Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 278.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Syfovre (pegcetacoplan)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Syfovre (pegcetacoplan)

II. Purpose/Objective:
To provide a policy of coverage regarding Syfovre (pegcetacoplan)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Syfovre (pegcetacoplan) binds to complement protein C3 and its activation fragment C3b with high affinity, regulating the cleavage of C3 and the generation of downstream effectors of complement activation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Syfovre (pegcetacoplan) will be considered medically necessary for the Commercial, Exchange, CHIP, and Medicare lines of business when ALL of the following criteria are met:

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of geographic atrophy (GA) using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Syfovre **AND**
- Medical record documentation that Syfovre will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Izervay)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Syfovre **AND**
- Medical record documentation of the absence, or resolution, of Retinal Vasculitis, Retinal Vascular Occlusion, and/or active Intraocular Inflammation (including but not limited to: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare) **AND**
- Medical record documentation that Syfovre will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to AMD (i.e. Izervay)

AND

- One of the following:
    - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Syfovre-treated eye(s) **OR**
    - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
    - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Syfovre outweigh the risks of Syfovre administration)

QUANTITY LIMIT: 0.2mL (30mg) per 25 days (15mg per eye per 25 days)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Syfovre [prescribing information]. Waltham, MA: Apellis Pharmaceuticals Inc; November 2023.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/25/23

Revised: 12/28/23 (references added), 9/17/24 (auth duration, BCVA & TD added, initial CNV deleted, Medicaid business segment deleted, LOB table, taglines)

Reviewed: 4/11/24

MA UM Committee approval: 12/31/23