Original Effective Date: 12/09/2023
Current Effective Date: 12/09/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C26436-A

Izervay (avacincaptad intravitreal)

PRODUCTS AFFECTED

Izervay (avacincaptad intravitreal)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. GEOGRAPHIC ATROPHY:
   1. Documentation of diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration
      AND

2. Documentation of baseline visual status and GA lesion area with notation of eye(s) being treated [DOCUMENTATION REQUIRED]
   AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Izervay (avacincaptad intravitreal) include: Ocular or Periocular Infections and Active Intraocular Inflammation]

CONTINUATION OF THERAPY:

A. GEOGRAPHIC ATROPHY:

1. Reauthorization request is for the same eye(s) as initial authorization
   NOTE: The continuation of therapy criteria is only for the same previously treated eye. If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of improvement or stabilization of disease state and visual status or GA lesion area [DOCUMENTATION REQUIRED]
   AND
4. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: up to 12 months total of therapy

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified ophthalmologist or retinal specialist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

51 years of age and older

QUANTITY:

2 mg (0.1 mL) to affected eye(s) once monthly (every 28 days ± 7 days)

Maximum Quantity Limits – 1 injection every 21 days

PLACE OF ADMINISTRATION:

The recommendation is that intravitreal medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravitreal injection

DRUG CLASS:

Ophthalmic Complement C5 Inhibitor

FDA-APPROVED USES:
Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Geographic atrophy (GA) is an advanced form of age-related macular degeneration (AMD) that leads to progressive and irreversible vision loss. GA is caused by the gradual breakdown of light-sensitive cells in the macula, resulting in the growth of irreversible lesions in the retinal pigment epithelium (RPE) that can lead to impaired vision or blindness. Progressive GA can eventually affect the fovea, or central part of the macula, which is responsible for high-acuity vision.
More than half of all patients with GA experience significant impairment of everyday vision, and about 20% of patients develop severe vision loss with visual acuity of 20/200 or worse. AMD occurs in progressive stages of severity, which are defined as early, intermediate, or advanced.
GA occurs only in the intermediate or advanced stages of AMD. In the intermediate stage, GA affects the RPE, but the center of the fovea is not involved; in the advanced stage of AMD, GA also affects the foveal center. Choroidal neovascularization (CNV) may also occur during the advanced stage of AMD. AMD with CNV is often referred to as exudative AMD (eAMD), neovascular AMD (nAMD), or wet AMD (wAMD).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Izervay (avacincaptad intravitreal) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Izervay (avacincaptad intravitreal) include: ocular or periocular infections, active intraocular inflammation.

OTHER SPECIAL CONSIDERATIONS:
Izervay (avacincaptad intravitreal) must be administered by a qualified physician.

CODING/BILLING INFORMATION

Note: 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

HCPCS CODE	DESCRIPTION
J3490	Unclassified drugs (avacincaptad intravitreal)

AVAILABLE DOSAGE FORMS:
Izervay SOLN 2MG/0.1ML

REFERENCES

1. Izervay (avacincaptad pegol intravitreal solution) [prescribing information]. Parsippany, NJ: IVERIC bio, Inc.; August 2023.
2. Fleckenstein M, Mitchell P, Freund KB, et al. The progression of geographic atrophy secondary to age- related macular degeneration. Ophthalmology 125.3 (2018):369-390. https://www.ncbi.nlm.nih.gov/pubmed/29110945.
3. Age-related macular degeneration. National Eye Institute Web site. 2021; https://nei.nih.gov/health/maculardegen/. Accessed August 25, 2023.
4. The Eye Diseases Prevalence Research Group. Prevalence of age-related macular degeneration in the United States. Arch Ophthalmol. 2004;122:564-572.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q4 2023