

Syfovre™ (pegcetacoplan) (Intravitreal)

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Last Review Date: 10/03/2023

Date of Origin: 04/04/2023

Dates Reviewed: 04/2023, 10/2023

I. Length of Authorization

Coverage will be provided annually and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Syfovre 150 mg/mL single-dose vial: 1 vial per eye every 25 days

B. 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}

Coverage 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

- Patient is free of ocular and/or peri-ocular 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 6, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**

Geographic Atrophy (GA) † ^{1,2,3}

- The patient has a diagnosis of GA as defined by a phenotype of central 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); ◊ Orphan Drug

IV. Renewal Criteria ^{1,2}

Coverage 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, 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 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(s):

- J3490 – Unclassified drugs (*Discontinue use on 10/01/2023*)
- C9151 – Injection, pegcetacoplan, 1 mg; 1 billable unit = 1 mg (*Discontinue use on 10/01/2023*)
- J2781 – Injection, pegcetacoplan, 1mg (*Effective 10/01/2023*)

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.; February 2023. Accessed September 2023.
2. Goldberg R, Heier JS, Clifton-Wyckoff 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 2019. Oct 2019. (Interim update March 2022).
4. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Retina Summary Benchmarks-2022. December 2022.
5. Chandra S, McKibbin M, Mahmood S, et al. The Royal College of Ophthalmologists Commissioning guidelines on age macular degeneration: executive summary. *Eye* 36, 2078–2083 (2022). <https://doi.org/10.1038/s41433-022-02095-2>

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
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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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