Effective Date **1/15/2024**
Next Review Date… **1/15/2025**
Coverage Policy Number **IP0581**

Avacincaptad Intravitreal Injection

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for avacincaptad pegol intravitreal injection (**Izervay**™).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Avacincaptad pegol (Izervay) is considered medically necessary when the following are met:

Geographic Atrophy. Individual meets **ALL** of the following criteria:
A. Geographic atrophy secondary to age-related macular degeneration
B. Best corrected visual acuity (BCVA) in the affected eye of between 20/25 and 20/320 letters
C. Medication is prescribed by, or in consultation with, an ophthalmologist

Dosing. BOTH of the following dosing regimens:

1. The dose is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection for each eye being treated
2. The dosing interval is not more frequent than once every 21 days for each eye being treated

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of avacincaptad pegol (Izervay) is considered medically necessary for geographic atrophy when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Background

OVERVIEW
Izervay, a complement C5 inhibitor, is indicated for the treatment of **geographic atrophy (GA) secondary to age-related macular degeneration (AMD)**.[1]

Disease Overview
AMD, a chronic, multifactorial, progressive central retinal disease, is the leading cause of irreversible blindness in the elderly population.[2-4] GA is a chronic progressive degeneration of the macula and is an advanced stage of AMD.[4,5] Approximately 20% of individuals with AMD will develop GA. GA is characterized by localized atrophy of the outer retinal tissue and irreversible loss of photoreceptors, retinal pigment epithelium, and choriocapillaris.[4-6] Initially, the GA lesions appear in the perifoveal macula but over time, the lesions often expand and coalesce to include the fovea. As the atrophic area expands, visual function and/or acuity decreases. In the clinical studies, patients had GA secondary to AMD with a best-corrected visual acuity (BCVA) between 20/25 and 20/320.[7,8]

References

1. Izervay™ intravitreal injection [prescribing information]. Parsippany, NJ: Iveric; August 2023.
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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. 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.