UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Vabysmo Utilization Management Medical Policy
- Vabysmo® (faricimab-svoa intravitreal injection – Genentech)

REVIEW DATE: 11/12/2025

OVERVIEW

Vabysmo, a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor, is given intravitreally for the treatment of ophthalmic conditions. Vabysmo is indicated for the following uses:[1]

- **Diabetic macular edema** (DME).
- **Macular edema following retinal vein occlusion** (RVO).
- **Neovascular (wet) age-related macular degeneration** (AMD).

For the indication of macular edema following RVO, Vabysmo is recommended for use for 6 months.[1] The prescribing information does not note a duration of treatment for DME or neovascular AMD.

Other Uses with Supportive Evidence

VEGF is a protein that plays a key role in retinal physiology and pathology.[2] Overexpression of VEGF may result in retinal and choroidal neovascularization and vascular leakage, which can contribute to vision loss associated with common retinal disorders. Intravitreal VEGF inhibitors are highly effective in reducing ocular neovascularization, macular edema, and exudation that can result in vision impairment and/or loss. Intravitreal VEGF inhibitors have been used off-label to manage eye conditions related to increased VEGF production. In addition to the labeled indications for the intravitreal VEGF inhibitors (e.g., neovascular AMD, diabetic macular edema, diabetic retinopathy), examples of other neovascular diseases of the eye that can potentially be treated with intravitreal VEGF inhibitors are angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovasculopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome. Of note, angioid streaks can occur secondary to systemic conditions such as pseudoxanthoma elasticum, Paget's disease of bone, and sickle cell disease. Research is ongoing and rapidly evolving on the use of intravitreal VEGF inhibitors in other neovascular eye disorders.

Dosing Information

The recommended dosing of Vabysmo for each indication is as follows[1]:

- DME: There are two recommended dosage regimens: 1) 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for at least four doses and then depending on clinical evaluation, dosing interval may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments; or 2) 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for the first six doses, followed by every 8 weeks (2 months). Some patients may require dosing every 4 weeks after the first four doses, although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks.
- Macular edema following RVO: The recommended dose is 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days) for 6 months.
- Neovascular AMD: The recommended dose is 6 mg administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first four doses. Thereafter, depending on clinical evaluation, dosing frequency can range from every 8 weeks to every 16 weeks. However, some patients may need every 4 week (monthly) dosing after the first four doses,

although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vabysmo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vabysmo as well as the monitoring required for adverse events and long-term efficacy, approval requires Vabysmo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vabysmo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. Diabetic Macular Edema. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every 4 weeks (approximately every 28 ± 7 days) for each eye being treated.

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2. Macular Edema Following Retinal Vein Occlusion. Approve for 6 months if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every 4 weeks (approximately every 28 ± 7 days) for each eye being treated.

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3. Neovascular (Wet) Age-Related Macular Degeneration. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
B) The dosing interval is not more frequent than once every 4 weeks (approximately every 28 ± 7 days) for each eye being treated.

Other Uses with Supportive Evidence

4. **Other Neovascular Diseases of the Eye.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.
   Note: Examples of other neovascular diseases of the eye include angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovasculopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome.

   Dosing. Approve if the requested dosing meets BOTH of the following (A and B):
   A) The dose is 6 mg administered by intravitreal injection for each eye being treated; AND
   B) The dosing interval is not more frequent than once every 4 weeks (approximately every 28 ± 7 days) for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vabysmo is not recommended in the following situations:

1. **Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor.** There is no evidence to support concomitant use of Vabysmo with another intravitreal vascular endothelial growth factor inhibitor.
   Note: Intravitreal vascular endothelial growth factor inhibitors are: bevacizumab intravitreal injection (compounded from Avastin® [bevacizumab, injection, for intravenous use] or its biosimilars; off-label use), aflibercept intravitreal injection (Eylea®/biosimilars, Eylea® HD), Beovu® (brolucizumab-dbll intravitreal injection), ranibizumab intravitreal injection (Lucentis®, biosimilars), and Susvimo® (ranibizumab intravitreal injection via ocular implant).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vabysmo™ intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; July 2024.
2. Hang A, Feldman S, Amin AP, et al. Intravitreal anti-vascular endothelial growth factor therapies for retinal disorders. *Pharmaceuticals*. 2023;16:1140. Doi.org/10.3390/ph16081140.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Macular Edema Following Retinal Vein Occlusion:** This condition and criteria for approval was added to the policy.	11/15/2023
Annual Revision	No criteria changes.	11/20/2024
Annual Revision	**Diabetic Macular Edema, Macular Edema Following Retinal Vein Occlusion, Neovascular (wet) Age-Related Macular Degeneration:** Dosing section is clarified that "every 4 weeks" is "approximately every 28 ± 7 days". **Other Uses with Supportive Evidence:** "Other Neovascular Diseases of the Eye" was added as a condition of approval. **Conditions Not Recommended for Approval:** "Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor" was added.	11/12/2025