CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Izervay (avacincaptad pegol)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Izervay, approved by the FDA in 2023, is a complement C5 inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). It is the second drug approved for this indication following C3 inhibitor pegcetacoplan.
There are 2 types of AMD: dry or wet (neovascular). Izervay is approved for dry AMD which is more common but progresses more slowly to vision loss than wet AMD. GA can occur in the intermediate and advanced stages of dry AMD and is caused by the breakdown of cells in the macula, resulting in irreversible lesions that can impair vision or lead to blindness.
Approval of Izervay was based the GATHER studies. Although it slows the growth rate of GA lesions, Izervay does not appear to preserve visual function. It may also accelerate the development of new-onset wet AMD.

Izervay (avacincaptad pegol) will be considered for coverage when the following criteria are met:

Geographic Atrophy (GA)

For **initial** authorization:
1. Member is at least 50 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a documented diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD); AND
4. Diagnosis has been confirmed by fundus autofluorescence (FAF) imaging showing all of the following:
   a) Total GA area must be ≥ 2.5 and ≤ 17.5 mm2 (1 and 7 disk areas [DA] respectively) and
   b) If GA is multifocal, at least one focal lesion must be ≥ 1.25 mm2 (0.5 DA)
   c) The GA lesion must be, in part, within 1.5 mm from, but NOT involving the foveal center; AND
5. Documentation of best corrected visual acuity (BCVA) between 20/25 and 20/320 in the affected eye(s); AND
6. Member does NOT have any of the following:
   a) GA secondary to any condition other than AMD
   b) History or current evidence of wet AMD
7. **Dosage allowed/Quantity limit:** Intravitreal injection to each affected eye once monthly.
   QL: 2 vials per 28 days

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. GA lesion growth rate has slowed or stabilized.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Izervay (avacincaptad pegol) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
09/18/2023	New policy for Izervay created.
03/06/2025	Updated references. Added renewal criteria; label no longer limits to 12 months total duration.

References:

1. Izervay [prescribing information]. IVERIC bio, Inc.; 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(4):576-586. doi:10.1016/j.ophtha.2020.08.027
3. Patel SS, Lally DR, Hsu J, et al. Avacincaptad pegol for geographic atrophy secondary to age-related macular degeneration: 18-month findings from the GATHER1 trial [published online ahead of print, 2023 Mar 24] [published correction appears in Eye (Lond). 2023 May 26;:]. *Eye (Lond)*. 2023;10.1038/s41433-023-02497-w. doi:10.1038/s41433-023-02497-w
4. Tzoumas N, Riding G, Williams MA, Steel DH. Complement inhibitors for age-related macular degeneration. *Cochrane Database Syst Rev*. 2023;6(6):CD009300. Published 2023 Jun 14. doi:10.1002/14651858.CD009300.pub3
5. Cruz-Pimentel M, Wu L. Complement Inhibitors for Advanced Dry Age-Related Macular Degeneration (Geographic Atrophy): Some Light at the End of the Tunnel?. *J Clin Med*. 2023;12(15):5131. Published 2023 Aug 4. doi:10.3390/jcm12155131
6. Vemulakonda GA, Bailey ST, Kim SJ, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. *Ophthalmology*. Published online February 7, 2025. doi:10.1016/j.ophtha.2024.12.018

Effective date: 10/01/2025
Revised date: 03/06/2025