

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Syfovre (pegcetacoplan)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Syfovre, approved by the FDA in 2023, is a complement (C3) inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). It is the first drug approved for this indication.

There are 2 types of AMD: dry or wet (neovascular). Syfovre is approved for dry AMD which is more common but progresses more slowly to vision loss than wet AMD. GA can occur in the intermediate and advanced stages of dry AMD and is caused by the breakdown of cells in the macula, resulting in irreversible lesions that can impair vision or lead to blindness.

Approval of Syfovre was based on combined analysis of the Phase 3 DERBY and OAKS trials. It was also studied in the Phase 2 FILLY trial. Although it slows the growth rate of GA lesions, Syfovre does not preserve visual function. It may also accelerate the development of new-onset wet AMD.

Syfovre (pegcetacoplan) will be considered for coverage when the following criteria are met:

Geographic Atrophy (GA)

For **initial** authorization:

1. Member is at least 50 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a documented diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD); AND
4. Diagnosis has been confirmed by fundus autofluorescence (FAF) imaging with both of the following:
 - a) Total GA area must be ≥ 2.5 and ≤ 17.5 mm² (1 and 7 disk areas [DA] respectively) and
 - b) If GA is multifocal, at least one focal lesion must be ≥ 1.25 mm² (0.5 DA); AND
5. Documentation of best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent); AND
6. Member does NOT have any of the following:
 - a) GA secondary to any condition other than AMD
 - b) History or current evidence of wet AMD.
7. **Dosage allowed/Quantity limit:** 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days. (QL: 4 vials per 60 days)

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. GA lesion growth rate has slowed or stabilized.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Syfovre (pegcetacoplan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/06/2023	New policy for Syfovre created.

References:

1. Syfovre [prescribing information]. Apellis Pharmaceuticals, Inc.; 2023.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
3. Liao DS, Grossi FV, El Mehdi D, et al. Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. *Ophthalmology*. 2020;127(2):186-195. doi:10.1016/j.ophtha.2019.07.011
4. Heier J, et al. Efficacy of intravitreal pegcetacoplan in geographic atrophy: results from the DERBY and OAKS trials. Presented at: Retina Society Annual Meeting; September 29–October 2, 2021; Chicago, IL. Accessed April 5, 2023. <https://apellismedicalhub.com/geographic-atrophy-ga/retina-society-2021/efficacy-of-intravitreal-pegcetacoplan-in-geographic-atrophy-results-from-the-derby-and-oaks-trials/>
5. Goldberg R, et al. Efficacy of intravitreal pegcetacoplan in patients with geographic atrophy (GA): 18-month results from the Phase 3 OAKS and DERBY studies. Presented at: 2022 ARVO Annual Meeting; May 3–7, 2022; Denver, CO. Accessed April 5, 2023. <https://apellismedicalhub.com/science/geographic-atrophy/the-association-for-research-in-vision-and-ophthalmology-arvo-2022/efficacy-of-intravitreal-pegcetacoplan-in-patients-with-geographic-atrophy-ga-18-month-results-from-the-phase-3-oaks-and-derby-studies/>
6. Heier J, et al. Efficacy of intravitreal pegcetacoplan in geographic atrophy: 24-month results from the phase 3 OAKS and DERBY trials. Presented at: Retina Society 55th Annual Meeting; November 2–5, 2022; Pasadena, CA. Accessed February 7, 2023. <https://investors.apellis.com/static-files/78d1b209-7324-4c4c-8b20-bf7778493bae>
7. Singh R, et al. Safety of intravitreal pegcetacoplan in geographic atrophy: 24-month results from the OAKS and DERBY phase 3 trials. Presented at: Retina Society 55th Annual Meeting; November 2–5, 2022; Pasadena, CA. Accessed February 7, 2023. <https://investors.apellis.com/static-files/faa3ab29-face-436a-b19d-4ec393f6436e>
8. Garg S, et al. Impact of baseline imbalances on the efficacy of pegcetacoplan for the treatment of geographic atrophy (GA): a post-hoc analysis of OAKS, DERBY, and FILLY. Presented at: 2022 ARVO Annual Meeting; May 3–7, 2022; Denver, CO. Accessed February 7, 2023. <https://apellismedicalhub.com/science/geographic-atrophy/the-association-for-research-in-vision-and-ophthalmology-arvo-2022/impact-of-baseline-imbalances-on-the-efficacy-of-pegcetacoplan-for-the-treatment-of-geographic-atrophy-ga-a-post-hoc-analysis-of-oaks-derby-and-filly/>

Effective date: 10/01/2023

Revised date: 04/06/2023