Drug Coverage Policy

Effective Date 6/1/2025
Coverage Policy Number.....IP0559
Policy Title..... Syfovre

Ophthalmology – Syfovre

- Syfovre™ (pegcetacoplan intravitreal injection – Apellis)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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]

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POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Syfovre. 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.

Syfovre is considered medically necessary when the following are met:

FDA-Approved Indication

1. **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):
     - **i.** Patient has a best-corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR
     - **ii.** 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Syfovre for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2781	Injection, pegcetacoplan, intravitreal, 1 mg

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Geographic Atrophy**. Revised the criterion regarding best-corrected visual acuity (BCVA) from "Best corrected visual acuity (BCVA) of 24 letters using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent), or better vision (for example, 20/70, 20/80, 20/200)". 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".	6/15/2024
Selected Revision	**Updated HCPCS Coding:** **Removed** J3590 **Added** J2781	NA
Annual Revision	No criteria changes.	6/1/2025

The policy effective date is in force until updated or retired.