Policy Name	Clinical Policy - Complement Inhibitors for Geographic Atrophy
Policy Number	1349.00
Department	Clinical Strategy
Subcategory	Medical Management
Original Approval Date	07/12/2023
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Current Effective Date	12/01/2025

Company Entities Supported (Select All that Apply):
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company')

ACRONYMS and DEFINITIONS	
AMD	Age Related Macular Degeneration
CNV	Choroidal neovascularization; abnormal growth of vessels from the choroidal vasculature to the neurosensory retina. This is seen in diseases such as exudative type of age related macular degeneration.
DA	Disc area
DD	Disc diameter
FA	Fluorescein angiogram
FAF	Fundus autofluorescence.
GA	Geographic atrophy
OCT	Optical Coherence Tomography

PURPOSE

To provide the medical necessity criteria to support the indication(s) for complement inhibitors. Applicable procedure codes are also defined.

POLICY

A. Background

Syfovre and Izervay are FDA approved treatments for geographic atrophy (GA), a complication of dry age-related macular degeneration (AMD). The mechanism of action for both drugs involves the complement system, a part of the immune system. The drugs block specific complement proteins, which reduces the inflammatory damage to retinal cells resulting in geographic atrophy. Syfovre has been associated with rare serious adverse events such as ischemic optic neuropathy and retinal vasculitis. For Izervay, the data currently shows that there is potentially lower risk of serious adverse events compared to Syfovre. However, for both drugs, data on long term safety profiles is still emerging. Individuals receiving either drug need to be monitored for signs of neovascular AMD.

B. Medically Necessary

1. Initial treatment with Syfovre may be considered medically necessary for adult patients when all the following criteria are met:

    a. Patient has diagnosis of vision threatening geographic atrophy (GA) secondary to age related macular degeneration.
    b. The GA is in the fovea, or, if extra foveal than total measure is greater than or equal (≥) to 0.5 DD or 0.25 DA.[1]

2. Initial treatment with Izervay may be considered medically necessary for adult patients when all the following criteria are met:

    a. Patient has diagnosis of vision threatening geographic atrophy (GA) secondary to age related macular degeneration.
    b. The GA may be either intra or extra foveal;
    c. Total lesion area should be between 2.5 and 17.5 mm^2 (1–7 disc areas). For multifocal lesions, at least 1 lesion should be 1.25 mm^2 (0.5 disc area) or larger.

3. Retreatment with Syfovre or Izervay may be medically necessary and approved when the submitted documentation shows:

    a. The drug specific criteria above continue to be met; and,
    b. The last treatment was at least 25 days prior; and,
    c. The intraocular pressure remains controlled; and,
    d. The previous treatment with the same drug was well tolerated; and,
    e. The patient has been evaluated for any signs or symptoms of conversion to CNV.

[1] OAKS and DERBY trials

C. Not Medically Necessary

Syfovre or Izervay may be contraindicated or may not be medically necessary when:

1. Patient has ocular or periocular infections; or,
2. Patient has active intraocular inflammation; or,
3. The patient's GA is secondary to a condition other than AMD, such as toxic maculopathy, or Stargardt [2]; or,
4. The eye has no visual acuity to preserve or protect from the GA.

D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale for it as in requirements above. All items must be available upon request to initiate or sustain previous payments. For any retrospective review, a full operative report and the medical plan of care is needed.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be signed by the physician, in either a handwritten or electronic signature. Stamped signatures are not acceptable. The required documentation to support medical necessity includes full clinical notes including the:

1. Anterior and posterior segment exams; and,
2. Measurements of the intraocular pressure and best corrected visual acuity; and,
3. Results of relevant testing including any OCT, FA, color fundus photographs, or FAF; and,
4. The evaluation and medical plan of care.

E. Procedural Detail

CPT / HCPCS Codes	
67028	Intravitreal injection of a pharmacologic agent, separate procedure.
J2781	Injection, pegcetacoplan, 1 mg (Syfovre)
J2782	Injection, avacincaptad pegol, 0.1 mg (Izervay)
Required Modifiers	
L, R, or 50 (bilateral)	

[2], [10] Appelis Syfovre Phase 3 trial exclusions Appelis Syfovre Phase 3 trial exclusions

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RELATED POLICIES	
1317	Vascular Endothelial Growth Factor Inhibitors
1346	Corticosteroid Implants and Injections

DOCUMENT HISTORY		
Approval Date	***Revision***	***Effective Date***
07/12/2023	Initial policy	01/01/2024
07/10/2024	Change of policy name; addition of new drug (Izervay) with criteria.	11/01/2024

07/09/2025	Added indication for Izervay to include intrafoveal geographic atrophy.	12/01/2025

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