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** Please note: The Clinical Coverage Guideline (CCG) is intended to supplement certain standard Alignment Health (Alignment) benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific mandates. Information is current at time of approval by the Quality Improvement Committee (QIC) and are subject to change.*

AHC Pegcetacoplan

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MCG Health
Ambulatory Care
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Clinical Indications

- Syfovre is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
 - Must not have geographic atrophy (GA) secondary to a condition other than dry age-related macular degeneration (AMD)
 - Must have a visual acuity in the affected eye(s) of 20/320 or better
- All other indications are considered experimental/investigational and not medically necessary.

Treatment Plan

- Initial treatment: Authorization of 12 months may be granted for treatment of geographic atrophy when the member has a diagnosis of geographic atrophy secondary to age-related macular degeneration.
- Continuation of therapy: Authorization of 12 months may be granted for continued treatment of AMD-caused geographic atrophy for members who have demonstrated a positive clinical response to therapy (e.g., a reduction or stabilization in the rate of vision decline or the risk of more severe vision loss, stabilization or normalization or reduction in total area of GA lesions).

Evidence Summary

Geographic atrophy is an advanced and severe form of dry age-related macular degeneration (AMD). It is caused by the gradual breakdown of light-sensitive cells in the macula resulting in the growth of irreversible lesions in the retinal pigment epithelium (RPE). GA progression causes a gradual loss of visual function. Symptoms include scotomas, difficulty recognizing faces, decreased reading speed, impaired dark adaptation, low luminance deficit (LLD), impaired contrast sensitivity, and difficulty driving at night. More than half of all patients with GA will experience significant impairment of everyday vision, and about 20% of patients will develop severe vision loss with visual acuity of 20/200 or worse.

The exact cause of GA is unknown but it is thought the disease is the result of a multifactorial process. The most significant risk factors include age and family history with genetics playing a role in disease development. Smoking and a higher body mass index are also risk factors.

Diagnosis is made by an ophthalmologist during a dilated exam and/or with retinal imaging. In a dilated exam, geographic atrophy appears as a patch of retina that's missing its dark melanin pigment. Imaging techniques including retinal color photographs, optical coherence tomography (OCT), or auto-fluorescence photographs can also be used to detect GA.

Syfovre is a C3 complement inhibitor indicated for the treatment of GA secondary to AMD. It is the first FDA-approved therapy for GA. It targets the complement overactivation generating GA progression, preventing lesion growth, and reducing the likelihood of severe disease.

GA can be secondary to other conditions outside of AMD. Those include Stargardt disease, cone rod dystrophy, or toxic maculopathies like plaquenil maculopathy. Syfovre has only been studied in patients with GA secondary to dry AMD and therefore should not be used to treat GA secondary to other conditions. If the patient has multiple eye conditions requiring treatment, such as wet and dry AMD, it is appropriate to treat both conditions simultaneously.

Syfovre has not been studied in patients with a visual acuity worse than 20/320. Its use should be limited to those patients with visual acuity equal to or better than 20/320.

References

- Syfovre [prescribing information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.
- Flaxel CJ, Adelman RA, Bailey ST, et al. Age-related macular degeneration preferred practice pattern. *Ophthalmology*. 2020 Jan (updated March 2022); 127 (1): 1 - 65.
- Clinicaltrials.gov. A study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525613).
- Clinicaltrials.gov. Study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525600).
- Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019.

Committee Approval

- 01/09/2024, 02/20/2025

Application

- This policy applies to the following states: Arizona, California, Nevada, North Carolina, and Texas.
- Please refer to the CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Policy Revision History

- 6/23/2023: Creation date
- 12/08/2023: Revision
- 11/05/2024: Annual review, Applicable state updated, Florida removed

Codes

HCPCS: J3490