Neighborhood Health Plan OF RHODE ISLAND™
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Syfovre (pegcetacloplan)
(Intravitreal)

Effective Date: 8/01/2023
Dates Reviewed: 6/2023, 12/7/2023
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed every 6 months.

II. Dosing Limits

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

- Syfovre 15 mg/0.1 mL in a single-dose vial: 1 injection per eye every 25 days

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

- 30 units every 25 days (Max units are based on administration to BOTH eyes)

III. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- The medication must be prescribed by or in consultation with a retina specialist; **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**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Patient does not have category 6, or higher, visual impairment or blindness (i.e., no light perception-total blindness); **AND**
- Patient does not have an ocular history of or active choroidal neovascularization (CNV) in the eye(s) to be treated; **AND**
- Chart notes or medical records confirming the patient has a diagnosis of Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD) 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**
- Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.); **AND**
- Total GA lesion size must be ≥2.5 and ≤17.5 mm2 and if GA is multifocal, at least 1 focal lesion must be ≥1.25 mm2; **AND**

- Patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent); **AND**
- Syfovre will not be used in combination with other intravitreal complement inhibitor therapies; **AND**
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient is at least 18 years of age; **AND**
- The medication must be prescribed by or in consultation with a retina specialist; **AND**
- Patient continues to meet the initial criteria 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 (e.g., smaller increases in GA lesion total area growth, reduction in total area of GA lesions) while on therapy compared to pre-treatment baseline as measured by any of the following:
    - Fundus Autofluorescence (FAF)
    - Optical Coherence Tomography (OCT)
    - Best corrected visual acuity (BCVA); **AND**
- Continued administration is necessary for the maintenance treatment of the condition and the patient and provider have discussed a potential decrease in the frequency of administrations.

V. Dosage/Administration

Indication	Dose
GA	The recommended dose for Syfovre is 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days.

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

- Syfovre 15 mg/0.1 mL Solution for Injection in a Single-dose Vial: 73606-0020-xx

VII. Investigational Use

All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical

Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

VIII. References

1. Syfovre [package insert]. Waltham, MA; Apellis Pharmaceuticals, Inc.; February 2023. Accessed November 2023.
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 2019. Oct 2019.

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 Articles (LCAs) and Local Coverage Determinations (LCDs) 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/LCA/LCD): 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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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