

Izervay™ (avacincaptad pegol intravitreal solution)

When requesting Izervay™ (avacincaptad pegol intravitreal solution), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Izervay is indicated for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD).

Coverage Guidelines

Geographic Atrophy

The individual must meet all of the following criteria for approval:

- Has geographic atrophy secondary to age-related macular degeneration;
- Has a best corrected visual acuity (BCVA) in the affected eye between 20/25 and 20/320;
- Izervay is administered by or under the supervision of an ophthalmologist.

Approval duration: 12 months

Dosing Recommendation

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 for up to 12 months.

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](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.

Izervay[™] (avacincaptad pegol intravitreal solution)