Utilization Review Policy 308

POLICY: Ophthalmology – Syfovre Utilization Management Medical Policy
- Syfovre™ (pegcetacoplan intravitreal injection – Apellis)

EFFECTIVE DATE: 06/15/2023
LAST REVISION DATE: 03/13/2024

COVERAGE CRITERIA FOR: All UCare Plans

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, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.[3,4] There are two types of AMD: exudative or neovascular ("wet") and nonexudative or ("dry"). GA, a chronic progressive degeneration of the macula, is an advanced stage of dry AMD.[4,5] GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.[4-6] Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea.[6,7] Area of the lesions is associated with a corresponding loss of visual function.[7]

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

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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):

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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 best corrected visual acuity (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 criteria (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; November 2023.
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. 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. 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.

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 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.	03/13/2024