| Policy Number | OTH903.044 |
|---|---|
| Policy Effective Date | 01/01/2026 |

# Faricimab-svoa

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## Disclaimer

*Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.*

### Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Legislative Mandates

**EXCEPTION: For HCSC members residing in the state of Ohio**, § 3923.60 requires any group or individual policy (Small, Mid-Market, Large Groups, Municipalities/Counties/Schools, State Employees, Fully-Insured, PPO, HMO, POS, EPO) that covers prescription drugs to provide for the coverage of any drug approved by the U. S. Food and Drug Administration (FDA) when it is prescribed for a use recognized as safe and effective for the treatment of a given indication in one or more of the standard medical reference compendia adopted by the United States Department of Health and Human Services or in medical literature even if the FDA has not approved the drug for that indication. Medical literature support is only satisfied when safety and efficacy has been confirmed in two articles from major peer-reviewed professional medical journals that present data supporting the proposed off-label use or uses as generally safe and effective. Examples of accepted journals include, but are not limited to, Journal of

American Medical Association (JAMA), New England Journal of Medicine (NEJM), and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. Coverage is never required where the FDA has recognized a use to be contraindicated and coverage is not required for non-formulary drugs.

## Coverage

Intravitreal injection of faricimab-svoa (Vabysmo®) **may be considered medically necessary** for the following conditions:

- Neovascular (wet) age-related macular degeneration; OR
- Diabetic macular edema; OR
- Macular edema following retinal vein occlusion.

Faricimab-svoa (Vabysmo®) **is considered experimental, investigational and/or unproven** for all other non-Food and Drug Administration approved indications.

## Policy Guidelines

Faricimab-svoa (Vabysmo®) is contraindicated in patients with ocular or periocular infections, as well as active intraocular inflammation.

## Description

Vascular endothelial growth factor (VEGF) is a protein in the body that stimulates the growth of new blood vessels needed for healing, such as when the body has sustained an injury. (2) In certain diseases in the eye, such as wet macular degeneration and macular edema, VEGF encourages the growth of abnormal blood vessels underneath the retina, as well as causing direct damage to existing blood vessels. These abnormal and/or damaged blood vessels are prone to breaking and leaking fluid and blood into the retina. The fluid that has leaked into the retina leads to swelling of the retinal cells, damage to the retina, and consequently, vision loss. Anti-VEGF medications stop VEGF production in order to reduce the threat of vision loss. Faricimab-svoa (Vabysmo®) is one of a number of anti-VEGF medications.

**Regulatory Status**

Faricimab-svoa (Vabysmo®) was approved by the U.S. Food and Drug Administration (FDA) in 2022 for the treatment of patients with neovascular (wet) age-related macular degeneration and diabetic macular edema. In 2023, the FDA approved Vabysmo for macular edema following retinal vein occlusion. (2)

## Rationale

This policy is based on the U.S. Food and Drug Administration (FDA) labeled indications for faricimab-svoa (Vabysmo®).

**Faricimab-svoa (Vabysmo®) (1)**

Neovascular (Wet) Age-Related Macular Degeneration (nAMD)

The safety and efficacy of Vabysmo were assessed in two randomized, multi-center, double-masked, active comparator-controlled, 2-year studies (TENAYA – NCT03823287 and LUCERNE – NCT03823300) in patients with nAMD.

A total of 1,329 newly diagnosed, treatment-naive patients were enrolled in these studies, and 664 patients received at least 1 dose of Vabysmo. Patient ages ranged from 50 to 99 with a mean of 75.9 years. The studies were identically designed two-year studies. Patients were randomized in a 1:1 ratio to one of two treatment arms: 1) aflibercept 2 mg administered fixed every 8 weeks (Q8W) after 3 initial monthly doses; and 2) Vabysmo 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to determine whether to give a 6 mg (0.05 mL of 120 mg/mL solution) dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; (also referred to as Q16W dosing); 2) Weeks 24, 36 and 48 (also referred to as Q12W dosing); or 3) Weeks 20, 28, 36 and 44 (also referred to as Q8W dosing). However, the utility of these criteria to guide dosing intervals has not been established.

At week 48, after 4 initial monthly doses in the Vabysmo arm, 45% of patients received the Weeks 28 and 44 dosing, 33% of patients received the Weeks 24, 36 and 48 dosing, and the remaining 22% of patients received dosing every 8 weeks. These percentages are reflective of what happened within the conduct of these trials and indicate that some patients did well on two doses spaced 16 weeks apart, or three doses spaced 12 weeks apart, but the percentages may not be generalizable to a broader nAMD population for a variety of reasons. The inclusion/exclusion criteria limited enrollment to a select subset of treatment naive, newly diagnosed nAMD patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison, which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the mean change from baseline in Best Corrected Visual Acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. The primary endpoint analysis was a noninferiority comparison for the mean change in BCVA between the aflibercept and the Vabysmo arm. The lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority. In both studies, Vabysmo treated patients had a non-inferior mean change from baseline in BCVA compared to patients

treated with aflibercept. Detailed results of both studies are shown in Table 1, Figure 1, and Figure 2 below. The clinical efficacy for the second year of the study has not been reviewed.

**Table 1. Primary Endpoint Results[a] in the TENAYA and LUCERNE Studies**

| | **TENAYA** | | **LUCERNE** | |
|---|---|---|---|---|
| | Vabysmo (N=334) | Aflibercept (N=337) | Vabysmo (N=331) | Aflibercept (N=327) |
| Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI) | 5.8 (4.6, 7.1) | 5.1 (3.9, 6.4) | 6.6 (5.3, 7.8) | 6.6 (5.3, 7.8) |
| Differences in LS mean (95% CI) | 0.7 (-1.1, 2.5) | | 0.0 (-1.7. 1.8) | |

[a] Average of weeks 40, 44 and 48.

BCVA: best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; CI: confidence interval; LS: least square.

**Figure 1. Mean Change in Visual Acuity from Baseline to Week 48 in TENAYA**

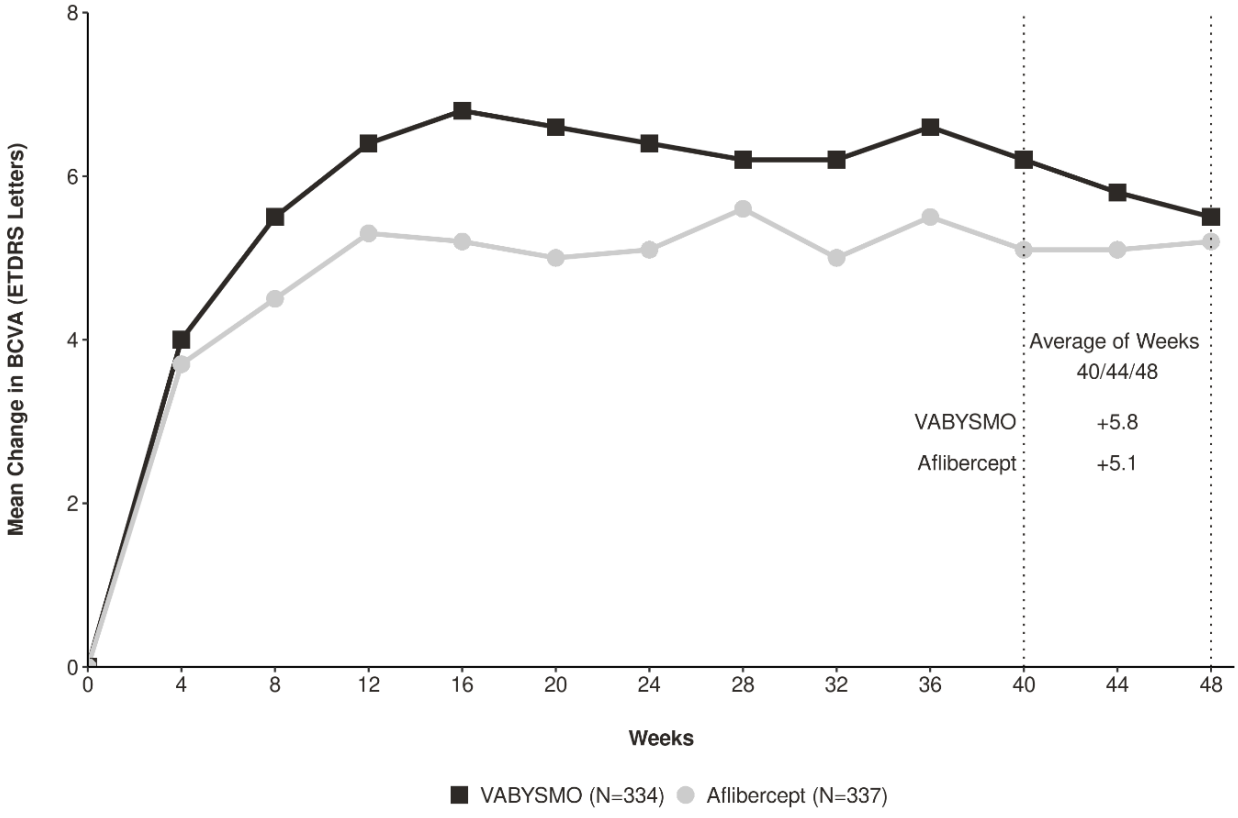
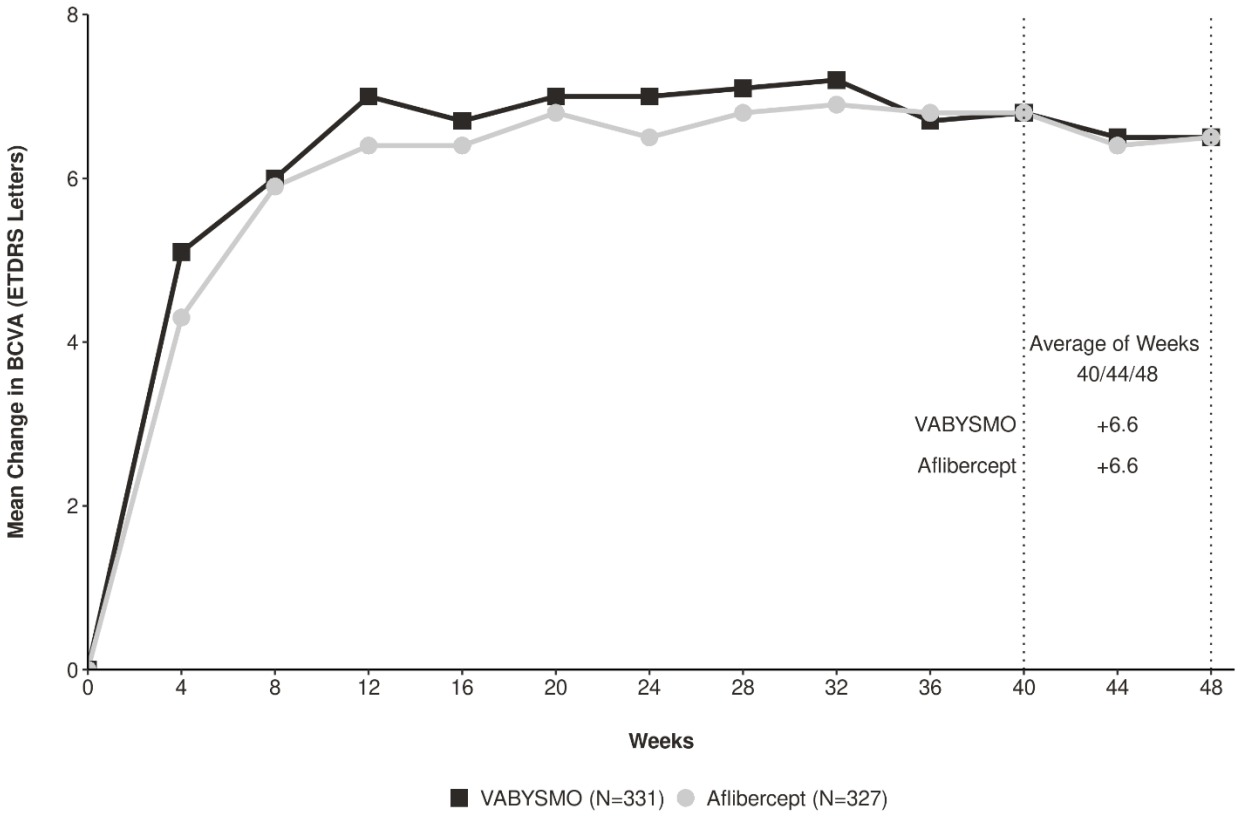



**Figure 2. Mean Change in Visual Acuity from Baseline to Week 48 in LUCERNE**




Treatment effects in evaluable subgroups (e.g., age, gender, race, baseline visual acuity) in each study were consistent with the results in the overall population.

Diabetic Macular Edema

The safety and efficacy of Vabysmo were assessed in 2 randomized, multi-center, double-masked, active comparator-controlled 2-year studies (YOSEMITE – NCT03622580 and RHINE – NCT03622593) in patients with DME.

A total of 1,891 diabetic patients were enrolled in the two studies with a total of 1,262 patients treated with at least 1 dose of Vabysmo. Patient ages ranged from 24 to 91 with a mean of 62.2 years. The overall population included both anti-VEGF naive patients (78%) and patients who had been previously treated with a VEGF inhibitor prior to study participation (22%).

The studies were identically designed 2-year studies. Patients were randomized in a 1:1:1 ratio to 1 of 3 treatment regimens: 1) aflibercept Q8W, patients received fixed aflibercept 2 mg administered every 8 weeks (Q8W) after the first 5 monthly doses; 2) Vabysmo Q8W, patients received fixed Vabysmo 6 mg administered Q8W after the first 6 monthly doses; and 3) Vabysmo Variable, patients received Vabysmo 6 mg administered every 4 weeks for at least 4 doses and until the central subfield thickness (CST) of the macula measured by optical coherence tomography was less than approximately 325 microns, then the interval of dosing was modified by up to 4-week interval extensions or reductions in up to 8 week interval increments based on CST and visual acuity disease activity criteria at study drug dosing visits.

After 4 initial monthly doses, the patients in the Vabysmo variable arm could have received between the minimum of three and the maximum of 11 total injections through Week 56 inclusive. At Week 56, 32% of patients had completed at least one Q12W interval followed by one full Q16W interval. Seventeen percent (17%) of patients were treated on Q8W and/or Q4W dosing intervals through Week 56 (7% only on Q4W). Sustainability of the Q16W dosing interval cannot be determined based on year 1 data alone. These percentages are reflective of what happened within the conduct of these trials, but the percentages are not generalizable to a broader DME population for a variety of reasons.

The inclusion/exclusion criteria limited enrollment to a select subset of DME patients and there is no empirical data that a similar magnitude would be observed if eligibility criteria allowed for broader enrollment. The disease activity criteria, which was instrumental in determining dose frequency, is unvalidated. Stricter criteria would have changed how patients were treated resulting in different percentages of subjects in each dose interval cohort. There was not a similarly dosed aflibercept arm for comparison which makes the percentages difficult to interpret.

Both studies demonstrated non-inferiority to the comparator control (aflibercept) at the primary endpoint, defined as the primary endpoint, defined as the mean change from baseline in BCVA at year 1 (average of the week 48, 52, and 56 visits), measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and Vabysmo groups. The lower bound of the 97.5% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare noninferiority. In both studies, Vabysmo Q8W and Vabysmo Variable treated patients had a mean change from baseline in BCVA that was non-inferior to the patients treated with aflibercept Q8W at the year 1 primary endpoint. Detailed results of both studies are shown in Tables 2 and 3, Figure 3, and Figure 4 below.

**Table 2. Efficacy Results at Year 1[a] in the YOSEMITE and RHINE Studies**

| | **YOSEMITE** | | | **RHINE** | | |
|---|---|---|---|---|---|---|
| | Vabysmo Q8W N=315 | Vabysmo Variable N=313 | Aflibercept Q8W N=312 | Vabysmo Q8W N=317 | Vabysmo Variable N=319 | Aflilbercept Q8W N=315 |
| Mean change in BCVA as measured by ETDRS letter score from baseline (97.5% CI year 1) | 10.7 (9.4, 12.0) | 11.6 (10.3, 12.9) | 10.9 (9.6, 12.2) | 11.8 (10.6, 13.0) | 10.8 (9.6, 11.9) | 10.3 (9.1, 11.4) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Differences in LS mean (97.5% CI year 1) | -0.2 (-2.0, 1.6) | 0.7 (-1.1, 2.5) | | 1.5 (-0.1, 3.2) | 0.5 (-1.1, 2.1) | |

[a] Average of weeks 48, 52, 56.

Q8W: every 8 weeks; BCVA: best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; CI: confidence interval; LS: least square.

**Table 3. Efficacy Results at Year 2[b] in the YOSEMITE and RHINE Studies**

| | **YOSEMITE** | | | **RHINE** | | |
|---|---|---|---|---|---|---|
| | Vabysmo Q8W N=262 | Vabysmo Variable N=270 | Aflibercept Q8W N=259 | Vabysmo Q8W N=259 | Vabysmo Variable N=282 | Aflilbercept Q8W N=254 |
| Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI year 2) | 10.7 (9.4, 12.1) | 10.7 (9.4, 12.1) | 11.4 (10.0, 12.7) | 10.9 (9.5, 12.3) | 10.1 (8.7, 11.5) | 9.4 (7.9, 10.8) |
| Differences in LS mean (95% CI year 2) | -0.7[c] | -0.7[c] | | 1.5[c] | 0.7[c] | |

[b] Average of Weeks 92, 96, 100

[c] A non-inferiority margin was not available for year 2

Q8W: every 8 weeks; BCVA: best corrected visual acuity; ETDRS: Early Treatment Diabetic Retinopathy Study; CI: confidence interval; LS: least square.

**Figure 3. Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in YOSEMITE**

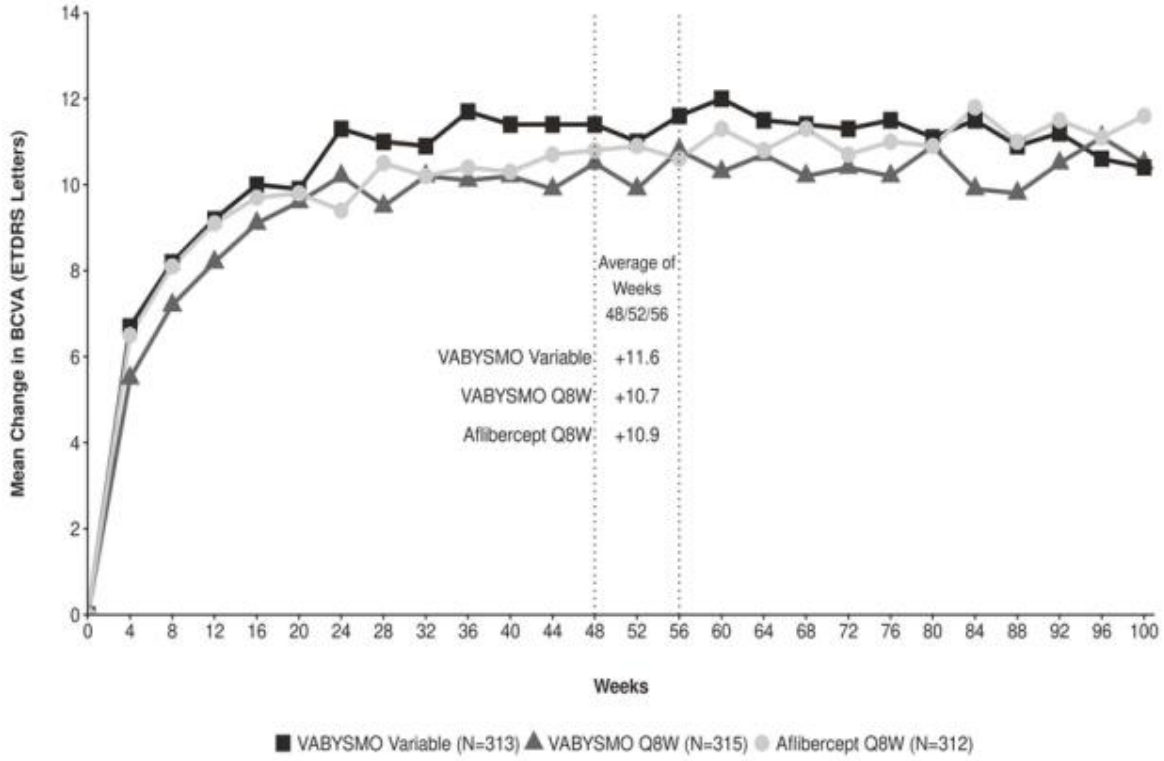
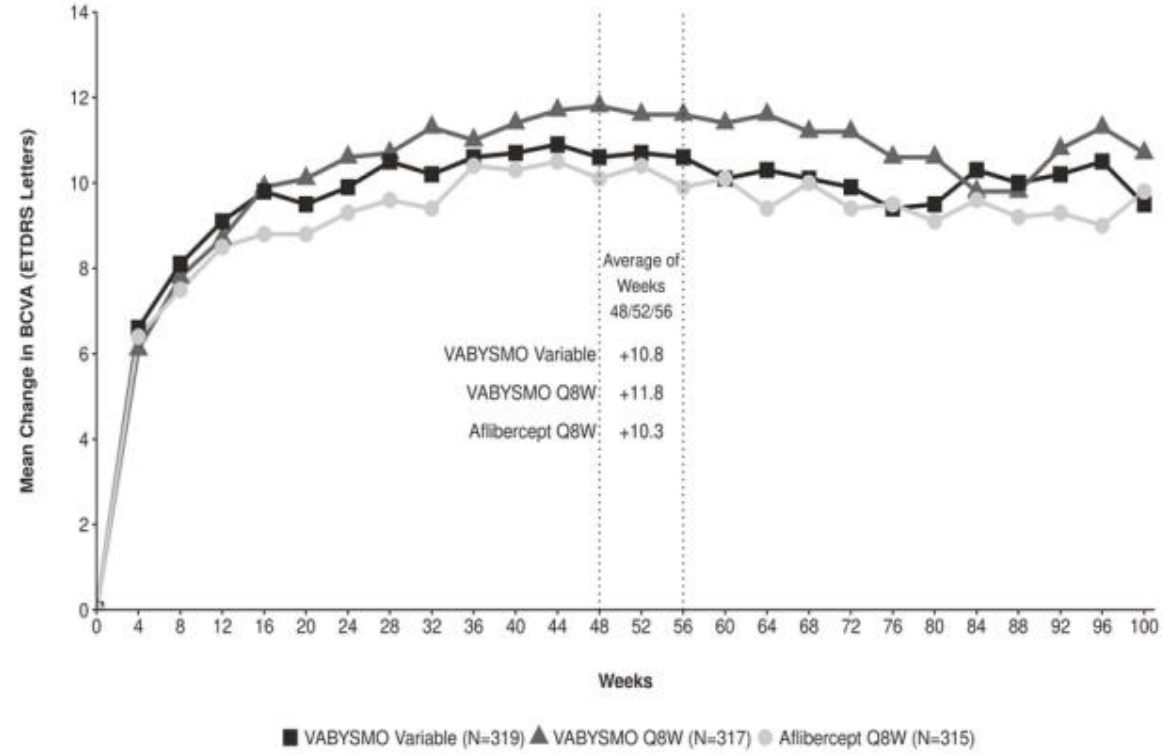



**Figure 4. Mean Change in Visual Acuity from Baseline to Year 2 (Week 100) in RHINE**



Treatment effects in the subgroup of patients who were anti-VEGF naive prior to study participation were similar to those observed in the overall population. Treatment effects in evaluable subgroups (e.g., by age, gender, race, baseline HbA1c, baseline visual acuity) in each study were generally consistent with the results in the overall population.

Macular Edema Following Retinal Vein Occlusion (RVO)

The safety and efficacy of Vabysmo were assessed in two randomized, multicenter, double-masked, studies (BALATON – NCT04740905 in patients with macular edema following branch retinal vein occlusion, and COMINO – NCT04740931 in patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion). Active comparator-controlled data are available through month 6.

A total of 1,282 newly diagnosed, treatment-naive patients were enrolled in these studies, of which 641 patients received at least one dose of Vabysmo through 6 months. Patient ages ranged from 28 to 93 with a mean of 64 years, and 22 to 100 with a mean of 65 years in BALATON and COMINO, respectively.

In both studies, patients were randomized in a 1:1 ratio to either 6 mg Vabysmo administered every 4 weeks (Q4W), or the control arm receiving aflibercept 2 mg injections every 4 weeks for a total of 6 injections.

In both studies, the Vabysmo 6 mg Q4W arm demonstrated non-inferiority to the comparator control (aflibercept) arm for the primary endpoint, which was defined as the change from baseline in BCVA at week 24, measured by the ETDRS Letter Score. The primary endpoint analysis was a non-inferiority comparison for the mean change in BCVA between the aflibercept and Vabysmo arms, where the lower bound of the 95% confidence interval for the mean change in BCVA could not be lower than minus 4 letters to declare non-inferiority.

Detailed results for both BALATON and COMINO studies are shown in Table 4, Figure 5, and Figure 6 below.

**Table 4. Primary Endpoint Results at Week 24 in the BALATON and COMINO Studies**

| | **BALATON** | | **COMINO** | |
|---|---|---|---|---|
| | Vabysmo N=276 | Aflibercept N=277 | Vabysmo N=366 | Aflibercept N=363 |
| Mean change in BCVA as measured by ETDRS letter score from baseline (95% CI) | 16.9 (15.7, 18.1) | 17.5 (16.3, 18.6) | 16.9 (15.4, 18.3) | 17.3 (15.9, 18.8) |
| Difference in LS mean (95% CI) | -0.6 (-2.2, 1.1) | | -0.4 (-2.5, 1.6) | |

BCVA: best corrected visual acuity; CI: confidence interval; ETDRS: Early Treatment Diabetic Retinopathy Study; LS: least square.

**Figure 5. Mean Change in Visual Acuity from Baseline to Week 24 in BALATON**

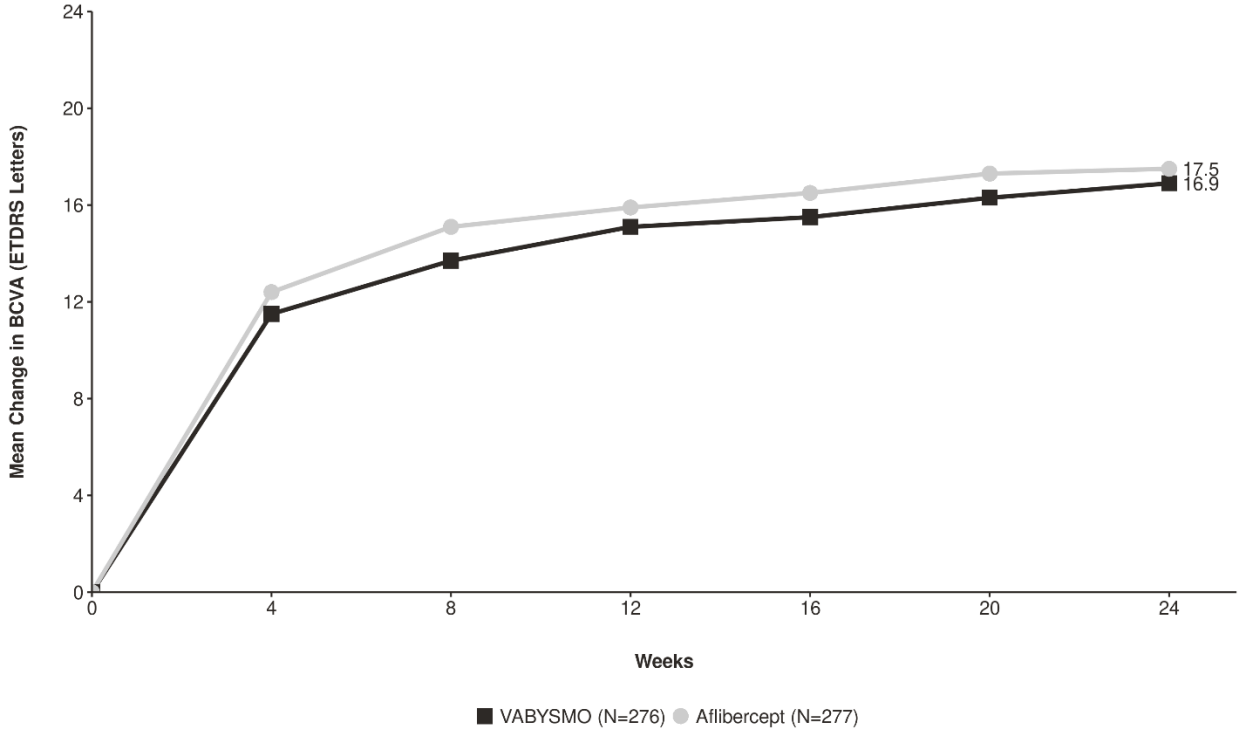
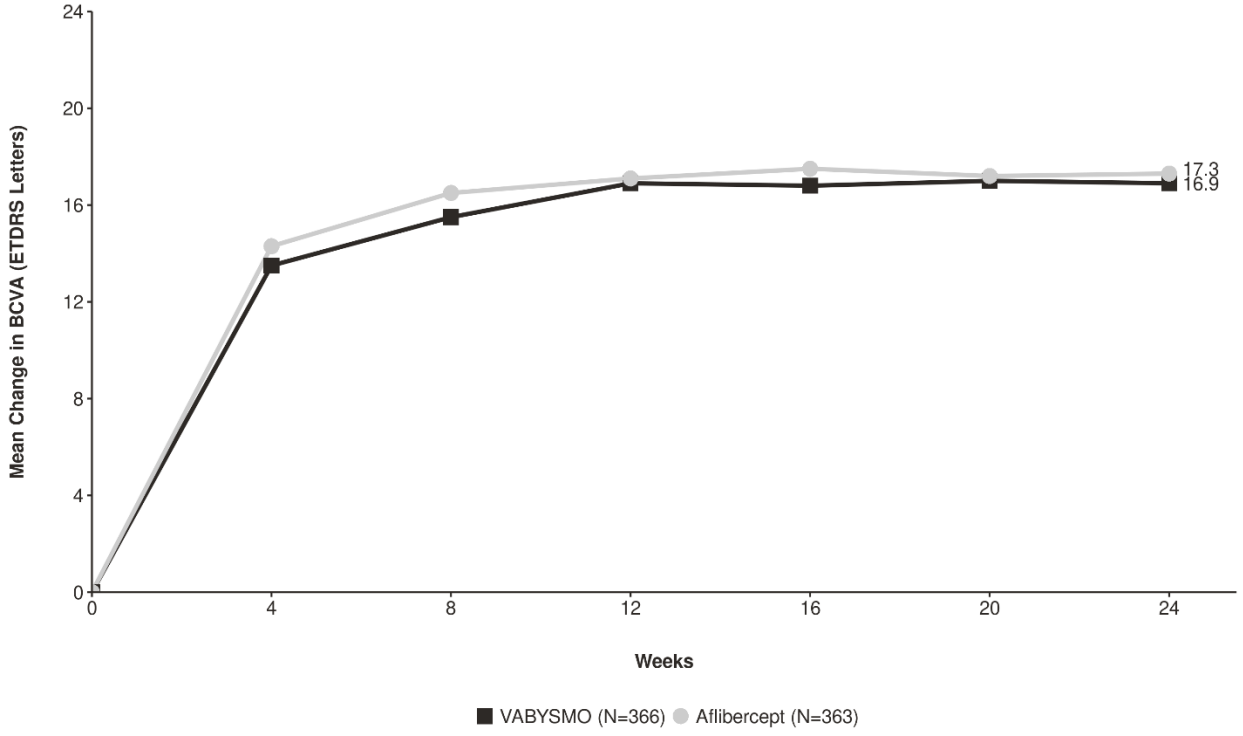



**Figure 6. Mean Change in Visual Acuity from Baseline to Week 24 in COMINO**




## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

| | |
|---|---|
| **CPT Codes** | 67028 |
| **HCPCS Codes** | J2777 |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

## References


**U.S. Food and Drug Administration Label**

1. FDA. Highlights of Prescribing Information Vabysmo® (faricimab-svoa). Revised 7/2024. Available at: <https://www.accessdata.fda.gov> (accessed on December 11, 2025).

**Other**

2. Lazarus R. How Do Anti-VEGF Injections Work? Available at <https://www.optometrists.org> (accessed December 11, 2025).
3. Vabysmo FDA Approval History. Available at <https://www.drugs.com> (accessed December 11, 2025).


## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

## Policy History/Revision

| Date | Description of Change |
|---|---|
| 01/01/2026 | Document updated. The following change was made to Coverage: Removed both Avastin step-therapy and continuation therapy language. Added reference 2 and 3; reference 1 updated. |

| | |
|---|---|
| 02/01/2025 | Document updated. The following change was made to Coverage: Added language regarding drug shortages/recalls to “Initial Therapy” criteria. No new references added. |
| 05/15/2024 | Document updated. The following change was made to Continuation Therapy in Coverage for faricimab-svoa (Vabysmo®): removed “through a previously authorized pharmacy or medical benefit” in the statement “Continuation of faricimab-svoa (Vabysmo®) therapy may be considered medically necessary for all members (including new members…” Now reads: Continuation of faricimab-svoa (Vabysmo®) therapy may be considered medically necessary for all Members (including new members): who are currently receiving the requested medication, AND who are experiencing benefit from therapy as evidenced by disease stability or disease improvement, AND when dosing is in accordance with an authoritative source.” No new references added. |
| 03/15/2024 | Document updated with literature review. The following change was made to Coverage: Added macular edema following retinal vein occlusion to the medical necessity statement. References revised. No new references added. |
| 10/01/2023 | Document updated. The following change was made to Coverage: Added preferred criteria for bevacizumab (Avastin™). No new references added. |
| 05/01/2023 | Document updated with literature review. Coverage unchanged. No new references added. |
| 07/01/2022 | New medical document. Faricimab-svoa (Vabysmo™) may be considered medically necessary for the treatment of patients with neovascular (wet) age-related macular degeneration or diabetic macular edema. Faricimab-svoa (Vabysmo™) is experimental, investigational and/or unproven for all other indications. |