CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Susvimo (ranibizumab)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient hospital
STATUS	Prior Authorization Required

Susvimo, an intravitreal ocular implant, was approved by the FDA in 2021. It is indicated for the treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication. VEGF inhibitors suppress endothelial cell proliferation, neovascularization, and vascular permeability.
Susvimo was previously referred to as Lucentis Port Delivery System (PDS) since it is essentially a longer lasting version of Lucentis, releasing ranibizumab over a 6-month period rather than needing to be administered monthly. After 6 months, the port can be re-filled. Lucentis is approved for other indications aside from just wet AMD.
Susvimo has a black box warning for endophthalmitis, an infection inside the eye which is a medical emergency. Approval was based on the phase 3 Archway trial which demonstrated equivalent visual acuity results between Susvimo and Lucentis.

Susvimo (ranibizumab) will be considered for coverage when the following criteria are met:

Neovascular (wet) Age-related Macular Degeneration (AMD)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a diagnosis of wet AMD; AND
4. Member has previously responded to at least 2 intravitreal injections of a VEGF inhibitor; bevacizumab is the preferred product (others require prior authorization); AND
5. Member does NOT have any ocular or periocular infections or active intraocular inflammation.
6. **Dosage allowed/Quantity limit:** 2 mg via surgical administration every 6 months. (1 single dose vial per eye per 6 months)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must include documentation of improved or stabilized visual acuity.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Susvimo (ranibizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/09/2021	New policy for Susvimo created.

References:

1. SUSVIMO [package insert]. South San Francisco, CA: Genentech, Inc; 2021.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
3. Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS. Anti-vascular endothelial growth factor for neovascular age-related macular degeneration. *Cochrane Database Syst Rev*. 2019;3(3):CD005139. Published 2019 Mar 4. doi:10.1002/14651858.CD005139.pub4
4. A Phase III Study to Evaluate the Port Delivery System With Ranibizumab Compared With Monthly Ranibizumab Injections in Participants With Wet Age-Related Macular Degeneration (Archway). ClinicalTrials.gov Identifier: NCT03677934. Updated October 28, 2021. Accessed November 10, 2021. https://clinicaltrials.gov/ct2/show/NCT03677934

Effective date: 07/01/2022
Revised date: 11/09/2021