Policy Title:	Susvimo (ranibizumab) for intravitreal use via ocular implant		
		Department:	PHA
Effective Date:	06/01/2022		
Review Date:	05/12/2022, 6/16/2022, 7/27/2023, 12/07/2023, 01/04/2024		

Purpose: To support safe, effective and appropriate use of Susvimo (ranibizumab) via intravitreal implant in patients with neovascular (wet) age related macular degeneration (AMD).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Susvimo (ranibizumab) via intravitreal implant is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Susvimo (ranibizumab) via intravitreal implant will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Susvimo (ranibizumab injection) for intravitreal use via Susvimo ocular implant is a vascular endothelial growth factor (VEGF) inhibitor approved for the treatment of Neovascular (wet) Age-related Macular Degeneration (AMD) in patients who have previously responded to at least two intravitreal injections of a VEGF inhibitor. Susvimo was approved based on efficacy data from a randomized, visual assessor-masked, active treatment-controlled study in which the difference of adjusted mean change from baseline in distance Best Corrected Visual Acuity (BCVA) score averaged over Week 36 and Week 40 was -0.3 (95%CI: -1.7, 1.1), demonstrating Susvimo was equivalent to intravitreal ranibizumab monthly injections. The most common adverse reactions included conjunctival hemorrhage (72%), conjunctival hyperemia (26%), iritis (23%) and eye pain (10%). The Susvimo implant has been associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab, as clinical trials demonstrated 2.0% of patients who received the Susvimo implant experienced endophthalmitis. The Susvimo implant and implant procedures may cause rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival retraction, conjunctival erosion, and conjunctival bleb.

Initial Criteria:

- Patient is at least 18 years of age or older; AND
- Prescribed by or in consultation with Retina Specialist; AND
- Must have a diagnosis of neovascular (wet) age related macular degeneration (AMD); AND
- Patient has previously responded to at least two intravitreal injections of a VEGF inhibitor medication (e.g., aflibercept, bevacizumab, brolucizumab, ranibizumab); AND

- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- The patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab, Byooviz (ranibizumab) AND Eylea (aflibercept); AND
- Patient is free of ocular and periocular infections; AND
- Patient does not have active intraocular inflammation; AND
- Therapy will not be used concurrently with other ophthalmic VEGF inhibitors (e.g., aflibercept, bevacizumab, brolucizumab, ranibizumab) unless supplemental treatment is clinically necessary after 16 weeks of monotherapy with Susvimo with documentation provided of treatment outcome (Refer to dosing and administration section below); AND
- Patient has not required removal of a Susvimo implant in the past; AND
- Patient does not have a hypersensitivity to other ranibizumab products (i.e., Lucentis, Byooviz, etc.); AND
- For patients that are currently on treatment with Susvimo (ranibizumab), they can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Continuation of Therapy Criteria:

- Patient continues to meet all initial criteria; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments, implant dislocation, vitreous hemorrhage, conjunctival erosion, and conjunctival retraction; AND
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition
- (Supplemental treatment only): Patient has had an insufficient response during initial or maintenance therapy with Susvimo administered every 24 weeks with documentation provided and requires supplemental treatment with intravitreal ranibizumab (Refer to dosing and administration section below)

Coverage Durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Susvimo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Susvimo according to Food and Drug Administration (FDA) approved labeling and/or

relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Quantity Limit/ Maximum Dose (1 billable unit = 0.1 mg)
Neovascular age-related macular degeneration (nAMD)	**Initial/Maintenance:** • 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo ocular implant with refills administered every 24 weeks (approximately 6 months) **Supplemental:** • Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the Susvimo implant is in place and if clinically necessary Note: • The initial fill and ocular implant insertion and implant removal are surgical procedures that must be performed in an operating room under aseptic conditions by a physician experienced in vitreoretinal surgery. • No more than 30 minutes should pass between the initial fill of the ocular implant and the insertion into the patient's eye. • The refill-exchange procedures must be performed under aseptic conditions by a physician experienced in ophthalmic surgery.	4mg or 40 units* every 168 days (approximately 6 months)

*based on administration to both eyes

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg

References:

1. Susvimo [package insert]. South San Francisco, CA; Genentech, Inc; November 2022. Accessed November 2023.
2. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2017. Nov 2017.
3. Heimann F, Barteselli G, Brand A, Dingeldey A, Godard L, Hochstetter H, Schneider M, Rothkegel A, Wagner C, Horvath J, Ranade S. A custom virtual reality training solution for ophthalmologic surgical clinical trials. Adv Simul (Lond). 2021 Apr 16;6(1):12. doi: 10.1186/s41077-021-00167-z.