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5.90.062

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Topical Products	Original Policy Date:	March 17, 2023
Subject:	Syfovre	Page:	1 of 5

Last Review Date: March 8, 2024

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 endophthalmitis, 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 have not been established (1).

Related policies

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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
- d. **NOT** used in combination with Vascular Endothelial Growth Factor (VEGF) Inhibitors for ocular indications (see Appendix 1)

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)

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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 endophthalmitis, retinal detachment, and neovascular AMD
- c. **NO** active intraocular inflammation
- d. **NO** ocular or periocular infection
- e. **NOT** used in combination with Vascular Endothelial Growth Factor (VEGF) Inhibitors for ocular indications (see Appendix 1)

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 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

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1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; November 2023.

Policy History

Date	Action
March 2023	Addition to PA
June 2023	Annual review
December 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

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Appendix 1 - List of VEGF Inhibitors for Ocular Indications

Generic Name	Brand Name
afibercept	Eylea
bevacizumab	Avastin
brolocizumab-dbl	Beovu
faricimab-svoa	Vabysmo
ranibizumab	Lucentis
ranibizumab	Susvimo