Syfovre® (pegcetacoplan)
(Intravitreal)

Document Number: IC-0697

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

- 30 billable units (30 mg) every 25 days

(Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria [1,2]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **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**

Universal Criteria [1]

- Patient is free of ocular and/or periocular 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 5, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**

Geographic Atrophy (GA) † [1-3]

- Patient has a diagnosis of GA as defined by a phenotype of geographic atrophy having 1 or more zones of well demarcated retinal pigmented epithelium (RPE) and/or choriocapillaris atrophy; **AND**
- Disease is secondary to age-related macular degeneration (AMD); **AND**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.)

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2]

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: endophthalmitis, retinal detachment, retinal vasculitis and/or retinal vascular occlusion, neovascular (wet) AMD or choroidal neovascularization, intraocular inflammation (e.g., vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare), 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:
    - Best corrected visual acuity (BCVA)
    - Fundus Autofluorescence (FAF)
    - Optical Coherence Tomography (OCT); **AND**
- Continued administration is necessary for the maintenance treatment of the condition and the patient and provider have discussed potential decrease in frequency of administrations.

V. Dosage/Administration [1]

Indication	Dose
Geographic Atrophy (GA)	Administer 15 mg (0.1 mL of 150 mg/mL solution) by intravitreal injection to each affected eye once every 25 to 60 days.
- Each vial and syringe should only be used for the treatment of a single eye.	

VI. Billing Code/Availability Information

HCPCS Code:

- J2781 – Injection, pegcetacoplan, 1mg; 1 billable unit = 1 mg

NDC:

- Syfovre 15 mg/0.1 mL solution for injection in a single-dose vial: 73606-0020-xx

VII. References

1. Syfovre [package insert]. Waltham, MA; Apellis Pharmaceuticals, Inc.; July 2025. Accessed August 2025.
2. Goldberg R, Heier JS, Clifton-Wykoff C, et al. Efficacy of intravitreal pegcetacoplan in patients with geographic atrophy (GA): 12-month results from the phase 3 OAKS and DERBY studies. Investigative Ophthalmology & Visual Science June 2022, Vol.63, 1500.

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 2024. Feb 2025.
4. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Retina Summary Benchmarks-2024. December 2024.
5. Chandra S, McKibbin M, Mahmood S, et al; AMD Commissioning Guidance Development Group. The Royal College of Ophthalmologists Commissioning guidelines on age macular degeneration: executive summary. Eye (Lond). 2022 Nov;36(11):2078-2083. doi: 10.1038/s41433-022-02095-2. Epub 2022 May 27. PMID: 35624304; PMCID: PMC9582190.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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

ICD-10	ICD-10 Description
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

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