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, 01/04/2024
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. Summary of Evidence

Syfovre (pegcetacoplan) intravitreal solution was approved for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). The efficacy is based on two phase three randomized, sham-controlled clinical trials (OAKS and DERBY) with 1258 patients, which demonstrated a reduction in the mean rate of GA lesion growth from baseline to month 24. OAKS monthly and every other month dosing had reductions of 22% and 18%, respectively, compared with sham ($p<0.0001$ and $p=0.0002$, respectively). DERBY monthly and every other month dosing had reductions of 19% and 16%, respectively, compared with sham ($p= 0.0004$ and $p = 0.0030$, respectively). Notably, Syfovre treatment did not prevent the worsening of vision in patients with a similar rate of decline in BCVA observed in the sham group. In addition, Syfovre did not meet the primary outcome in the DERBY trial for a change in lesion growth compared to sham. Serious adverse effects include increased rates of neovascular AMD (12% monthly dose, 7% every other month dose, and 3% in control group), endophthalmitis and retinal detachments, intraocular inflammation, and increased intraocular pressure.

IV. 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

V. 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.

VI. 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.

VII. 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

VIII. 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.

IX. 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.
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

Policy Rationale:

Syfovre was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Syfovre according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.