

## Medical Policy:

### Syfovre (pegcetacoplan) intravitreal injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.383	October 7, 2024	May 11, 2023

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Syfovre, a complement 3 inhibitor, is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). 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.

## Length of Authorization

12 Months and may be renewed

## Dosing Limits [Medical Benefit]

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

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

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

- 30 mg every 25 days

(Max units are based on administration to BOTH eyes)

## Guideline

### I. Initial Criteria

#### 1. Geographic Atrophy.

- A. Patient has geographic atrophy secondary to age-related macular degeneration; **AND**
- B. Patient has a baseline assessment for all the following: best corrected visual acuity (BCVA), fundus autofluorescence (FAF) imaging, and optical coherence tomography (OCT); **AND**
- C. Conditions other than AMD have been ruled out (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies, etc.); **AND**
- D. The medication is administered by, or under the supervision of, an ophthalmologist; **AND**
- E. Patient meets **ONE** of the following:
  - i. 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

### II. Renewal Criteria

- A. Absence of unacceptable toxicity from the drug); **AND**  
*(NOTE: 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)*
- B. 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:
  - i. Best corrected visual acuity (BCVA)
  - ii. Fundus Autofluorescence (FAF)
  - iii. Optical Coherence Tomography (OCT)

## Applicable Procedure Codes

Code	Description
J2781	Syfovre 15mg/0.1 ML Solution, Injection, pegcetacoplan, intravitreal, 1 mg

## Applicable NDCs

Code	Description
73606-0020-01	Syfovre 15mg/0.1mL Solution of Injection in a Single-dose Vial

## ICD-10 Diagnoses

Code	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

## Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	10/7/2024	Revision: Initial Criteria- Removed: "Note: BCVA of 24 letters or better is approximately 20/320 Snellen equivalent)" from Note section and expanded it out into the criteria for clarity as follows: "Patient meets ONE of the following: Patient has a best corrected visual acuity (BCVA) of 24 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; <b>OR</b> Patient has a best-corrected visual acuity (BCVA) of 20/320 or better using the Snellen chart"
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: Removed Codes J3590 and C9151, added J2781
EmblemHealth & ConnectiCare	05/11/2023	New Policy

## References

1. Syfovre™ intravitreal injection [prescribing information]. Waltham, MA: Apellis; February 2023.