

PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmology – Syfovre Prior Authorization Policy

- Syfovre™ (pegcetacoplan intravitreal injection – Apellis)

REVIEW DATE: 03/13/2024

OVERVIEW

Syfovre, a complement 3 inhibitor, is indicated for the treatment of **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**.¹ Syfovre is administered by intravitreal injection to each affected eye.

In the pivotal studies (OAKS and DERBY), all eligible patients had a best-corrected visual acuity (BCVA) of 24 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Snellen chart equivalent of 20/320 or better).²

Disease Overview

AMD, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.^{3,4} 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.^{4,5} GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.⁴⁻⁶ Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea.^{6,7} Area of the lesions is associated with a corresponding loss of visual function.⁷

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Syfovre. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Syfovre as well as the monitoring required for adverse events and long-term efficacy, approval requires Syfovre to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Syfovre is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Geographic Atrophy.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A)** Patient has geographic atrophy secondary to age-related macular degeneration; **AND**
 - B)** Patient meets ONE of the following (i or ii):
 - i.** Patient has a best-corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; **OR**
 - ii.** Patient has a best-corrected visual acuity (BCVA) of 20/320 or better using the Snellen chart; **AND**
 - C)** The medication is administered by or under the supervision of an ophthalmologist.

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Syfovre is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Syfovre™ intravitreal injection [prescribing information]. Waltham, MA: Apellis; November 2023.
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3. Rein DB, Wittenborn JS, Burke-Conte Z, et al. Prevalence of age-related macular degeneration in the US in 2019. *JAMA Ophthalmol*. 2022;140:1202-1208.
4. 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.
5. 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 March 4, 2024.
6. Fleckenstein M, Mitchel P, Freud KB, et al. The progression of geographic atrophy secondary to age-related macular degeneration. *Ophthalmology*. 2018;125:369-390.
7. 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.