

Policy Number	OTH903.044
Policy Effective Date	02/01/2025
Policy End Date	12/31/2025

Faricimab-svoa

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. 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 acceptable standards of medical practice. 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

Continuation Therapy

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.

Initial Therapy

Intravitreal injection of faricimab-svoa (Vabysmo®) **may be considered medically necessary** contingent on the following coverage criteria:

- Individual has tried and failed, or has a clinical reason to avoid, or there is a documented drug shortage or recalls from a wholesaler, manufacturer, the ASHP (American Hospital of Health-System Pharmacist) Drug Shortage web page or the US Food and Drug Administration of intravitreal injection(s) of bevacizumab (Avastin™) as an anti-VEGF (vascular endothelial growth factor) therapy for the following conditions:
 - Neovascular (wet) age-related macular degeneration (nAMD); OR
 - Diabetic macular edema (DME); OR
 - Macular edema following retinal vein occlusion (RVO).

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

Policy Guidelines

None.

Description

Angiogenesis inhibitors such as faricimab-svoa (Vabysmo®) are being evaluated for the treatment of retinal circulation. They can be given via intraocular injections as a treatment for disorders of choroidal and retinal circulation. Ophthalmic disorders affecting the choroidal circulation include age-related macular degeneration (AMD or ARMD), central serous chorioretinopathy (CSC), pathologic myopia, presumed ocular histoplasmosis syndrome, angioid streaks, idiopathic choroidal neovascularization (CNV), uveitis, choroidal rupture, or

trauma, and chorioretinal scars. Ophthalmic disorders affecting the retinal circulation include proliferative diabetic macular edema (DME), diabetic retinopathy (DR), central (CRVO) or branch retinal vein occlusion (BRVO), and retinopathy of prematurity (ROP).

Vascular endothelial growth factor (VEGF) has been implicated in the pathogenesis of a variety of ocular vascular conditions characterized by neovascularization and macular edema. The macula, with the fovea at its center, has the highest photoreceptor concentration and is where visual detail is discerned. Anti-VEGF agents are used to treat CNV associated with ARMD and are being evaluated for the treatment of disorders of retinal circulation (e.g., DME, macular edema following retinal vein occlusion, ROP).

For the treatment of ocular disorders, these agents are given by intravitreal injection every 1 to 2 months. The distinct pharmacologic properties of available VEGF inhibitors suggest that safety and efficacy data from one agent cannot be extrapolated to another. These agents may vary by penetration, potency, half-life, localization to the retina, and initiation of the immune system.

Faricimab-svoa is a humanized bispecific immunoglobulin G1 (IgG1) antibody that binds both vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2). By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization, and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with neovascular (wet) age-related macular degeneration (nAMD) and DME. The contribution of Ang-2 inhibition to the treatment effect and clinical response for nAMD and DME has yet to be established.

Diabetic Macular Edema and Diabetic Retinopathy

Diabetic retinopathy is a common microvascular complication of diabetes and a leading cause of blindness in adults. The 2 most serious complications for vision in patients with diabetes are DME and DR. At its earliest stage, microaneurysms occur. With disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses, blood vessels that provide nourishment to the retina are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or non-proliferative stages of the disease. Although proliferative disease is the main blinding complication of DR, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Tight glycemic and blood pressure control is the first line of treatment to control DME and DR, followed by laser photocoagulation for patients whose retinopathy is approaching the high-risk stage. Although laser photocoagulation is effective at slowing the progression of retinopathy and reducing vision loss, it results in collateral damage to the retina and does not restore lost vision. Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser photocoagulation, while diffuse

macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit VEGF production but are associated with serious adverse effects including cataracts and glaucoma with damage to the optic nerve. Corticosteroids can also worsen diabetes control. VEGF inhibitors such as ranibizumab, reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), and are being evaluated for the treatment of DME and proliferative DR. For DME, outcomes of interest include macular thickness and visual acuity. For proliferative and non-proliferative DR, outcomes of interest are operative and perioperative outcomes and visual acuity.

Age-Related Macular Degeneration

Neovascular AMD is characterized by CNV, which is the growth of abnormal choroidal blood vessels beneath the macula, which causes severe loss of vision and is responsible for most of the loss of vision caused by AMD. In its earliest stages, AMD is characterized by minimal visual impairment and the presence of large drusen and other pigmentary abnormalities on ophthalmoscopic examination. As AMD progresses, 2 distinctively different forms of degeneration may be observed. The first, called the atrophic or areolar or dry form, evolves slowly. Atrophic AMD is the most common form of degeneration and is often a precursor of the second form, the more devastating exudative neovascular form, also referred to as disciform or wet degeneration. The wet form is distinguished from the atrophic form by serous or hemorrhagic detachment of the retinal pigment epithelium and the development of CNV, sometimes called neovascular membranes. Risk of developing severe irreversible loss of vision is greatly increased by the presence of CNV. The pattern of CNV, as revealed by fluorescein or indocyanine angiography, is further categorized as classic or occult. For example, classic CNV appears as an initial lacy pattern of hyperfluorescence followed by more irregular patterns as the dye leaks into the subretinal space. Occult CNV lacks the characteristic angiographic pattern, either due to the opacity of coexisting subretinal hemorrhage or, especially in CNV associated with AMD, by a tendency for epithelial cells to proliferate and partially or completely surround the new vessels. Interestingly, lesions consisting only of classic CNV carry a worse visual prognosis than those made up of only occult CNV, suggesting that the proliferative response that obscures new vessels may also favorably alter the clinical course of AMD.

Intravitreal triamcinolone acetonide is one of the first pharmacologic compounds evaluated for the treatment of CNV secondary to AMD. The most important effects of this treatment consist of the stabilization of the blood-retinal barrier and the down-regulation of inflammation. Triamcinolone acetonide also has antiangiogenic and anti-fibrotic properties and remains active for months after intravitreal injection. However, cataracts are a common adverse effect, and steroid-related pressure elevation occurs in approximately one third of patients, with some requiring filtration surgery.

Macular Edema Following Retinal Vein Occlusion

Retinal vein occlusions (RVO) are classified by whether the central retinal vein or one of its branches is obstructed. Central retinal vein occlusion and branch retinal vein occlusion differ in pathophysiology, clinical course, and therapy. Central retinal vein occlusions are categorized as

ischemic or nonischemic. Ischemic central retinal vein occlusions are referred to as severe, complete, or total vein obstruction, and account for 20% to 25% of all central retinal vein occlusions. Macular edema and permanent macular dysfunction occur in virtually all patients with ischemic central retinal vein occlusion, and in many patients with nonischemic central retinal vein occlusion. Branch retinal vein occlusion is a common retinal vascular disorder in adults between 60 and 70 years of age and occurs approximately 3 times more often than central retinal vein occlusion.

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. (1)

Rationale

This medical policy was developed in June 2022 and is based on the clinical studies provided to the U. S. Food and Drug Administration for approval of the drug. The most current review was conducted through February 22, 2024.

Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (1)

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-naïve 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

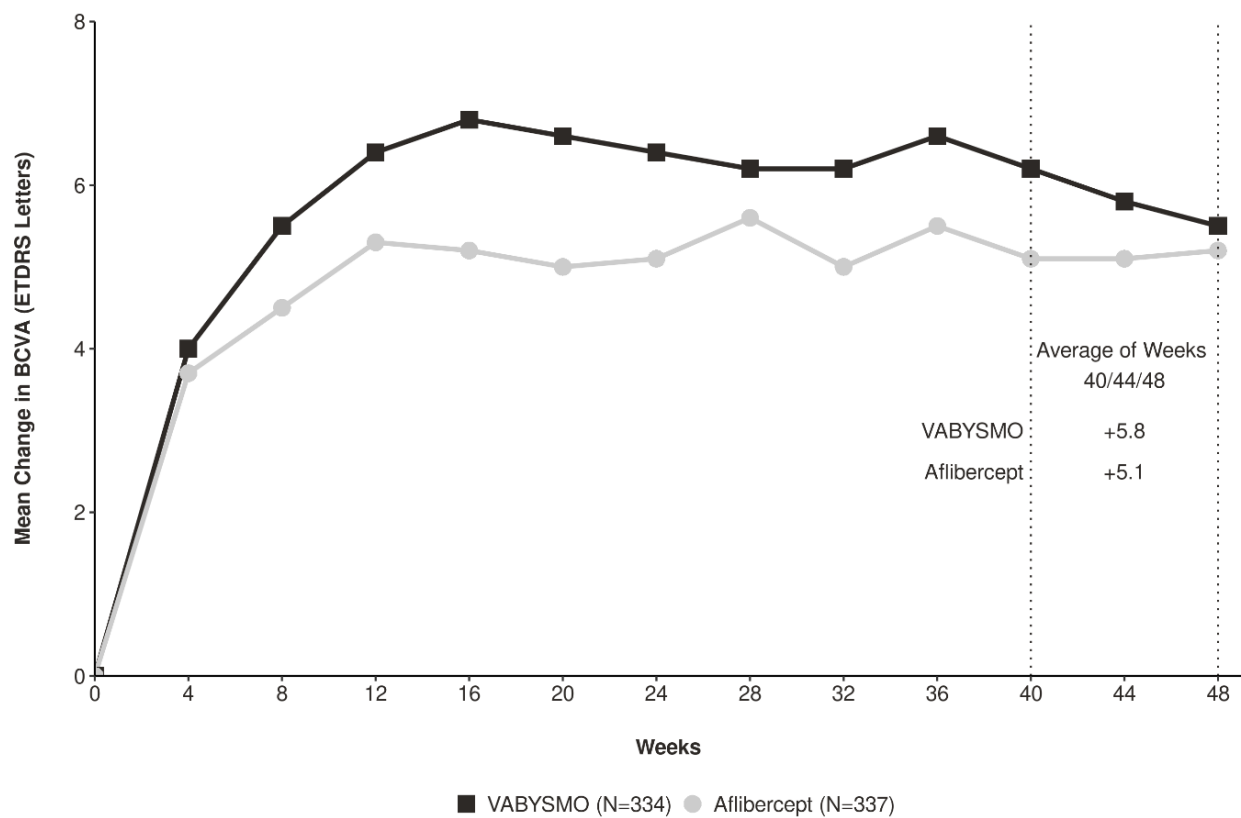
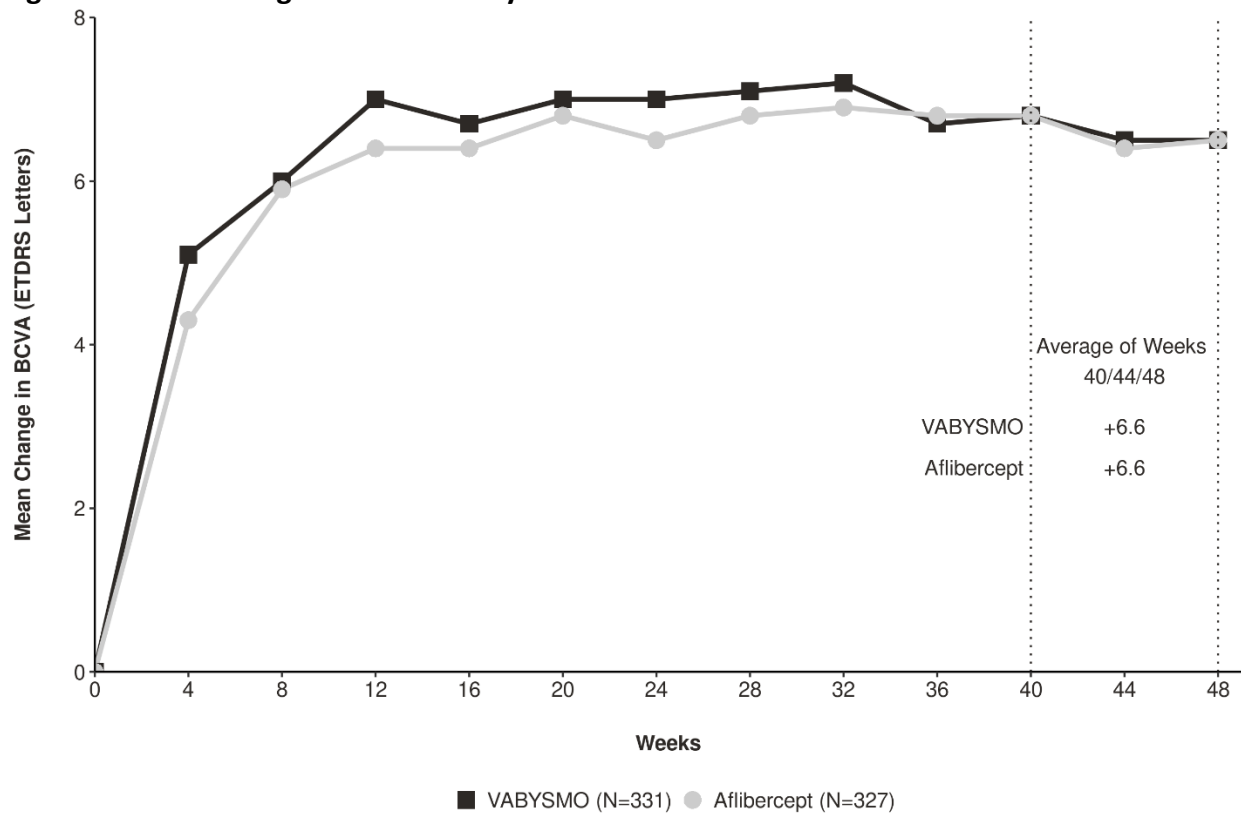


Figure 2. Mean Change in Visual Acuity from Baseline to Week 48 in LUCERNE



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 (1)

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. However, the utility of these disease activity criteria to guide dosing intervals has not been established.

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. Detailed results of both studies are shown in Table 2, Figure 3, and Figure 4 below. The clinical efficacy for the second year of the study has not been reviewed.

Table 2. Primary Endpoint Results^a in the YOSEMITE and RHINO Studies

	YOSEMITE			RHINO		
	Vabysmo Q8W N=315	Vabysmo Variable N=313	Aflibercept Q8W N=312	Vabysmo Q8W N=317	Vabysmo Variable N=319	Aflibercept Q8W N=315
Mean change in BCVA as measured by ETDRS letter score from baseline (97.5% CI)	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)	-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.

Figure 3. Mean Change in Visual Acuity from Baseline to Year 1 (Week 56) in YOSEMITE

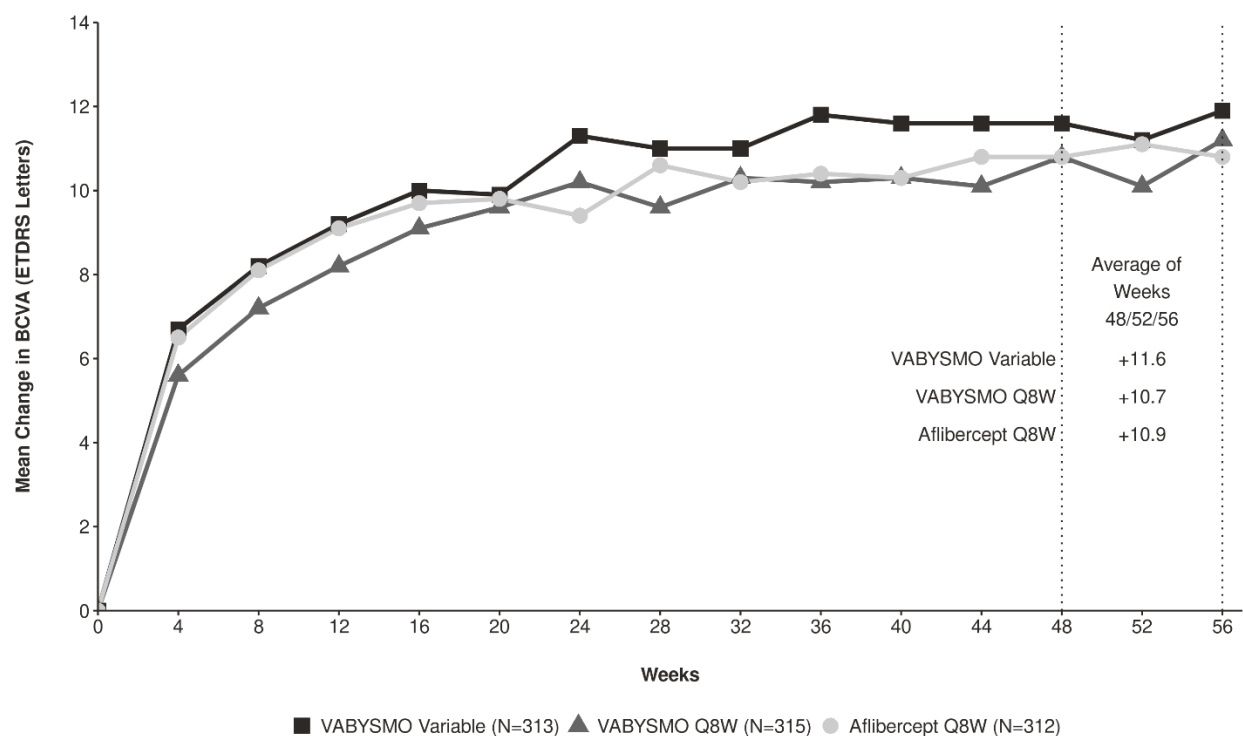
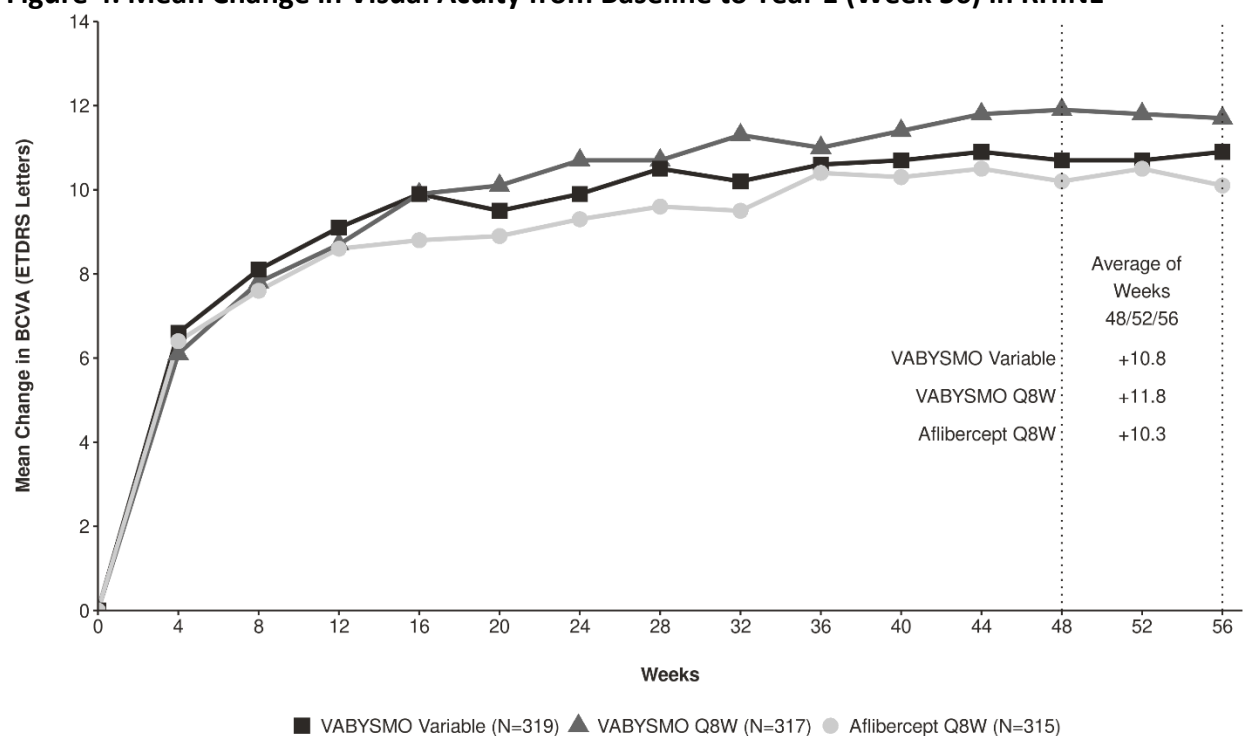


Figure 4. Mean Change in Visual Acuity from Baseline to Year 1 (Week 56) in RHINE



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) (1)

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-naïve 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 3, Figure 5, and Figure 6 below.

Table 3. 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

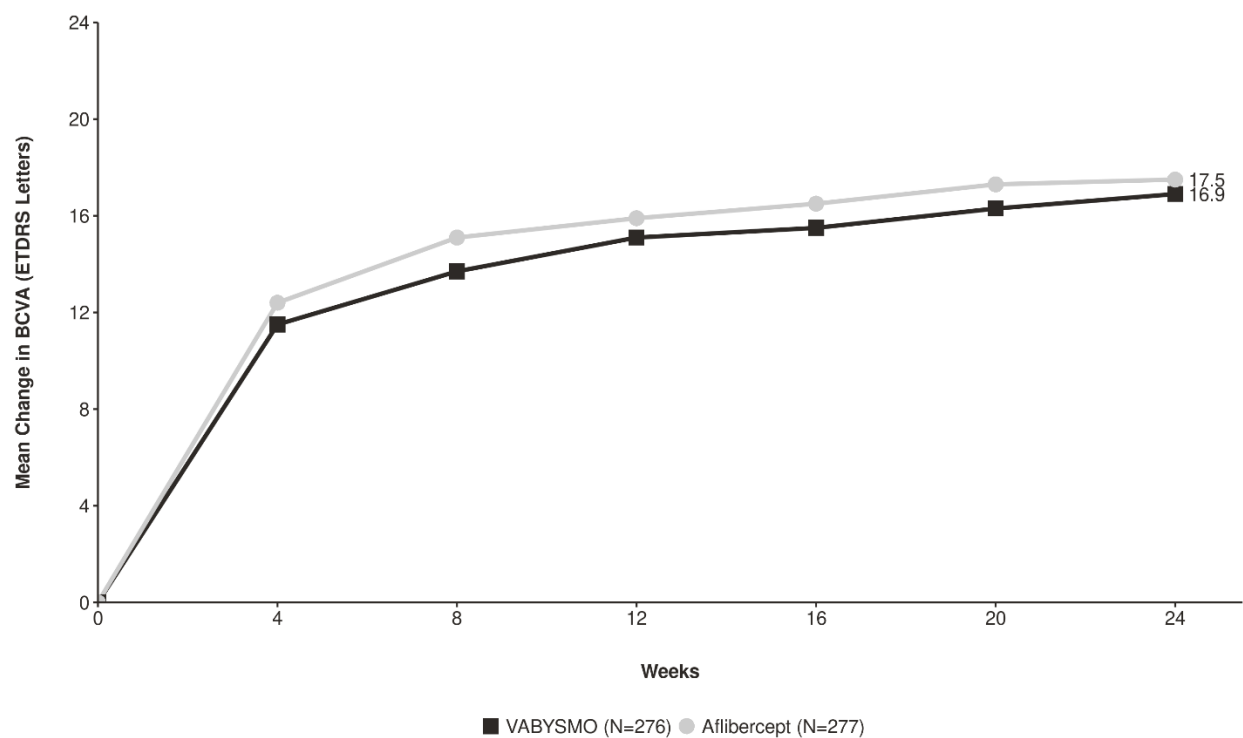
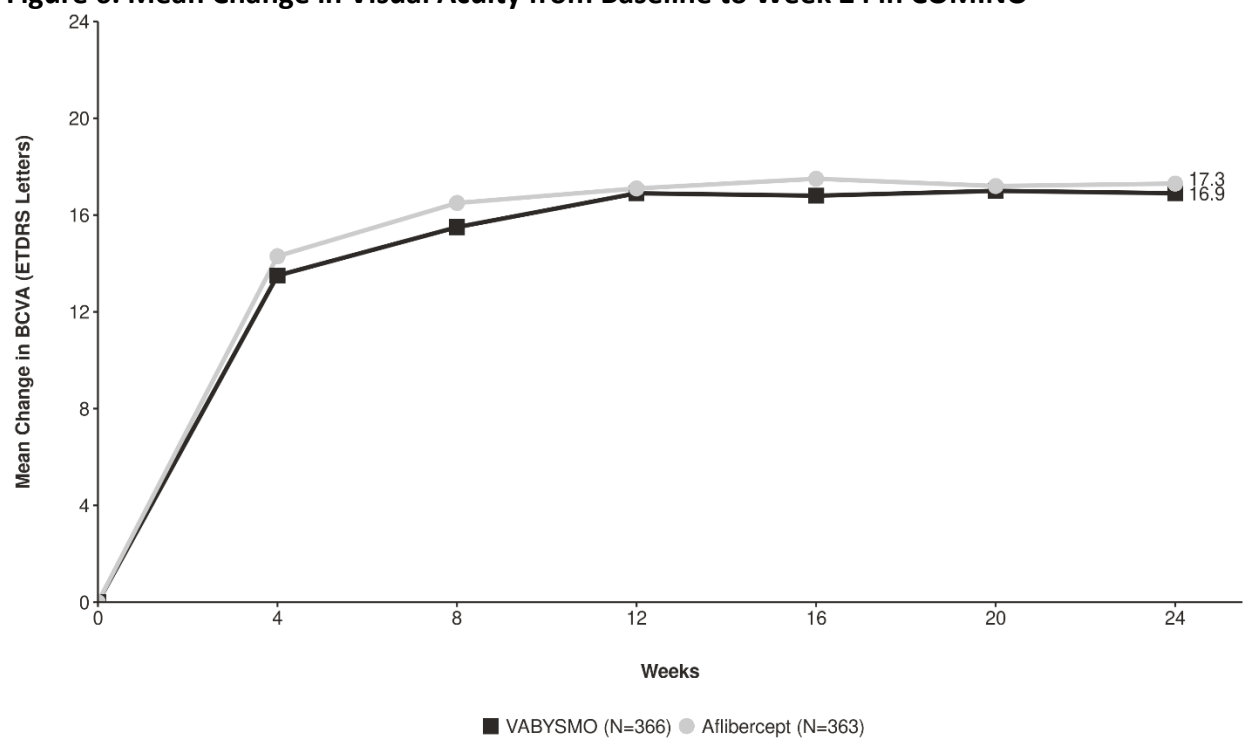


Figure 6. Mean Change in Visual Acuity from Baseline to Week 24 in COMINO



Summary of Evidence

Based on the clinical studies provided to the U.S. Food and Drug Administration for approval, faricimab-svoa (Vabysmo™) may be medically necessary for the treatment of patients with neovascular (wet) age-related macular degeneration (nARMD), diabetic macular edema (DME), or macular edema following retinal vein occlusion (RVO). All other indications are considered experimental, investigational and/or unproven due to lack of clinical evidence.

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, [Deleted 10/2022:C9097]

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

References

1. U.S. Food and Drug Administration. Highlights of Prescribing Information. Vabysmo® (faricimab-svoa). October 2023. Available at: <<https://www.accessdata.fda.gov>> (accessed February 22, 2024).

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
------	-----------------------

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.