POLICY: Ophthalmology – Syfovre Utilization Management Medical Policy

- Syfovre™ (pegcetacoplan intravitreal injection – Apellis)

EFFECTIVE DATE: 06/15/2023
LAST REVISION DATE: 03/19/2025

COVERAGE CRITERIA FOR: All UCare 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.

In the pivotal studies (OAKS and DERBY), all eligible patients had a best corrected visual acuity (BCVA) of 24 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Snellen chart equivalent of 20/320 or better).[2]

Disease Overview

AMD is a leading cause of severe, irreversible vision impairment.[3-5] In 2019, in the US, there was an estimated 20 million individuals with AMD; of these, 18.34 million had early stages of AMD and 1.49 million had late stages of AMD.[3] Advanced AMD is defined as either neovascular (wet) AMD or GA involving the center of the macula.[3-5] GA, an advanced form of non-neovascular AMD, characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris. GA involving the foveal center causes approximately 10% of all AMD-related vision loss of 20/200 or worse.[3]

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 indication. 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

2. Geographic Atrophy. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient has geographic atrophy secondary to age-related macular degeneration; AND
- **B)** Patient meets ONE of the following (i or ii):
  a. Patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR
  b. Patient has a BCVA of 20/320 or better using the Snellen chart; AND
- **C)** The medication is administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets BOTH of the following (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; December 2024.
2. Heier JS, Lad EM, Holz FG, et al. Pegcetacoplan for the treatment of geographic atrophy secondary to age-related macular degeneration (OAKS and DERBY): two multicentre, randomised, double-masked, sham-controlled, phase 3 trials. *Lancet.* 2023 Oct 21;402(10411):1434-1448.
3. American Academy of Ophthalmology. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. San Francisco, CA: American Academy of Ophthalmology; 2024. Available at: www.aao.org/ppp. Accessed on February 13, 2025.
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. Reviewed on September 22, 2024. Accessed on March 13, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	03/01/2023
Annual Revision	**Geographic Atrophy**. Previously, the criterion regarding best-corrected visual acuity (BCVA) used the threshold "24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts" and the Snellen equivalent to BCVA of 24 letters or better using ETDRS charts (20/320) was listed in a Note. The criterion was revised such that the required BCVA can be the patient has "24 letters or better using Early	03/13/2024

	Treatment Diabetic Retinopathy Study (ETDRS) charts OR 20/320 or better using the Snellen chart". The Note regarding the Snellen equivalent of ETDRS was removed.	
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	03/19/2025