

Izervay™ (avacincaptad pegol) (Intravitreal)

Document Number: IC-0721

Last Review Date: 05/05/2025

Date of Origin: 09/05/2023

Dates Reviewed: 09/2023, 05/2024, 03/2025, 05/2025

I. Length of Authorization

Coverage will be provided annually and may be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 40 billable units (4 mg) every 28 days
(Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient has a baseline assessment for all the following: best corrected visual acuity (BCVA), fundus autofluorescence (FAF) imaging, and optical coherence tomography (OCT); **AND**

Universal Criteria ^{1,6}

- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Will not be used in combination with other intravitreal complement inhibitor therapies; **AND**
- Patient does not have category 5, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**

Geographic Atrophy (GA) † ¹⁻⁵

- The patient has a diagnosis of GA as defined by a phenotype of geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; **AND**
- Disease is secondary to age-related macular degeneration (AMD); **AND**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.); **AND**
- Patients must have an inadequate response to an adequate trial of, or contraindication, or intolerance to Syfovre

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, retinal detachment, neovascular (wet) AMD or choroidal neovascularization, increased intraocular pressure that cannot be adequately treated, etc.; **AND**
- Patient has had disease stabilization or slowing of the rate of disease progression while on therapy compared to pre-treatment baseline as measured by any of the following:
 - Best corrected visual acuity (BCVA)
 - Fundus Autofluorescence (FAF)
 - Optical Coherence Tomography (OCT); **AND**
- Continued administration is necessary for the maintenance treatment of the condition and the patient and provider have discussed potential decrease in frequency administrations

V. Dosage/Administration ¹

Indication	Dose
Geographic Atrophy	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 every 28 ± 7 days).
<ul style="list-style-type: none">- Keep refrigerated. Prior to use, allow Izervay to reach room temperature, and may be kept at room temperature for up to 24 hours.- Each vial and syringe should only be used for the treatment of a single eye.	

VI. Billing Code/Availability Information

HCPCS Code:

- J2782 – Injection, avacincaptad pegol, 0.1 mg; 1 billable unit = 0.1 mg

NDC:

- Izervay 2 mg/0.1 mL solution for injection in a single-dose vial: 82829-0002-xx

VII. References

1. Izervay [package insert]. Northbrook, IL; Astellas Pharma US, Inc.; March 2025. Accessed 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. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2024. September 2024.
4. 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. *Eye (Lond)*. 2023 Dec;37(17):3551-3557. doi: 10.1038/s41433-023-02497-w. Epub 2023 Mar 24. Erratum in: *Eye (Lond)*. 2023 Dec;37(17):3705. doi: 10.1038/s41433-023-02548-2. PMID: 36964259; PMCID: PMC10686386.
5. Khanani AM, Patel SS, Staurengi G, et al; GATHER2 trial investigators. Efficacy and safety of avacincaptad pegol in patients with geographic atrophy (GATHER2): 12-month results from a randomised, double-masked, phase 3 trial. *Lancet*. 2023 Oct 21;402(10411):1449-1458. doi: 10.1016/S0140-6736(23)01583-0. Epub 2023 Sep 8. PMID: 37696275.
6. Dandona L, Dandona R. Revision of visual impairment definitions in the International Statistical Classification of Diseases. *BMC Med*. 2006 Mar 16;4:7. doi: 10.1186/1741-7015-4-7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1435919/>

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H35.3113	Nonexudative age-related macular degeneration, right eye advanced atrophic without subfoveal involvement
H35.3114	Nonexudative age-related macular degeneration, right eye advanced atrophic with subfoveal involvement
H35.3123	Nonexudative age-related macular degeneration, left eye advanced atrophic without subfoveal involvement
H35.3124	Nonexudative age-related macular degeneration, left eye advanced atrophic with subfoveal involvement
H35.3133	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic without subfoveal involvement
H35.3134	Nonexudative age-related macular degeneration, bilateral eye advanced atrophic with subfoveal involvement
H35.3193	Nonexudative age-related macular degeneration, unspecified eye advanced atrophic without subfoveal involvement
H35.3194	Nonexudative age-related macular degeneration, unspecified eye advanced atrophic with subfoveal involvement

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify

benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC