MVP Health Care Medical Policy

Medicare Part B: Izervay

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**04/01/2024**
Effective Date:	**04/01/2024**
Related Policies:	Syfovre

Refer to the MVP Medicare website for the Medicare Part D formulary and Part D policies.

Drugs Requiring Prior Authorization under the medical benefit

J2782 Izervay (Avacincaptad Pegol) Solution for Intravitreal Injection

Overview/Summary of Evidence

Izervay (Avacincaptad Pegol) solution for intravitreal injection is a complement C5 inhibitor which is FDA approved for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Indications/Criteria

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

Izervay may be considered for coverage for Geographic atrophy (GA) secondary to age-related macular degeneration (AMD) when all of following criteria is met:

- Chart notes confirming a diagnosis of geographic atrophy secondary to age-related macular degeneration
- Prescribed and administered by an ophthalmologist

- Baseline best-corrected visual acuity (BCVA) is between 20/25 and 20/320
- Member is not currently utilizing any other intravitreal complement inhibitor therapies confirmed by claims history

Initial approval for 6 months

Extension requests for Izervay may be covered for an additional 6 months after initial approval for the following situations. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye):

- Member continues to meet initial approval criteria above
- Documentation that the member is tolerating the medication well (absence of adverse effects such as endophthalmitis, increased intraocular pressure, etc.)
- Documentation of objective test results supporting slowed progression and clinical benefit compared to baseline such as visual function test results, optical coherence tomography (OCT), and/or fundus autofluorescence photographs (FAF)
- Member has not received greater than 12 total months of therapy
- Extension requests where Izervay did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing

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Exclusions

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

The use of Izervay will not be covered for the following situations:

- Members with ocular or periocular infections
- Members with active intraocular inflammation
- Dosing, age, and/or frequency exceeding the FDA approved package labeling.
- Member has already received 12 months of therapy. Izervay may not be used for more than 12 months of total therapy (12 doses max per eye)
- GA secondary to a condition other than AMD such as Stargardt disease in either eye
- Member is currently utilizing another intravitreal complement inhibitor

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References

1. Avacincaptad Pegol. In: Specific Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: publication year [updated 9 Feb. 2024; cited 14 Feb. 2024]. Available from: http://online.lexi.com. Subscription required to view.
2. Izervay (avacincaptad pegol intravitreal solution) NDA 217225. FDA. Revised 8/2023. label (fda.gov)
3. Gaffe 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.
4. Izervay (avacincaptad pegol intravitreal solution). Prescribing Information. Iveric Bio, Inc. Parsippany, NJ. Revised 8/2023.