

Izervay® (avacincaptad pegol) (Intravitreal)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

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

Prior authorization is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member 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}

- Member does NOT have any FDA labeled contraindications to the requested agent; **AND**
- Will not be used in combination with other intravitreal complement inhibitor therapies; **AND**
- Member does not have category 5, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**

Geographic Atrophy (GA) † ¹⁻⁵

- Member 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**
- Members must have an inadequate response to an adequate trial of, or contraindication, or intolerance to Syfovre

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity may be renewed based upon the following criteria:

- Member 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**
- Member 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 member and provider have discussed potential decrease in frequency administrations

V. Dosage/Administration ¹

Indication	Dose
Geographic Atrophy (GA)	Administer 2 mg (0.1 mL of 20 mg/mL solution) by intravitreal injection to each affected eye once monthly (approximately every 28 ± 7 days).
- 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.; February 2026. Accessed March 2026.

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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
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