

STANDARD MEDICARE PART B MANAGEMENT

VABYSMO (faricimab-svoa)

POLICY

I. 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

Vabysmo is indicated for the treatment of patients with:

- A. Diabetic macular edema
- B. Neovascular (wet) age-related macular degeneration
- C. Macular edema following retinal vein occlusion

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

II. CRITERIA FOR INITIAL APPROVAL

A. Diabetic Macular Edema^{1,2}

Authorization of 6 months may be granted for treatment of diabetic macular edema.

B. Neovascular (Wet) Age-Related Macular Degeneration

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

C. Macular Edema Following Retinal Vein Occlusion

Authorization of 6 months may be granted for treatment of macular edema following retinal vein occlusion.

III. 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:

1. The member is currently receiving therapy with Vabysmo
2. Vabysmo is being used to treat an indication enumerated in Section II
3. 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).

Reference number(s)
5160-A

IV. SUMMARY OF EVIDENCE

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

1. The prescribing information for Vabysmo.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology
3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration.
5. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusion.

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

V. EXPLANATION OF RATIONALE

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

VI. REFERENCES

1. Vabysmo [package insert]. South San Francisco, CA: Genentech, Inc.; October 2023.
2. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
3. 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/preferred-practice-pattern/age-related-macular-degeneration-ppp>.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.