

PHARMACY POLICY STATEMENT

Ohio 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 0912 0 612 526.28 16.025 re W* n 5 Tf 1 0 0 1 55.275 383.6 Tm n BT /F2 11.2 Tf 1 0 0 1 1

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: ET Q q 0.0000912 0 612 792 re W* n