



Geographic Atrophy
Syfovre (pegcetacoplan) J2781,
Izervay (avacincaptad pegol) J2782
Prior Authorization Request
Medicare Part B Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
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Date Requested _____			
Requestor _____	Clinic name: _____	Phone _____	/ Fax _____

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Pegcetacoplan (Syfovre): Seven(7) 15 mg vials intravitreally per 6 months. (per eye)
 Avacincaptad Pegol (Izervay): Six(6) 2 mg vials intravitreally per 6 months. (per eye)

Other Regimen _____

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ Description: _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

Syfovre J2781
 Izervay J3490/J3590

New Start or Initial Request: (Clinical documentation required for all requests)

- Diagnosis of geographic atrophy of the macula secondary to age-related macular degeneration
- Diagnosis has been verified by geographic atrophy sensitive tests (including but not limited to optical coherence tomography, fluorescein angiography, fundus photography).
- Patient has a best-corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR ii.
- Patient has a best-corrected visual acuity (BCVA) of 20/320 or better using the Snellen chart

Dosing MUST meet BOTH criteria:

- The dose is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection for each eye being treated; AND
- The dosing interval is not more frequent than once every 25 days for each eye being treated.

- Requests for may **NOT** be approved for the following:
 - Geographic atrophy that is secondary to a condition other than age-related macular degeneration (including but not limited to Stargardt disease, cone rod dystrophy or toxic maculopathies); OR
 - Patient has a history of or active choroidal neovascularization or wet age-related macular degeneration; OR,
 - Individual has an ocular or periocular infection(s); OR,
 - Individual has active intraocular inflammation;

Continuation Requests: (Clinical documentation required for all requests)

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** _____ / _____ / _____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION DOES NOT GUARANTEE PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.



Prior Authorization Group – Complement Inhibitor PA

Drug Name(s):

SYFOVRE
IZERVAY

PEGCETACOPLAN AVACINCAPTAD PEGOL

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Additional utilization management criteria:**
 - a. Total GA area size of $\geq 2.5 \text{ mm}^2$ and $\leq 17.5 \text{ mm}^2$ (1 and 7 disk areas [DA] respectively); AND
 - b. If GA multifocal, at least 1 focal lesion of $\geq 1.25 \text{ mm}^2$ (0.5 DA); AND
 - c. Presence of any pattern of hyper autofluorescence in the junctional zone of GA
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

- Ocular or periocular infections
- Active intraocular inflammation

Prescriber Restrictions:

- **Ophthalmologist**

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Syfovre

- Geographic Atrophy (GA) secondary to Nonexudative age-related macular degeneration
- Paroxysmal nocturnal hemoglobinuria

Izervay

- Geographic Atrophy (GA) secondary to Nonexudative age-related macular degeneration

Off-Label Uses:

Syfovre

- N/A

Age Restrictions:

- Safety and effectiveness have not been established in pediatric patients

Other Clinical Considerations:

• N/A

Resources:

https://www-micromedexsolutions-com.liboff.ohsu.edu/micromedex2/librarian/CS/F5DCB3/ND_PR/evidenceexpert/ND_P/evidenceexpert/DUPLICATIONSHIELDSYNC/3E565D/ND_PG/evidenceexpert/ND_B/evidenceexpert/ND_AppProduct/evidenceexpert/ND_T/evidenceexpert/PFActionId/evidenceexpert.DolIntegratedSearch?SearchTerm=svfovre&UserSearchTerm=svfovre&SearchFilter=filterNone&navitem=searchAll



Part B Prior Authorization Step Therapy Guidelines

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