



POLICIES AND PROCEDURE MANUAL

Policy: MBP 316.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Izervay (avacincaptad pegol)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Izervay (avacincaptad pegol)

II. Purpose/Objective:

To provide a policy of coverage regarding Izervay (avacincaptad pegol)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION:

Izervay (avacincaptad pegol) is an RNA aptamer, a PEGylated oligonucleotide that binds to and inhibits complement protein C5. By inhibiting C5, avacincaptad pegol may prevent its cleavage to C5a and C5b thus decreasing membrane attack complex (MAC) formation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Izervay (avacincaptad pegol) will be considered medically necessary for the Commercial, Exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of GA using imaging modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Izervay **AND**
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD) (e.g. Syfovre)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Izervay **AND**
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Syfovre)

AND

- One of the following:
 - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Izervay-treated eye(s) **OR**
 - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
 - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Izervay outweigh the risks of Izervay administration)

QUANTITY LIMIT: 0.2 mL (4 mg) per 28 days (2 mg per eye per 28 days)

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Izervay [Prescribing Information]. Parsippany NJ. IVERIC bio, Inc. August 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/16/24

Revised: 9/17/24 (auth duration, BCVA added, initial CNV deleted, Medicaid business segment deleted, LOB table, taglines)

Reviewed:

MA UM Committee approval: 5/22/24