Original Effective Date: 04/27/2022
Current Effective Date: 12/01/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C22795-A

Vabysmo (faricimab-svoa)

PRODUCTS AFFECTED

Vabysmo (faricimab-svoa)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Neovascular (Wet) Age-Related Macular Degeneration (NAMD), Diabetic Macular Edema (DME), Macular Edema Following Retinal Vein Occlusion (RVO)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ALL INDICATIONS:
   1. Documented diagnosis of ANY of the following: Neovascular (Wet) age-related macular degeneration, Diabetic macular edema, or Macular Edema following Retinal Vein Occlusion (RVO)

AND

2. Documentation of baseline visual status with notation of eye(s) being treated [DOCUMENTATION REQUIRED]
   AND
3. Documentation of an inadequate response (defined as 1-2 injections with minimal to no improvement), serious side effects, or contraindication to bevacizumab OR bevacizumab is indicated by the provider as unavailable and there is documentation of an inadequate response, serious side effects or contraindication to ranibizumab
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Vabysmo (faricimab-svoa) include: Ocular or periocular infection, active intraocular inflammation, hypersensitivity]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (EXCEPT RVO):
   1. Reauthorization request is for the same eye(s) as initial authorization
      NOTE: The continuation of therapy criteria is only for the same previously treated eye(s). If member has developed condition in an untreated eye, Prescriber must submit new request with Initial Coverage criteria.
      AND
   2. Documentation of improvement or stabilization of disease state and visual status [DOCUMENTATION REQUIRED]
      AND
   3. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan
      AND
   4. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (i.e., endophthalmitis and retinal detachments; increase in intraocular pressure or arterial thromboembolic events)

DURATION OF APPROVAL:

RVO: Initial authorization: 6 months, Continuation of Therapy: N/A
ALL OTHER INDICATIONS: Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified ophthalmologist, ophthalmic surgeon or retinal specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

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

6mg by intravitreal injection every 4 weeks (approximately every 28 +/- 7 days) x 4 doses.
This is followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens:
1) Weeks 28 and 44;
2) Weeks 24, 36 and 48;
or
3) Weeks 20, 28, 36 and 44.

Although additional efficacy was not demonstrated in most patients when faricimab was administered every 4

weeks compared to every 8 weeks, some patients may still require every 4-week dosing after receipt of the initial doses. Patients should be assessed regularly.

Maximum quantity allowable: 6mg every 4 weeks

Diabetic Macular Edema (DME)
6mg by intravitreal injection every 4 weeks (approximately every 28 +/- 7 days) x 4 doses

If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then:
1) interval of dosing may be modified by extensions of up to 4-week interval increments or reductions of up to 8- week interval increments based on CST and visual acuity evaluations;
or
2) 6 mg dose of VABYSMO can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months).

Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4-week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

Maximum quantity allowable: 6mg every 4 weeks

Macular Edema Following Retinal Vein Occlusion (RVO)

6mg by intravitreal injection every 4 weeks (approximately every 28 +/- 7 days) for 6 months

Maximum quantity allowable: 6mg every 4 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intravitreal injectable products be administered in a place of service that is a non- hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravitreal injection

DRUG CLASS:
Ophthalmic - Multiple Receptor Angiogenesis Inhibitors

FDA-APPROVED USES:
Indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)
- Macular Edema Following Retinal Vein Occlusion (RVO)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Age-related macular degeneration (AMD) is a degenerative disease of the central portion of the retina (the macula) that results primarily in loss of central vision. Central vision is required for activities such as driving, reading, watching television, and performing activities of daily living.

AMD is classified as dry (atrophic) or wet (neovascular or exudative) for clinical purposes. Different classifications and grading schemes have been used in epidemiologic and therapeutic studies of AMD. Many epidemiologic studies make a distinction between age-related maculopathy (ARM) and AMD. All wet lesions and dry lesions that reduce visual acuity are considered AMD, but early dry lesions that do not reduce vision may be classified as ARM rather than AMD. A further source of confusion is that AMD is often abbreviated as ARMD.

The finding of either large soft drusen or RPE pigmentary clumping increases the risk of developing wet AMD. Wet AMD is characterized by growth of abnormal vessels into the subretinal space, usually from the choroidal circulation and less frequently from the retinal circulation. These abnormal blood vessels leak, leading to collections of subretinal fluid and/or blood beneath the retina. The abnormal blood vessels emanating from the choroid are also referred to as choroidal neovascularization.

Diabetic Macular Edema (DME)
Diabetic macular edema is a potential complication of diabetic retinopathy and is defined as a retinal thickening (≥250 µm) within 1 disk diameter of the center of the macula or the presence of definite hard exudates in this region. Through the deterioration of the blood-retinal barrier in the eye, capillary leakage results in diffuse edema within the central area of the retina. Since the risk of visual loss is greatest if macular edema is at the center of the macula, DME is subdivided as either center-involved (CI-DME) or non-center-involved (NCI-DME). Treatment choice depends partially on the location of the macula affected. As the prevalence of diabetes mellitus increases, so does the prevalence of diabetic eye disorders. The exact prevalence of DME is unknown; however, the overall weighted prevalence of DME in the United States is thought to be about 3.8%, or about 746,000 individuals 40 years of age and older. According to some studies, nearly 1 in 3 people with diabetes have at least some evidence of macular edema.

Macular Edema Following Retinal Vein Occlusion (RVO)
The safety and efficacy of Vabysmo were assessed in two randomized, multicenter, double-masked, studies. BALATON (NCT04740905) included patients with macular edema following branch retinal vein occlusion, and COMINO (NCT04740931) included patients with macular edema following central retinal vein occlusion/hemiretinal vein occlusion. Active comparator-controlled data are available through month 6 of treatment. 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, 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. The primary endpoint was 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.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Vabysmo (faricimab-svoa) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Vabysmo (faricimab-svoa) include: Ocular or periocular infection, active intraocular inflammation, hypersensitivity.

Exclusions/Discontinuation:
Do not use Vabysmo (faricimab-svoa) with other ophthalmic VEGF inhibitors (i.e., aflibercept, bevacizumab, brolucizumab, ranibizumab, etc.).

OTHER SPECIAL CONSIDERATIONS:
Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
The recommended dose for Vabysmo is 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 inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

Diabetic Macular Edema (DME)
VABYSMO is recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; or 2) 6 mg dose of Vabysmo can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks.
Although additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J2777	Injection, faricimab-svoa, 0.1 mg

AVAILABLE DOSAGE FORMS:
Vabysmo SOLN 6MG/0.05ML single-dose vial
Vabysmo SOSY 6MG/0.05ML single-dose prefilled syringe

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2025
REVISION- Notable revisions: Required Medical Information	Q1 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Quantity Available Dosage Forms References	Q4 2024

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity Background References	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Coding/Billing Information Available Dosage Forms References	Q4 2023
NEW CRITERIA DEVELOPED	Q2 2022