

Syfovre™ (pegcetacoplan injection)

When requesting Syfovre™ (pegcetacoplan injection), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Syfovre is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Coverage Guidelines

Geographic Atrophy

The individual must meet all of the following criteria for approval:

- Has geographic atrophy secondary to age-related macular degeneration;
- Meets ONE of the following:
 - Has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR
 - Best corrected visual acuity (BCVA) of 20/320 or better using the Snellen chart;
- Syfovre is administered by or under the supervision of an ophthalmologist.

Approval duration: 12 months

Dosing Recommendation

The recommended dose for Syfovre is 15 mg administered by intravitreal injection to each affected eye once every 25 to 60 days.

References

1. Syfovre™ intravitreal injection [prescribing information]. Waltham, MA: Apellis; November 2023.
2. Heiger JS, Lad EM, Holz FG, et al. Pegcetacoplan for the treatment of geographic atrophy secondary to age-related macular degeneration (OAKS and DERBY): two multicenter randomized, double-masked, sham-controlled, phase 3 trials. *Lancet*. 2023 Oct 21;402(10411):1434-1448.
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. doi: 10.1038/s41598-022-22404-9.