

Medical Policy Manual

Draft Revised Policy: Do Not Implement

Pegcetacoplan (Syfovre™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY**

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 are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Initial Requests: Chart notes or medical records confirming the diagnosis of geographic atrophy (GA) ~~secondary to AMD.~~
- Continuation Request: Chart notes or medical records confirming a positive clinical response to therapy.

EXCLUSION

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

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an ophthalmologist.

COVERAGE CRITERIA FOR INITIAL APPROVAL

Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)

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

This document has been classified as public information

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Authorization of 12 months may be granted for continued treatment of an indication listed in **coverage criteria** section ~~IV~~ 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 reduction in total area of **geographic atrophy (GA)** lesions).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; November 2023.
2. Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed December 16, 2024. <https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp>

EFFECTIVE DATE

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