Syfovre (pegcetacoplan injection)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Syfovre (pegcetacoplan) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Syfovre (pegcetacoplan injection) is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
    a. Chart notes or medical record documentation confirming the diagnosis of geopraphic atrophy (GA) secondary to age-related macular degeneration via Fundus Autofluorescence imaging, optical coherence tomography or other imaging techniques

B. Continuation requests:
    a. Chart notes or medical record documentation confirming a positive clinical response to therapy

Prescriber Specialties

Syfovre (pegcetacoplan injection) must be prescribed by or in consultation with an ophthalmologist.

Criteria for Initial Approval

A. Syfovre (pegcetacoplan injection) is considered **medically necessary** for treatment of geographic atrophy (GA) secondary to age-related macular degeneration when ALL of the following criteria are met:
   1. Member has a diagnosis of geographic atrophy secondary to age-related macular degeneration confirmed via Fundus Autofluorescence imaging, optical coherence tomography or other imaging techniques
   2. Syfovre is being prescribed by or in consultation with an ophthalmologist
   3. Total GA lesion size is ≥ 2.5 and ≤ 17.5 mm^2 (if multifocal, at least 1 focal lesion ≥ 1.25 mm^2)
   4. Member does not have any of the following:
      a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
      b) Ocular or periocular infection(s)
      c) Active intraocular inflammation
      d) History of or active choroidal neovascularization or exudative age-related macular degeneration

Approval will be for **12 months.**

Continuation of Therapy

A. Syfovre (pegcetacoplan injection) is considered **medically necessary** for continuation of treatment of geographic atrophy (GA) secondary to age-related macular degeneration when the following criteria are met:
   1. Syfovre is being prescribed by or in consultation with an ophthalmologist
   2. The member has demonstrated a positive clinical response to therapy (e.g., a reduction or stabilization in the rate of vision decline or the risk of more severe vision loss, stabilization or normalization or reduction in total area of GA lesions).
   3. Member does not have any of the following:
      a) Geographic atrophy that is secondary to a condition other than age-related macular degeneration (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).
      b) Ocular or periocular infection(s)
      c) Active intraocular inflammation
      d) History of or active choroidal neovascularization or exudative age-related macular degeneration

Approval will be for **12 months.**

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

Syfovre (pegcetacoplan) is the first therapy indicated for the treatment of GA secondary to AMD. Syfovre is administered by intravitreal injection to each affected eye once every 25 to 60 days. The efficacy and safety of Syfovre (pegcetacoplan) were evaluated in two phase III, randomized, double-masked, sham-controlled trials (OAKS and DERBY). In the OAKS trial, Syfovre (pegcetacoplan) was significantly better than the sham injection, both administered once monthly and every other month, at slowing down progression of GA lesions secondary to AMD at 12 months and 24 months of treatment; results in the DERBY trial were not significant for the primary 12-month endpoint. Both trials are unpublished and there were high rates of therapy discontinuation in all study arms. There was a reduction in the mean rate of GA

lesion growth observed in both studies.The most common adverse events associated with Syfovre (pegcetacoplan) treatment were ocular discomfort, neovascular AMD, vitreous floaters, and conjunctival hemorrhage. Syfovre is contraindicated in patients with ocular or periocular infections and in patients with active intraocular inflammation. Warnings and precautions with Syfovre (pegcetacoplan) include endophthalmitis and retinal detachments, neovascular AMD, intraocular inflammation, and increased intraocular pressure (IOP).

Safety

Adverse Events in Study Eye Reported in ≥ 2% of Patients Treated with Syfovre (pegcetacoplan) and Occurring More Frequently Than in Patients Receiving Sham

Adverse Event	Syfovre 15 mg Intravitreally Monthly (n = 419)	Syfovre 15 mg Intravitreally Every Other Month (n = 420)	Sham Pooled (n = 417)
Ocular discomfort	13%	10%	11%
Neovascular AMD	12%	7%	3%
Vitreous floaters	10%	7%	1%
Conjunctival hemorrhage	8%	8%	4%
Vitreous detachment	4%	6%	3%
Retinal hemorrhage	4%	5%	3%
Punctate keratitis	5%	3%	< 1%
Posterior capsule opacification	4%	4%	3%
Intraocular inflammation	4%	2%	< 1%
↑ IOP	2%	3%	< 1%

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9151 – Injection, pegcetacoplan, 1 mg (cancelled 10/1/2023)
- C9399 – Unclassified drugs or biologics (when specified as [Syfovre] (pegcetacoplan) (intravitreal))
- J2781 – Injection, pegcetacoplan, intravitreal, 1 mg (effective 10/1/23)
- J3490 – Unclassified drugs (when specified as [Syfovre] (pegcetacoplan) (intravitreal))
- J3590 – Unclassified biologics (when specified as [Syfovre] (pegcetacoplan) (intravitreal))

REFERENCES

- Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.
- Liao DS, Grossi FV, El Mehdi D, et al. Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. Ophthalmology. 2020 Feb;127(2):186-195.
- A Study to Compare the Efficacy and Safety of Intravitreal APL-2 Therapy With Sham Injections in Patients With Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration. NCT03525613. Clinicaltrials.gov.
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- Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed May 22, 2023.

- Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern®. Ophthalmology. 2020 Jan;127(1):P1-P65.

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POLICY HISTORY

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