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| <b>Section:</b>    | Prescription Drugs | <b>Effective Date:</b>       | July 1, 2025      |
| <b>Subsection:</b> | Topical Products   | <b>Original Policy Date:</b> | November 19, 2021 |
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**Last Review Date:** June 12, 2025

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## Susvimo

### Description

Susvimo (ranibizumab) for intravitreal use via Susvimo ocular implant

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### Background

Susvimo (ranibizumab) is a vascular endothelial growth factor (VEGF) inhibitor used to treat patients with wet (neovascular) age-related macular degeneration (AMD) and diabetic macular edema (DME). The VEGF inhibitors block the effects of VEGF-A and prevents the interaction of VEGF-A with its receptors (VEGFR<sub>1</sub> and VEGFR<sub>2</sub>) on the surface of endothelial cells, reducing endothelial cell growth, vascular leakage, and new blood vessel formation (1).

### Regulatory Status

FDA-approved indications: Susvimo (ranibizumab), a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with: (1)

- Neovascular (wet) Age-related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.
- Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a VEGF inhibitor.

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).

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Susvimo has additional warnings for the following: rhegmatogenous retinal detachment, implant dislocation, septum dislodgement, 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).

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#### 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** if the conditions indicated below are met.

Susvimo may be considered **investigational** for all other indications.

#### Prior-Approval Requirements

**Age** 18 years of age or older

#### Diagnoses

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Patient must have **ONE** of the following:

1. Neovascular (wet) age-related macular degeneration (AMD)
2. Diabetic macular edema (DME)

**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 for ocular indications (see Appendix 1) other than Lucentis (ranibizumab)

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## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Neovascular (wet) age-related macular degeneration (AMD)
2. Diabetic macular edema (DME)

**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 for ocular indications (see Appendix 1) other than Lucentis (ranibizumab)

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### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Quantity** 4 single-dose vials

**Duration** 12 months

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#### Prior – Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Susvimo (ranibizumab) is a VEGF inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME). 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.; February 2025.

### Policy History

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

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|----------------|--|
| June 2022      | Annual review  |
| September 2022 | Annual review and reference update   |
| December 2022  | Annual review  |
| June 2023      | Annual review  |
| December 2023  | Annual review  |
| March 2024     | Annual review  |
| May 2024       | Added requirement not to use in combination with Syfovre                                   |
| September 2024 | Annual review  |
| February 2025  | Per FEP, removed requirement not to use in combination with Syfovre for ocular indications |
| March 2025     | Annual review  |
| April 2025     | Per PI update, added indication of DME   |
| June 2025      | Annual review  |

### Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.**

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**Appendix 1 - List of VEGF Inhibitors for Ocular Indications**

| Generic Name     | Brand Name     |
|------------------|----------------|
| aflibercept      | Eylea/Eylea HD |
| bevacizumab      | Avastin        |
| brolocizumab-dbl | Beovu          |
| faricimab-svoa   | Vabysmo        |
| ranibizumab*     | Lucentis*      |
| ranibizumab      | Susvimo        |

\*Dual therapy is allowed with Lucentis (ranibizumab)