

POLICY: Ophthalmology – Syfovre Utilization Management Medical Policy

- Syfovre™ (pegcetacoplan intravitreal injection – Apellis)

EFFECTIVE DATE: 06/15/2023

LAST REVISION DATE: 03/01/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Syfovre, a complement 3 inhibitor, is indicated for the treatment of **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**.¹ 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.^{2,3} 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.^{3,4} GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.³⁻⁵ Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea.^{5,6} Area of the lesions is associated with a corresponding loss of visual function.⁶

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Syfovre. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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 the following criteria (A, B, and C):
 - A) Patient has geographic atrophy secondary to age-related macular degeneration; AND
 - B) Patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; AND
Note: BCVA of 24 letters or better is approximately 20/320 Snellen equivalent.
 - C) The medication is administered by or under the supervision of an ophthalmologist.
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Dosing. Approve if the dose meets both criteria (A and B):

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

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; February 2023.
2. 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.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/01/2023