# Syfovre™ (pegcetacoplan injection)(for Louisiana Only)

**Policy Number:** CSLA2023D00118A
**Effective Date:** TBD

Instructions for Use

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## Application

This Medical Benefit Drug Policy only applies to the state of Louisiana.

## Coverage Rationale

Syfovre is proven and medically necessary when the following criteria are met:

- For initial therapy, all of the following:
  - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) confirmed by all of the following using Fundus Autofluorescence (FAF) imaging:
    - Total GA area size of ≥2.5 $mm^2$ and ≤17.5 $mm^2$ (1 and 7 disk areas [DA] respectively); and
    - If GA multifocal, at least 1 focal lesion of ≥1.25 $mm^2$ (0.5 DA); and
    - Presence of any pattern of hyperautofluorescence in the junctional zone of GA and
  - Dosing is in accordance with the United States Food and Drug Administration approved labeling; and
  - Authorization is for no more than 12 months.
- For continuation of therapy, all of the following:
  - Documentation of a positive response to therapy with Syfovre [i.e., smaller increases in GA lesion total area growth); and
  - Dosing is in accordance with the United States Food and Drug Administration approved labeling; and
  - Authorization is for no more than 12 months.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The

inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description |
|---|---|
| C9399 | Unclassified drugs or biologicals |
| J3490 | Unclassified drugs |
| J3590 | Unclassified biologics |

| Diagnosis Code | Description |
|---|---|
| H35.3113 | Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement |
| H35.3114 | Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement |
| H35.3123 | Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement |
| H35.3124 | Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement |
| H35.3133 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement |
| H35.3134 | Nonexudative age-related macular degeneration, bilateral, advanced atrophic with subfoveal involvement |

## Background

Geographic atrophy (GA) is an advanced form of dry age-related macular degeneration (AMD) caused by destruction of retinal cells through irreversible lesion growth. GA is a progressive disease that typically starts in the prifoveal region and expands to involve the fovea with time, leading to permanent loss of visual acuity. In the United States, GA affects approximately 1 million people, and it is one of the leading causes of blindness.

Lesion growth in geographic atrophy is driven in part by excessive complement activation. Genetic variants of complement C3, play a central role in driving the downstream damaging effects of complement overactivation in the progression of geographic atrophy. Pegcetacoplan is pegylated complement C3 inhbitor peptide that regulates excessive activation of the complement cascade.

## Clinical Evidence

### Proven

Pegcetacoplan injection is proven for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

The efficacy of pegcetacoplan was evaluated in DERBY and OAKS, two Phase 3, randomized, double-masked, sham-controlled studies in 1,258 patients with geographic atrophy secondary to AMD. Patients were randomized to intravitreal injections of pegcetacoplan monthly, pegcetacoplan every other month, or sham. The primary endpoint was the change in total area of geographic atrophy lesion(s) based on fundus autofluorescence imaging at 12 months (p-value < 0.05). Monthly and every-other-month treatment with pegcetacoplan met the primary endpoint in OAKS, significantly reducing GA lesion growth by 22% (p=0.0003) and 16% (p=0.0052), respectively, compared to pooled sham at 12 months. DERBY did not meet the primary endpoint, showing a reduction in GA lesion growth of 12% (p=0.0528) and 11% (p=0.0750) with monthly and every-other-month treatment, respectively, compared to pooled sham at 12 months. In a prespecified analysis of the combined DERBY and OAKS studies, monthly and every-other-month treatment with pegcetacoplan reduced GA lesion growth by 17% (p<0.0001) and 14% (p=0.0012), respectively, compared to pooled sham at 12

months. In a prespecified analysis of the primary endpoint, pegcetacoplan demonstrated a greater effect in patients with extrafoveal lesions at baseline. Patients with GA typically present first with extrafoveal lesions, which then progress toward the fovea where central vision is impacted. In the combined studies, monthly and every-other-month treatment with pegcetacoplan decreased GA lesion growth by 26% ($p<0.0001$) and 23% ($p=0.0002$), respectively, in patients with extrafoveal lesions compared to pooled sham at 12 months.

Patients in DERBY and OAKS continued to receive masked treatment for 24 months. In a pre-specified analysis, both monthly and every-other-month pegcetacoplan showed a reduction in lesion growth from baseline compared to sham (all p-values are nominal) at month 24: DERBY: 19% monthly ($p = 0.0004$) and 16% every-othermonth ($p = 0.0030$); OAKS: 22% monthly ($p < 0.0001$) and 18% every-other-month ($p = 0.0002$).

The pooled rate of new-onset exudations was 6.0% of patients in the monthly pegcetacoplan groups, 4.1% in the every-other-month pegcetacoplan groups, and 2.4% in the sham groups. Two cases of confirmed infectious endophthalmitis and one case of suspected infectious endophthalmitis were observed in the study eye out of a total of 6,331 injections (0.047%). Thirteen events of intraocular inflammation were observed in the studies (0.21% per injection). No events of retinal vasculitis or retinal vein occlusion were observed. There were no clinically relevant changes in vision for patients who developed infectious endophthalmitis or intraocular inflammation.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Pegcetacoplan injection is indicated in adult patients for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

## References


1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.
2. Apellis Pharmaceuticals Press Release. Apellis Pharmaceuticals Web site. Apellis announces 24-month results showing increased effects over time with pegcetacoplan in Phase 3 DERBY and OAKS studies in geographic atrophy (GA). https://investors.apellis.com/news-releases/news-release-details/apellisannounces-24-month-results-showing-increased-effects. August 24, 2022. Accessed September 6, 2022.
3. Apellis Pharmaceuticals Press Release. Apellis Pharmaceuticals Web site. Apellis announces FDA acceptance and Priority Review of the New Drug Application for pegcetacoplan for the treatment of geographic atrophy (GA). https://investors.apellis.com/news-releases/news-release-details/apellisannounces-fda-acceptance-and-priority-review-new-drug-0. July 19, 2022. Accessed September 6, 2022. Apellis Pharmaceuticals Press Release.
4. Apellis Pharmaceuticals Web site. Apellis announces top-line results from Phase 3 DERBY and OAKS studies in geographic atrophy (GA) and plans to submit NDA to FDA in the first half of 2022. https://investors.apellis.com/news-releases/news-release-details/apellis-announces-topline-results-phase-3-derby-and-oaks. September 9, 2021. Accessed September 6, 2022


## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| TBD | New Medical Benefit Drug Policy CSLA2023D00118A. |

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## Archived Policy Versions

| Effective Date | Policy Number | Policy Title |
|---|---|---|
| 12/01/2021 – 03/31/2022 | CSLA021D0105A | Amondys 45™ (Casimersen) |