Utilization Review Policy 316

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Ophthalmology – Izervay Utilization Management Medical Policy

- Izervay™ (avacincaptad pegol intravitreal injection – Iveric)

EFFECTIVE DATE: 11/15/2023
LAST REVISION DATE: 03/19/2025

COVERAGE CRITERIA FOR: All UCare Plans

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]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Izervay. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Izervay is recommended in those who meet the following criteria:

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 of the following (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).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Izervay is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/16/2023
Annual Revision	No criteria changes.	08/28/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Early Annual Revision	No criteria changes.	03/19/2025