Reference number(s)
6106-A

STANDARD MEDICARE PART B MANAGEMENT

IZERVAY (avancincaptad pegol)

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
Izervay 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:
Chart notes or medical records confirming the diagnosis of geographic atrophy (GA) secondary to AMD.

III. EXCLUSION

A. Coverage will not be provided beyond 12 months of therapy.
B. 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. PRESCRIBER SPECIALTIES

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

V. CRITERIA FOR INITIAL APPROVAL

Geographic atrophy (GA) secondary to age-related macular degeneration
Authorization of up to 12 months may be granted when all of the following criteria are met:
A. Member has a diagnosis of geographic atrophy secondary to age-related macular degeneration.
B. Member will receive 2mg injection into each affected eye once monthly for up to 12 months.

VI. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Izervay.
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
3. Age-Related Macular Degeneration PPP 2019

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

VII. EXPLANATION OF RATIONALE

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

VIII. REFERENCE

1. Izervay [package insert]. Parsippany, NJ: Iveric Bio Inc; August 2023.
2. Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed August 7, 2023. https://www.aao.org/preferredpractice-pattern/age-related-macular-degeneration-pp