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Medical benefit drug policies are a source for WyoBlue Advantage medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/03/2024

Syfovre™ (pegcetacoplan)

HCPCS: J2781

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Must not have geographic atrophy (GA) secondary to a condition other than dry age-related macular degeneration (AMD)
   d. Must have a visual acuity in the affected eye(s) of 20/320 or better
   e. Must not be used in combination with Izervay™ or any other medication for GA
   f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in WyoBlue Advantage's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Geographic atrophy is an advanced and severe form of dry age-related macular degeneration (AMD). It is caused by the gradual breakdown of light-sensitive cells in the macula resulting in the growth of irreversible lesions in the retinal pigment epithelium (RPE). GA progression causes a gradual loss of visual function. Symptoms include scotomas, difficulty recognizing faces, decreased reading speed, impaired dark adaptation, low luminance deficit (LLD), impaired contrast sensitivity, and difficulty driving at night. More than half of all patients with GA will experience significant impairment of everyday vision, and about 20% of patients will develop severe vision loss with visual acuity of 20/200 or worse.

- The exact cause of GA is unknown but it is thought the disease is the result of a multifactorial process. The most significant risk factors include age and family history with genetics playing a role in disease development. It is thought errors found in the genes of the complement cascade may cause inflammation making the eye more susceptible to GA. Smoking and a higher body mass index are also risk factors.

- Diagnosis is made by an ophthalmologist during a dilated exam and/or with retinal imaging. In a dilated exam, geographic atrophy appears as a patch of retina that's missing its dark melanin pigment. Imaging techniques including retinal color photographs, optical coherence tomography (OCT), or autofluorescence photographs can also be used to detect GA.

- Syfovre is a C3 complement inhibitor indicated for the treatment of GA secondary to AMD. It is the first FDA approved therapy for GA. It targets the complement overactivation generating GA progression, preventing lesion growth, and reducing the likelihood of severe disease.

- GA can be secondary to other conditions outside of AMD. Those include Stargardt disease, cone rod dystrophy, or toxic maculopathies like plaquenil maculopathy. Syfovre has only been studied in patients with GA secondary to dry AMD and therefore should not be used to treat GA secondary to other conditions. If the patient has multiple eye conditions requiring treatment, such as wet and dry AMD, it is appropriate to treat both conditions simultaneously.

- Syfovre has not been studied in patients with a visual acuity worse than 20/320. Use should be limited to those patients with visual acuity equal to or better than 20/320.

References:

1. Syfovre [prescribing information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; November 2023.
2. The Eye Diseases Prevalence Research Group. Prevalence of age-related macular degeneration in the United States. Arch Ophthalmol. 2004; 122 (4): 564 – 572.
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020 Jan (updated March 2022); 127 (1): 1 - 65.
4. Clinicaltrials.gov. A study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525613). Available at: https://clinicaltrials.gov/ct2/show/NCT03525613?term=NCT03525613&draw=2&rank=1. Accessed on February 20, 2023.
5. Clinicaltrials.gov. Study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525600). Available at: https://clinicaltrials.gov/ct2/show/NCT03525600. Accessed on February 20, 2023.

Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*