Drug Coverage Policy

Effective Date.....6/1/2025
Coverage Policy Number.....IP0581
Policy Title..... Izervay

Ophthalmology – Izervay

- Izervay™ (avacincaptad pegol intravitreal injection – Iveric)

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

Izervay, a complement C5 inhibitor, is indicated for the treatment of **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**.[1]

The recommended dose for Izervay is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days).[1] In the clinical

studies, eligible patients had GA secondary to AMD with a best-corrected visual acuity (BCVA) between 20/25 and 20/320.[2,3]

Disease Overview
AMD is a leading cause of severe, irreversible vision impairment.[4-6] 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.[4] Advanced AMD is defined as either neovascular (wet) AMD or GA involving the center of the macula.[4-6] GA, an advanced form of non-neovascular AMD, is 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.[4]

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POLICY STATEMENT
Prior Authorization is required for prescription benefit coverage of Izervay. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Izervay as well as the monitoring required for adverse events and long-term efficacy, approval requires Izervay to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Izervay 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 has a best corrected visual acuity (BCVA) in the affected eye of between 20/25 and 20/320 letters; 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 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 21 days for each eye being treated.
   Note: The dosing interval is once monthly (approximately every 28 ± 7 days).

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.

Izervay 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
J2782	Injection, avacincaptad pegol, 0.1 mg

References

1. Izervay™ intravitreal injection [prescribing information]. Parsippany, NJ: Iveric; March 2025.
2. Jaffe GJ, Westby K, Csaky KG, et al. C5 inhibitor avacincaptad pegol for geographic atrophy due to age-related macular degeneration: a randomized pivotal Phase 2/3 trial. *Ophthalmology*. 2021;128:576-586.
3. Khanani AM, Patel SS, Staurenghi G, et al. Efficacy and safety of avacincaptad pegol in patients with geographic atrophy (GATHER2): 12-month results from a randomized, double-masked, phase 3 trial. *Lancet*. 2023;402(10411):1449-1458.
4. 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.
5. 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.
6. 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	**Updated** policy title from "Avacincaptad Intravitreal Injection to "Ophthalmology – Izervay." **Updated Coding:** **Removed** C9399, J3490, J3590 **Added** J2782 (effective 4/1/2024)	11/15/2024
Annual Revision	No criteria changes.	6/1/2025

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