Clinical Policy: Avacincaptad Pegol (Izervay)

Reference Number: LA.PHAR.641
Effective Date: 06.06.24
Last Review Date: 06.13.25
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

Avacincaptad pegol (Izervay ™) is a C5 complement inhibitor.

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that Izervay is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Geographic Atrophy (must meet all)**:**

1. Diagnosis of GA secondary to AMD;
2. GA has all of the following characteristics confirmed on fundus autofluorescence imaging (a, b, c, and d):
   a. Total GA area ≥ 2.5 and ≤ 17.5 mm^2 (1 and 7 disk areas [DA], respectively);
   b. If GA is multifocal, at least one focal lesion ≥ 1.25 mm^2 (0.5 DA);
   c. Presence of hyperautofluorescence in the junctional zone of GA;
   d. GA is not centered in the fovea;
3. Prescribed by or in consultation with an ophthalmologist;
4. Age ≥ 50 years;
5. Best corrected visual acuity (BCVA) between 20/25 and 20/320;
6. Member does not have any of the following (a, b, and c):
   a. GA that is secondary to a condition other than AMD (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies);
   b. Signs of diabetic retinopathy in either eye;
   c. Evidence of choroidal neovascularization in the eye(s) affected by GA;
7. Izervay is not used in combination with other intravitreal complement inhibitor therapy (e.g., Syfovre®);
8. Dose does not exceed 2 mg (0.1 mL of 20 mg/mL solution) in each affected eye every 21 days.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

II. Continued Therapy

A. Geographic Atrophy (must meet all)**:**
   a. Member is currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Izervay is not used in combination with other intravitreal complement inhibitor therapy (e.g., Syfovre);
4. If request is for a dose increase, new dose does exceed 2 mg (0.1 mL of 20 mg/mL solution) in each affected eye every 21 days.

Approval duration: 12 monthsOther diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255;
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AMD: age-related macular degeneration
BCVA: best corrected visual acuity
DA: disk area
FDA: Food and Drug Administration
GA: geographic atrophy

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): ocular or periocular infections, active intraocular inflammation
- Boxed warning(s): none

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
GA	2 mg (0.1 mL of 20 mg/mL solution) via intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days)	2 mg/21 days

VI. Product Availability

Single-dose vial for intravitreal injection: 20 mg/mL

VII. References

1. Izervay Prescribing Information. Parsippany, NJ: IVERIC bio; February 2025. Available at: https://www.astellas.com/us/system/files/izervay_pi.pdf. Accessed February 27, 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.
3. Khanani AM, Patel SS, Staurenghi G, et al. 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;402(10411):1449-1458.
4. Danzig CJ, Khanani AM, Kaiser PK, et al. Vision Loss Reduction with Avacincaptad Pegol for Geographic Atrophy: A 12-Month Post Hoc Analysis of the GATHER1 and GATHER2 Trials. Ophthalmol Retina. Published online May 7, 2024.
5. American Academy of Ophthalmology Retina/Vitreous Committee. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2024. Available at: https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp. Accessed February 27, 2025.
6. Regillo CD, Nijm LM, Shechtman DL, et al. Considerations for the identification and management of geographic atrophy: Recommendations from an expert panel. Clinical Ophthalmology. 2024; 18: 325-335.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2782	Injection, avacincaptad pegol, 0.1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	01.04.24	05.06.24
Removed HCPCS codes [C9399, J3490] and added HCPCS code [J2782].	09.13.24	01.02.25
Annual review: clarified that diagnostic characteristics must be confirmed on fundus autofluorescence imaging per health plan	06.13.25	

Reviews, Revisions, and Approvals	Date	LDH Approval Date
request in alignment with Syfovre GA criteria and per pivotal study design; added exclusions for GA that is secondary to a condition other than AMD and for combination use with other intravitreal complement inhibitor therapies per competitor analysis; per updated FDA label removal of the one-year duration limit for the treatment of GA, removed continued authorization criterion for treatment exceeding 12 months; increased Medicaid/HIM continued approval duration from 6 months to 12 months for this chronic condition.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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