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: 08/16/2023

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 administered by intravitreal injection to each affected eye once a month (approximately every 28 ± 7 days) for up to 12 months.

Disease Overview

AMD, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.[2-4] GA is a chronic progressive degeneration of the macula and is an advanced stage of AMD.[4,5] Approximately 20% of individuals with AMD will develop GA. GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.[4-6] Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea. As the atrophic area expands, visual function and/or acuity decreases. In the clinical studies, patients had GA secondary to AMD with a best-corrected visual acuity (BCVA) between 20/25 and 20/320.[7,8]

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 indications. 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 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).

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; August 2023.
2. Kawa M, Machalinska A, Roginska D, Machalinski R. Complement system in pathogenesis of AMD: dual player in degeneration and protection of retinal tissue. *J Immunol Res.* 2014;483960.
3. Rein DB, Wittenborn JS, Burke-Conte Z, et al. Prevalence of age-related macular degeneration in the US in 2019. *JAMA Ophthalmol*. 2022;140:1202-1208.
4. 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):169.
5. 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. Accessed on August 7, 2023.
6. Fleckenstein M, Mitchel P, Freud KB, et al. The progression of geographic atrophy secondary to age-related macular degeneration. *Ophthalmology*. 2018;125:369-390.
7. 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.
8. Data on file. Izervay – GATHER2 study. Iveric; received on August 7, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/16/2023