# PRIOR AUTHORIZATION POLICY

**POLICY:** Ophthalmology – Izervay Prior Authorization Policy
- Izervay™ (avacincaptad pegol intravitreal injection – Iveric)

**REVIEW DATE:** 08/28/2024

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## OVERVIEW

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

Izervay is given by intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days) for up to 12 months.[1] In the Izervay clinical studies, patients had GA secondary to AMD with a best-corrected visual acuity (BCVA) between 20/25 and 20/320.[2,3]

## Disease Overview

AMD, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.[4,5] There are two types of AMD: exudative or neovascular ("wet") and nonexudative or ("dry"). GA, a chronic progressive degeneration of the macula, is an advanced stage of dry AMD.[5,6] GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.[5-7] Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea.[7,8] Area of the lesions is associated with a corresponding loss of visual function.[8]

## POLICY STATEMENT

Prior Authorization is recommended 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.

**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.

## 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; February 2024.
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. Data on file. Izervay – GATHER2 study. Iveric; received on August 7, 2023.
4. 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.
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. Accessed on March 4, 2024.
7. Fleckenstein M, Mitchel P, Freud KB, et al. The progression of geographic atrophy secondary to age-related macular degeneration. *Ophthalmology*. 2018;125:369-390.
8. Pfau M, Schmitz-Valckenberg S, Ribeiro R, et al. Association of complement C3 inhibitor pegcetacoplan with reduced photoreceptor degeneration beyond areas of geographic atrophy. *Sci Rep*. 2022;12:17870.