Complement Inhibitors for Geographic Atrophy: Izervay (avacincaptad pegol injection) Syfovre (pegcetacoplan injection)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Complement Inhibitors for Geographic Atrophy policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Syfovre (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
B. Izervay (avacincaptad pegol injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

POLICY

Required Documentation

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

A. Initial requests:
    a. Chart notes or medical record documentation confirming the diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration via Fundus Autofluorescence imaging, optical coherence tomography or other imaging techniques

B. Continuation requests:
    a. Chart notes or medical record documentation confirming a positive clinical response to therapy

Prescriber Specialties

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

Criteria for Initial Approval

A. Syfovre (pegcetacoplan injection) is considered **medically necessary** for treatment of geographic atrophy (GA) secondary to age-related macular degeneration when ALL of the following criteria are met:
    1. Member has a diagnosis of geographic atrophy secondary to age-related macular degeneration confirmed via Fundus Autofluorescence imaging, optical coherence tomography or other imaging techniques
    2. Syfovre is being prescribed by or in consultation with an ophthalmologist
    3. Total GA lesion size is ≥ 2.5 and ≤ 17.5 mm^2 (if multifocal, at least 1 focal lesion ≥ 1.25 mm^2)
    4. Member does not have any of the following:
        a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
        b) Ocular or periocular infection(s)
        c) Active intraocular inflammation
    5. The requested medication will not be used in combination with Izervay

Approval will be for **12 months.**

B. Izervay (avacincaptad pegol injection) is considered **medically necessary** for treatment of geographic atrophy (GA) secondary to age-related macular degeneration when ALL of the following criteria are met:
    1. Member has a diagnosis of geographic atrophy secondary to age-related macular degeneration confirmed via Fundus Autofluorescence imaging, optical coherence tomography or other imaging techniques
    2. Izervay is being prescribed by or in consultation with an ophthalmologist
    3. Total GA lesion size is ≥ 2.5 and ≤ 17.5 mm^2 (if multifocal, at least 1 focal lesion ≥ 1.25 mm^2)
    4. Member does not have any of the following:
        a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
        b) Ocular or periocular infection(s)
        c) Active intraocular inflammation
    6. The requested medication will not be used in combination with Syfovre

Approval will be for **12 months.**

Continuation of Therapy

A. Syfovre (pegcetacoplan injection) is considered **medically necessary** for continuation of treatment of geographic atrophy (GA) secondary to age-related macular degeneration when the following criteria are met:
    1. Syfovre is being prescribed by or in consultation with an ophthalmologist
    2. The member has 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).
    3. Member does not have any of the following:
        a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
        b) Ocular or periocular infection(s)

c) Active intraocular inflammation
d) History of or active choroidal neovascularization or exudative age-related macular degeneration

B. Izervay (avacincaptad pegol injection) is considered **medically necessary** for continuation of treatment of geographic atrophy (GA) secondary to age-related macular degeneration when the following criteria are met:
1. Izervay is being prescribed by or in consultation with an ophthalmologist
2. The member has 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).
3. Member does not have any of the following:
   a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
   b) Ocular or periocular infection(s)
   c) Active intraocular inflammation
   d) History of or active choroidal neovascularization or exudative age-related macular degeneration

Approval will be for **12 months.**

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9162 – Injection, avacincaptad pegol, 0.1 mg (cancelled 3/31/2024)
- C9151 – Injection, pegcetacoplan, 1 mg (cancelled 10/1/2023)
- C9399 – Unclassified drugs or biologics
- J2781 – Injection, pegcetacoplan, intravitreal, 1 mg (effective 10/1/2023)
- J2782 – Injection, avacincaptad pegol, 0.1 mg (effective 4/1/2024)
- J3490 – Unclassified drugs
- J3590 – Unclassified biologics

REFERENCES

- Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; March 2025.
- Izervay [package insert]. Parsippany, NJ: Iveric Bio Inc; February 2025.
- Liao DS, Grossi FV, El Mehdi D, et al. Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. Ophthalmology. 2020 Feb;127(2):186-195.
- A Study to Compare the Efficacy and Safety of Intravitreal APL-2 Therapy With Sham Injections in Patients With Geographic Atrophy (GA) 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 (GA) Secondary to Age-Related Macular Degeneration. NCT03525600. Clinicaltrials.gov.

- Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed May 22, 2023.
- Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. Ophthalmology. 2020 Jan;127(1):P1-P65.

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POLICY HISTORY

Policy #: 05.04.98
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