Reference number(s)
5794-A

STANDARD MEDICARE PART B MANAGEMENT

SYFOVRE (pegcetacoplan)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Syfovre is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Initial Requests: chart notes or medical records confirming the diagnosis of geographic atrophy (GA) secondary to AMD.
B. Continuation Request: chart notes or medical records confirming a positive clinical response to therapy.

III. EXCLUSION

Coverage will not be provided for the treatment of geographic atrophy (GA) secondary to a condition other than AMD (such as Stargardt disease, cone rod dystrophy, toxic maculopathies).

IV. CRITERIA FOR INITIAL APPROVAL

Geographic atrophy (GA) secondary to age-related macular degeneration
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.

V. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when ALL of the following criteria are met:
A. The member is currently receiving therapy with the requested product.
B. The requested product is being used to treat an indication enumerated in Section IV.
The medication has been effective for treating the diagnosis or condition (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).

VI. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Syfovre.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

    Age-Related Macular Degeneration Preferred Practice Pattern 2019

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Syfovre are covered.

VII. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VIII. REFERENCE

1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; February 2023.
2. Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed February 20, 2023. https://www.aao.org/preferredpractice-pattern/age-related-macular-degeneration-ppp