Reference number(s)
5046-A

Standard Medicare Part B Management Susvimo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Susvimo	ranibizumab	injection

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

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

Susvimo 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.

Diabetic Macular Edema (DME)

Susvimo is indicated for the treatment of patients with Diabetic Macular Edema (DME) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.

Diabetic Retinopathy (DR)

Susvimo is indicated for the treatment of patients with Diabetic Retinopathy (DR) who have previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor medication.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Reference number(s)
5046-A

Coverage Criteria

Neovascular (Wet) Age-Related Macular Degeneration (AMD)[1,2]

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration when all of the following criteria are met:

- Member has a diagnosis of neovascular (wet) age-related macular degeneration.
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea) within the past 6 months.
- Must be used in conjunction with the Susvimo ocular implant.

Diabetic Macular Edema (DME)[1]

Authorization of 6 months may be granted for the treatment of diabetic macular edema when all of the following criteria are met:

- Member has a diagnosis of diabetic macular edema .
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea).
- Must be used in conjunction with the Susvimo ocular implant.

Diabetic Retinopathy (DR)[1]

Authorization of 9 months may be granted for the treatment of diabetic retinopathy when all of the following criteria are met:

- Member has a diagnosis of diabetic retinopathy.
- Member has previously responded to at least two intravitreal injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor (e.g., Avastin, Eylea).
- Must be used in conjunction with the Susvimo ocular implant.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or vision field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Susvimo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Susvimo are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

References

1. Susvimo. [package insert]. San Francisco, CA: Genentech, Inc.; May 2025.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp