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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Topical Products	**Original Policy Date:**	November 19, 2021
Subject:	Susvimo	**Page:**	1 of 6

Last Review Date: June 16, 2022

Susvimo

Description

Susvimo (ranibizumab) for intravitreal use via Susvimo ocular implant

Background
Susvimo (ranibizumab) is a vascular endothelial growth factor (VEGF) inhibitor used to treat patients with wet (neovascular) age-related macular degeneration (AMD). The VEGF inhibitors block the effects of VEGF-A and prevents the interaction of VEGF-A with its receptors ($VEGFR_1$ and $VEGFR_2$) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1).

Regulatory Status
FDA-approved indication: Susvimo (ranibizumab), a vascular endothelial growth factor (VEGF) inhibitor, 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 VEGF inhibitor (1).

Susvimo has a boxed warning regarding a 3-fold higher rate of endophthalmitis than the monthly intravitreal injections of ranibizumab (1).

Susvimo is contraindicated in ocular or periocular infections and in patients with active intraocular inflammation (1).

Susvimo has additional warnings for the following: rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion or retraction, conjunctival bleb,

postoperative decrease in visual acuity, air bubbles causing improper filling of the implant, and deflection of the implant (1).

The Susvimo initial fill and ocular implant insertion and implant removal procedures must be performed under aseptic conditions by a physician experienced in vitreoretinal surgery. The Susvimo ocular implant must be surgically implanted in the eye or removed from the eye (if medically necessary) in an operating room using aseptic technique. Susvimo refill-exchange procedures must be performed under aseptic conditions by a physician experienced in ophthalmic surgery (1).

The recommended dose of Susvimo is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the Susvimo implant with refills every 24 weeks (approximately 6 months). Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary (1).

Safety and effectiveness of Susvimo in pediatric patients less than 18 years of age have not been established (1).

Related policies
Bevacizumab, Lucentis, VEGF Inhibitors

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Susvimo may be considered **medically necessary** in patients 18 years of age or older with neovascular (wet) age-related macular degeneration (AMD) and if the conditions indicated below are met.

Susvimo may be considered **investigational** for patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Neovascular (wet) age-related macular degeneration (AMD)

AND ALL of the following:

a. Patient has previously responded to at least **TWO** intravitreal injections of a VEGF inhibitor (see Appendix 1)
b. Documented baseline visual acuity test
c. Prescriber agrees to monitor for endophthalmitis
d. **NO** ocular or periocular infection
e. **NO** active intraocular inflammation
f. **NOT** used in combination with other vascular endothelial growth factor (VEGF) inhibitors (see Appendix 1) other than Lucentis (ranibizumab)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Neovascular (wet) age-related macular degeneration (AMD)

AND ALL of the following:

a. Patient has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss)
b. Prescriber agrees to monitor for endophthalmitis
c. **NO** ocular or periocular infection
d. **NO** active intraocular inflammation
e. **NOT** used in combination with other vascular endothelial growth factor (VEGF) inhibitors (see Appendix 1) other than Lucentis (ranibizumab)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 single-dose vials

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Susvimo (ranibizumab) prevents the binding and activation of VEGF receptors leading to a decrease in the neovascularization and vascular permeability associated with neovascular AMD. Patients on Susvimo must be monitored for endophthalmitis. Susvimo is an intravitreal injection for use via Susvimo ocular implant. Safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Susvimo while maintaining optimal therapeutic outcomes.

References

1. Susvimo [package insert]. South San Francisco, CA: Genentech, Inc.; October 2021.

Policy History

Date	Action
November 2021	Addition to PA
December 2021	Annual review
March 2022	Annual review. Vabysmo added to Appendix 1
June 2022	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.

Appendix 1 - List of VEGF Inhibitors for Ocular Indications

Generic Name	Brand Name
aflibercept	Eylea
bevacizumab	Avastin
brolucizumab-dbll	Beovu
faricimab-svoa	Vabysmo
ranibizumab*	Lucentis*
ranibizumab	Susvimo

*Dual therapy is allowed with Lucentis (ranibizumab)