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Pegcetacoplan Intravitreal Injection

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Related Coverage Resources

INSTRUCTIONS FOR USE

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Overview

This policy supports medical necessity review for pegcetacoplan intravitreal injection (Syfovre™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Pegcetacoplan (Syfovre) is considered medically necessary when the following are met:

Geographic Atrophy. Individual meets ALL of the following criteria:

- A. Geographic atrophy secondary to age-related macular degeneration
B. Best corrected visual acuity (BCVA) of 24 letters using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent), or better vision (for example, 20/70, 20/80, 20/200)
C. Medication is prescribed by, or in consultation with, an ophthalmologist

**Dosing. BOTH** of the following:<sup>1</sup>

1. The dose is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection for each eye being treated
2. The dosing interval is not more frequent than once every 25 days for each eye being treated

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Pegcetacoplan (Syfovre) is considered medically necessary for continued use when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HCPCS Codes	Description
J3590	Unclassified biologics

## Background

### OVERVIEW

Syfovre, a complement 3 inhibitor, is indicated for the treatment of **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**.<sup>1</sup> The recommended dose for Syfovre is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.

### Disease Overview

AMD, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.<sup>2,3</sup> There are two types of AMD: exudative or neovascular (“wet”) and nonexudative or (“dry”). GA, a chronic progressive degeneration of the macula, is an advanced stage of dry AMD.<sup>3,4</sup> GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.<sup>3-5</sup> Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea.<sup>5,6</sup> Area of the lesions is associated with a corresponding loss of visual function.<sup>6</sup>

## References

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3. Nabbioso M, Lambiase A, Cerini A, et al. Therapeutic approaches with intravitreal injections in geographic atrophy secondary to age-related macular degeneration: current drugs and potential molecules. *Int J Molec Sciences.* 2019; 20(7):1693.
4. Shae YS, Krogh Nielsen M, Do DV, et al. Geographic atrophy. Available at: [https://eyewiki.aao.org/Geographic\\_Atrophy#:~:text=Geographic%20atrophy%20\(GA\)%20is%20a,retinal%20pigment%20epithelium%20and%20choriocapillaris](https://eyewiki.aao.org/Geographic_Atrophy#:~:text=Geographic%20atrophy%20(GA)%20is%20a,retinal%20pigment%20epithelium%20and%20choriocapillaris). Accessed on February 21, 2023.
5. Fleckenstein M, Mitchel P, Freud KB, et al. The progression of geographic atrophy secondary to age-related macular degeneration. *Ophthalmology.* 2018; 125:369-390.
6. Pfau M, Schmitz-Valckenberg S, Ribeiro R, et al. Association of complement C3 inhibitor pegcetacoplan with reduced photoreceptor degeneration beyond areas of geographic atrophy. *Sci Rep.* 2022; 12:17870. doi: 10.1038/s41598-022-22404-9.

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