



Effective Date: 04/27/2022
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
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)

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

A. FOR ALL INDICATIONS:

1. Documented diagnosis of ANY of the following: Neovascular (Wet) age-related macular degeneration OR Diabetic macular edema
AND
2. Documentation that member is free of ocular and/or peri-ocular infections
AND
3. Documentation of trial/failure or contraindication to bevacizumab
AND

Drug and Biologic Coverage Criteria

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]
AND
5. Vabysmo (faricimab-svoa) is being prescribed as monotherapy: Member is not on additional anti-VEGF medications

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Documentation of improvement or stabilization of disease state and visual status that has been submitted
AND
2. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan
NOTE: Therapy may be discontinued due to poor adherence upon recommendation of the Molina Medical Director when adherence < 85% has been demonstrated in at least two months during the course of therapy
AND
3. Documentation of absence of unacceptable toxicity from the drug (i.e. endophthalmitis and retinal detachments; increase in intraocular pressure or arterial thromboembolic events)
AND
4. Vabysmo (faricimab-svoa) is being prescribed as monotherapy: Member is not on additional anti- VEGF medications

DURATION OF APPROVAL:

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 within 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

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Drug and Biologic Coverage Criteria

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 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

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)

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

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.

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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 ($\geq 250 \mu\text{m}$) 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.

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

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 ± 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

Drug and Biologic Coverage Criteria

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

HCPCS CODE	DESCRIPTION
J3590	Unclassified biologics

AVAILABLE DOSAGE FORMS:

Vabysmo SOLN 6MG/0.05ML Injection: 120 mg/mL solution in a single-dose vial

REFERENCES

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5. Lushchik T, Amarakoon S, Martinez-Ciriano JP, et al: Bevacizumab in age-related macular degeneration: a randomized controlled trial on the effect of injections every 4 weeks, 6 weeks and 8 weeks. *Acta Ophthalmol* 2013; 91(6):e456-e461.
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9. Bressler NM. Age-related macular degeneration is the leading cause of blindness.. *JAMA*. 2004 Apr 21;291(15):1900-1. doi: 10.1001/jama.291.15.1900. PMID: 15108691.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA DEVELOPED	Q2 2022