Neighborhood Health Plan OF RHODE ISLAND™
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Izervay™ (avacincaptad pegol)
(Intravitreal)

Effective Date: 01/01/2024
Dates Reviewed: 12/2023, 01/2024, 04/2024
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for six months initially and may be renewed for 6 months, for no more than 12 months (i.e., 12 doses per each eye) of total therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Izervay 2 mg/0.1 mL solution for injection in a single-dose vial: 1 vial per eye every 28 days

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

- 4 mg (40 units) every 28 days up to 12 months

(Max units are based on administration to BOTH eyes)

III. Summary of Evidence

Izervay (avacincaptad pegol) is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Izervay is the second drug to be approved for GA. AMD affects approximately 11 million people in the U.S and is the leading cause of severe visual impairment and sight loss in people 65 and older, including about 1 million with GA. The approval of Izervay was based on results from the Phase 3 GATHER1 (n=177) and GATHER2 (n=447) studies, which evaluated the safety and efficacy of Izervay compared with sham treatment. Over 12 months, the primary analysis of each trial showed a statistically significant reduction in the rate of GA lesion growth in patients treated with Izervay, with a 35% reduction in GATHER1 and 18% in GATHER2. The most common adverse effects associated with Izervay were conjunctival hemorrhage (13%), increased IOP (9%), blurred vision (8%), choroidal neovascularization (7%), eye pain (4%), vitreous floaters (2%), and blepharitis (2%).

IV. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- The medication must be prescribed by or in consultation with a retina specialist; **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**
- 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 6, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**
- Patient does not have an ocular history of or active choroidal neovascularization (CNV) in the eye(s) to be treated; **AND**
- Chart notes or medical records confirming the patient has a diagnosis of Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD)as defined by a phenotype of central geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; **AND**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.); **AND**
- Total GA lesion size must be ≥2.5 and ≤17.5 mm^2 and if GA is multifocal, at least 1 focal lesion must be ≥1.25 mm^2; **AND**
- GA is nonfoveal (lesions within 1500 µm of the foveal center, not involving the center point of fovea); **AND**
- Patient has a best corrected visual acuity (BCVA) between 20/25 and 20/320; **AND**
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

V. Renewal Criteria [1,2]

Coverage can be renewed based upon the following criteria:

- Patient is at least 18 years of age; **AND**
- The medication must be prescribed by or in consultation with a retina specialist; **AND**
- Patient continues to meet the initial criteria 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, etc. that cannot be adequately treated; **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:
    - Fundus Autofluorescence (FAF)
    - Optical Coherence Tomography (OCT)
    - Best corrected visual acuity (BCVA); **AND**
- Continued administration is necessary for the maintenance treatment of the condition and the patient and provider have discussed potential decrease in frequency administrations; AND
- Patient has not received a total of 12 months (i.e., 12 doses per each eye) of therapy

VI. 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) for up to 12 months.
- 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.	

VII. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VIII. Investigational Use

All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

IX. References

1. Izervay [package insert]. Parsippany, NJ; Iveric bio, Inc.; August 2023. Accessed February 2024.
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 2019. Oct 2019.

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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

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

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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

Policy Rationale:

Izervay was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Izervay according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.