ition CPT Code:		
NDC:					
	Prij	mary Insuran	ice		
Is SYFOVRE Covered: Yes			Network Benefits: In network Out of Network		
Individual Deductible:		Buy and Bil	Buy and Bill:		
Amount Met:		Specialty P	harmacy:	Required: 🗌 Optional: 🗌	
Drug Copay/	Office Vis			Admin Copay/	
Co-Insurance:	Co-Insura	nce: Co-Insurance:			
Prior Authorization Required: Yes No		Online:			
Prior Authorization Submission Details:			Electronic:		
		Fax:	Fax: Phone:		
	_				
		ndary Insura			
Is SYFOVRE Covered: Yes	5 🗌 No	Network B Buy and Bil		network Out of Networ	
Amount Met:			i: harmacy:	Required: Optional:	
Drug Copay/	Office Vis			Admin Copay/	
Co-Insurance:	Co-Insura	ince:		Co-Insurance:	
Prior Authorization Required: Yes No		Prior Authorization Submission:			
Prior Authorization Submission Details:		Electronic:			
		Fax:			
		Phone:			

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.





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

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.



Please see additional Important Safety Information throughout and the full <u>Prescribing Information</u>.



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, and in patients with active intraocular inflammation





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^a

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^{b,c}

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

^aProgram eligibility criteria, including annual household income limits, apply.

^bThe 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.

^cThe 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

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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

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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









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