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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	March 17, 2023
Subject:	Syfovre	**Page:**	1 of 4

Last Review Date: March 7, 2025

Syfovre

Description

Syfovre (pegcetacoplan) injection

Background
Syfovre (pegcetacoplan) binds to complement protein C3 and its activation fragment C3b with high affinity thereby regulating the cleavage of C3 and the generation of downstream effectors of complement activation (1).

Regulatory Status
FDA-approved indication: Syfovre is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (1).

Syfovre is contraindicated in patients with ocular or periocular infections and in patients with active intraocular inflammation (1).

Syfovre also contains warnings regarding endopthalmitis, retinal detachments, and neovascular AMD. 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 (1).

The safety and effectiveness of Syfovre in pediatric patients under 18 years of age have not been established (1).

Related policies
Bevacizumab, Lucentis, Susvimo, VEGF Inhibitors

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Syfovre may be considered **medically necessary** if the conditions indicated below are met.

Syfovre may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

AND ALL of the following:

a. Prescriber agrees to monitor for endophthalmitis, retinal detachment, and neovascular AMD
b. **NO** active intraocular inflammation
c. **NO** ocular or periocular infection

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

AND ALL of the following:

a. Patient has had a clinical benefit from therapy (e.g., slowed rate of GA lesion growth)
b. Prescriber agrees to monitor for endopthalmitis, retinal detachment, and neovascular AMD
c. **NO** active intraocular inflammation
d. **NO** ocular or periocular infection

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 6 single-dose vials per 75 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Syfovre is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration. Syfovre is contraindicated in patients with ocular or periocular infections and in patients with active intraocular inflammation. The safety and effectiveness of Syfovre in pediatric patients under 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Syfovre while maintaining optimal therapeutic outcomes.

References

1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; December 2024.

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Policy History

Date	Action
March 2023	Addition to PA
June 2023	Annual review
December 2023	Annual review
March 2024	Annual review and reference update
February 2025	Per FEP, removed requirement not to use in combination with VEGF inhibitors for ocular indications
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.