Medical Policy:

Syfovre (pegcetacoplan) intravitreal injection

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

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; **OR** 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.