Drug Coverage Policy

Effective Date 3/1/2026
Coverage Policy Number.....IP0542
Title.....Vabysmo

Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Vabysmo

- Vabysmo® (faricimab-svoa intravitreal injection – Genentech)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Vabysmo is considered medically necessary when ONE of the following is met:
FDA-Approved Indications

1. **Diabetic Macular Edema (DME).** Approve for 1 year if the patient meets BOTH of the following (A and B):
    A. Medication is administered by, or under the supervision of an ophthalmologist; AND
    B. Preferred product criteria is met for the product as listed in the below table.

    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

2. **Macular Edema Following Retinal Vein Occlusion.** Approve for 6 months if the patient meets BOTH of the following (A and B):
    A. Medication is administered by, or under the supervision of an ophthalmologist; AND
    B. Preferred product criteria is met for the product as listed in the below table.

    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

3. **Neovascular (Wet) Age-Related Macular Degeneration.** Approve for 1 year if the patient meets both of the following (A and B):
    A. Medication is administered by, or under the supervision of an ophthalmologist; AND
    B. Preferred product criteria is met for the product as listed in the below table.

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

Other Use with Supportive Evidence

4. **Other Neovascular Diseases of the Eye.** Approve for 1 year if the patient meets BOTH of the following (A and B):
    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.
    A. Medication is administered by, or under the supervision of an ophthalmologist; AND
    B. Preferred product criteria is met for the product as listed in the below table.

    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.

Employer Plans and Individual and Family Plans:

Product	Criteria
Vabysmo (faricimab-svoa intravitreal injection)	**ONE** of the following (A or B): A. Patient is currently receiving therapy with Vabysmo; OR B. Patient meets ONE of the following (i, ii, iii, or iv): i. Patient meets BOTH of the following [a and b]: a. Patient has previously tried repackaged bevacizumab; AND b. Either inadequate efficacy or intolerability was demonstrated; OR ii. According to the prescriber, patient has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters); OR iii. In the professional opinion of the prescriber, the safety of using repackaged bevacizumab is of significant concern; OR iv. In the professional opinion of the prescriber, the supplier of repackaged bevacizumab is of significant concern.

Conditions Not Covered

Vabysmo for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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).

Coding Information

Note:
1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J2777	Injection, faricimab-svoa, 0.1 mg

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.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Dosing:** **Updated** dosing **from** "6 mg administered by intravitreal injection not more frequent than once every 4 weeks for each eye being treated" **to** "The requested dose of faricimab (Vabysmo) meets the following: 1. 6 mg administered by intravitreal injection for each eye being treated; 2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated" for all indications. **Preferred Product Table:** **Added** criteria "Documentation of ONE of the following: 1. Currently receiving Vabysmo; 2. ONE of the following: a. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab; b. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern" for all indications for both employer plans and individual and family plans. **Added** new exclusion criterion: According to the prescriber, patient has diabetic macular edema and a baseline ETDRS BCVA of 20/50 or worse (< 69 ETDRS letters).	12/1/2024
Annual Revision	**No criteria changes**	2/15/2025
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. **Employer and Individual and Family Plan:**	3/1/2026

	Updated from "Documentation of **ONE** of the following: 1. Currently receiving Vabysmo 2. **ONE** of the following: a. According to the prescriber, patient has diabetic macular edema and a baseline Early Treatment Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) of 20/50 or worse (< 69 ETDRS letters) b. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab c. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern" **to** "Neovascular (Wet) Age-Related Macular Degeneration; Diabetic Macular edema; Other Neovascular Diseases of the Eye. 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. ONE of the following: 1. Patient has tried one of Eylea, Eylea HD or Pavblu; OR 2. Patient is currently receiving therapy with Vabysmo Macular Edema following Retinal Vein Occlusion. ONE of the following: 1. Patient has tried one of Eylea (not HD) or Pavblu; OR 2. Patient is currently receiving therapy with Vabysmo Note: If the patient had a trial of Eylea and cannot continue to use, an additional trial of Pavblu would not be required." **Conditions Not Recommended for Approval:** **"**Concomitant Use with Another Intravitreal Vascular Endothelial Growth Factor Inhibitor" was added.	

The policy effective date is in force until updated or retired.

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