

## Clinical Policy: Faricimab-svoa (Vabysmo)

Reference Number: LA.PHAR.581

Effective Date: 10.25.23

Last Review Date: ~~05.06.24~~02.23.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**\*\*Please note: This policy is for medical benefit\*\***

### Description

Faricimab-svoa (Vabysmo™<sup>®</sup>) is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor.

### FDA Approved Indication(s)

Vabysmo is 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)

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of Louisiana Healthcare Connections<sup>®</sup> that Vabysmo is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Ophthalmic Disease (must meet all):

1. Diagnosis of one of the following (a, b, or c):
  - a. nAMD;
  - b. DME;
  - c. Macular edema following RVO;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age  $\geq$  18 years;
4. Failure of bevacizumab intravitreal solution, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for bevacizumab intravitreal solution. Requests for IV formulations of Avastin, Mvasi, and Zirabev will not be approved*
5. Dose does not exceed (a, b, or c):
  - a. nAMD: 6 mg (1 vial/syringe) every 4 weeks for the first 4 doses;
  - b. DME: one of the following (i or ii):
    - i. Fixed dosing regimen: 6 mg (1 vial/syringe) every 4 weeks for the first 6 doses, then 6 mg ~~every 8~~every 8 weeks thereafter;

## CLINICAL POLICY

### Faricimab-svoa

- ii. Variable dosing regimen: 6 mg (1 vial/syringe) every 4 weeks for at least 4 doses and until a central subfield thickness (CST) of  $< 325 \mu\text{M}$  is achieved, then one of the following (1 or 2):
  - 1) 6 mg (1 vial/syringe) every 8 to 16 weeks;
  - 2) 6 mg (1 vial/syringe) every 4 weeks, and one of the following (a or b):
    - a) Member has had an inadequate response to every 8-week dosing, defined as one of the following (i or ii):
      - i) CST has increased between  $> 10\%$  and  $\leq 20\%$  with an associated  $\geq 5$ - to  $< 10$ -letter best-corrected visual acuity (BCVA) decrease from the reference values (*see Appendix D*);
      - ii) CST has increased by  $> 20\%$  without an associated  $\geq 10$ -letter BCVA decrease from the reference values (*see Appendix D*);
    - b) Member has had an inadequate response to every 12-week dosing, defined as  $> 10\%$  increase in CST and  $\geq 10$ -letter BCVA decrease from the reference value (*see Appendix D*);
- c. RVO: 6 mg (1 vial/syringe) every 4 weeks for 6 months.

#### Approval duration:

**nAMD** – 4 months (first 4 doses)

**DME** – 6 months (up to 6 doses)

**RVO** – 6 months (up to 6 doses)

#### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

## II. Continued Therapy

#### A. Macular Edema Following Retinal Vein Occlusion (~~must meet all~~):

1. Re-authorization is not permitted.

**Approval duration: Not applicable**

#### B. All Other Indications (must meet all):

~~1. 1.~~ Currently receiving medication via Louisiana Healthcare Connections benefit or —  
———member has previously met initial approval criteria;

- ~~1.~~
2. ~~2.~~ Member is responding positively to therapy as evidenced by one of the following (a, ~~—————~~b, c, or d):
  - a. Detained neovascularization;
  - b. Improvement in visual acuity;
  - c. Maintenance of corrected visual acuity from prior treatment;

## CLINICAL POLICY

### Faricimab-svoa

- d. Supportive findings from optical coherence tomography or fluorescein angiography;
3. ~~3.~~ If request is for a dose increase, new dose does not exceed (a or b):
  - a. nAMD: one of the following (i, ii, or iii):
    - i. 6 mg (1 vial/syringe) every 16 weeks;
    - ii. 6 mg (1 vial/syringe) every 12 weeks if member has documented active disease (*see Appendix D*) at week 24;
    - iii. 6 mg (1 vial/syringe) every 8 weeks if member has documented active disease (*see Appendix D*) at week 20;
  - b. DME: one of the following (i or ii):
    - i. Fixed dosing regimen: 6 mg (1 vial/syringe) every 8 weeks;
    - ii. Variable dosing regimen: 6 mg (1 vial/syringe) every 4 weeks until a CST of < 325  $\mu$ M is achieved, then one of the following (1 or 2):
      - 1) 6 mg (1 vial/syringe) every 8 to 16 weeks;
      - 2) 6 mg (1 vial/syringe) every 4 weeks, and one of the following (a or b):
        - a) Member has had an inadequate response to every 8-week dosing, defined as one of the following (i or ii):
          - i) CST has increased between > 10% and  $\leq$  20% with an associated  $\geq$  5- to < 10-letter BCVA decrease from the reference values (*see Appendix D*);
          - ii) CST has increased by > 20% without an associated  $\geq$  10-letter BCVA decrease from the reference values (*see Appendix D*);
        - b) Member has had an inadequate response to every 12-week dosing, defined as > 10% increase in CST and  $\geq$  10-letter BCVA decrease from the reference value (*see Appendix D*).

**Approval duration: 6 months**

#### **B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

### **III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – LA.PMN.53 for Medicaid or evidence of coverage documents.

### **IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

Ang-2: angiopoietin-2

BCVA: best-corrected visual acuity

## CLINICAL POLICY

### Faricimab-svoa

CST: central subfield thickness  
 DME: diabetic macular edema  
 FDA: Food and Drug Administration  
 nAMD: neovascular age-related macular degeneration

OCT: optical coherence tomography  
RVO: retinal vein occlusion  
 VEGF: vascular endothelial growth factor

#### Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bevacizumab (Avastin®)	<b>nAMD:</b> 1.25 to 2.5 mg administered by intravitreal injection every 4 weeks.	2.5 mg/month
	<b>DME:</b> 1.25 mg administered by intravitreal injection every 6 weeks	1.25 mg/6 weeks
	<b>Macular edema secondary to RVO:</b> 1 mg to 2.5 mg administered by intravitreal injection every 4 weeks	2.5 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

#### Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): ocular or periocular infection, active intraocular inflammation, hypersensitivity
- Boxed warning(s): none reported

#### Appendix D: General Information

- For the indication of nAMD, active disease is defined as any of the following:
  - Optical coherence tomography (OCT) (a or b):
    - a. Increase in CST > 50 μM compared to average CST over previous 2 visits;
    - b. Increase in CST ≥ 75 μM compared with lowest CST recorded at either of previous 2 visit;
  - Visual acuity (a or b):
    - a. Decrease of ≥ 5 letters of BCVA compared with average BCVA over previous 2 visits, due to nAMD;
    - b. Decrease of ≥ 10 letters of BCVA compared with highest BCVA recorded over previous 2 visits, due to nAMD;
  - Presence of new macular hemorrhage.
- For the indication of nAMD, clinical criteria for every 4-week dosing following the initial every 4-week dosing was not defined nor evaluated in the clinical studies.

## CLINICAL POLICY

### Faricimab-svoa

- Reference CST is defined as the CST value when the initial CST threshold (< 325 μM) is met. Reference CST is adjusted if CST decreases by > 10% from the previous reference CST for two consecutive drug dosing visits and the values obtained are within 30 μM. The CST value obtained at the latter visit will serve as the new reference CST starting immediately at that visit.
- Reference BCVA is defined as the mean of the three best BCVA scores obtained at any time prior to study drug dosing visit.
- For the indication of DME, CST and BCVA should be examined at each dosing interval to determine subsequent dosing frequency for variable dosing regimens.
- For the indication of macular edema following RVO, treatment greater than 6 months was not evaluated in the clinical studies.

### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
nAMD	<p>6 mg (1 vial/<u>syringe</u>) administered by intravitreal injection every 4 weeks for the first 4 doses, followed by OCT and visual acuity evaluation 8 and 12 weeks later to inform whether to give 6 mg dose on one of the following regimens outlined below:</p> <ol style="list-style-type: none"> <li>1) Weeks 28 and 44</li> <li>2) Weeks 24, 36 and 48 or</li> <li>3) Weeks 20, 28, 36, and 44</li> </ol> <p><i>Although Vabysmo may be dosed as frequently as every 4 weeks, additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to 8 weeks. Some patients may need every 4-week dosing after the first 4 doses.</i></p>	6 mg every 4 weeks*
DME	<p>Administered using one of the following dosing regimens:</p> <ol style="list-style-type: none"> <li>1) 6 mg (1 vial/<u>syringe</u>) administered by intravitreal injection every 4 weeks for 4 doses. If after the first 4 doses, resolution of edema based on CST of the macula as measured by OCT is achieved, then the interval dosing may be modified by extension of up to 4-week increments or reduction of up to 8-week increments based on CST and visual acuity evaluation through Week 52</li> <li>2) 6 mg (1 vial/<u>syringe</u>) administer by intravitreal injection every 4 weeks for the first 6 doses, followed by 6 mg every 8 weeks over the next 28 weeks.</li> </ol>	6 mg every 4 weeks

## CLINICAL POLICY

### Faricimab-svoa

Indication	Dosing Regimen	Maximum Dose
	<i>Although Vabysmo may be dosed as frequently as every 4 weeks, additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to 8 weeks. Some patients may need every 4-week dosing after the first 4 doses.</i>	
RVO	6 mg (1 vial/ <u>syringe</u> ) administered by intravitreal injection every 4 weeks for 6 months	6 mg every 4 weeks

*\*This dosing regimen has not been evaluated in clinical studies beyond the initial doses.*

### VI. Product Availability

- ~~Solution in single~~Single-dose vial: 6 mg/0.05 mL (120 mg/mL)
- Single-dose prefilled syringe: 6 mg/0.05 mL (120 mg/mL)

### VII. References

1. Vabysmo Prescribing Information. South San Francisco, CA: Genentech, Inc.; ~~October 2023~~July 2024. Available at: [www.vabysmo.com](http://www.vabysmo.com). Accessed ~~October 31, 2023~~July 17, 2024.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; October 2019. Available at [www.aao.org/ppp](http://www.aao.org/ppp). Accessed January ~~25, 2023~~31, 2024.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; September 2019. Available at: [www.aao.org/ppp](http://www.aao.org/ppp). Accessed ~~December 8, 2023~~January 31, 2024.
4. ~~Faricimab Drug Monograph. Clinical Pharmacology. Available at <http://www.clinicalkeys.com/pharmacology>. Accessed October 31, 2023.~~
5. Heier J, Khanani A, Quezada RC, et al. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. *Lancet* 2022; 399(10326):729-740. doi: [https://doi.org/10.1016/S0140-6736\(22\)00010-1](https://doi.org/10.1016/S0140-6736(22)00010-1)
6. ~~Heier J, Basu K, Ives J, et al. Faricimab in neovascular age-related macular degeneration TENAYA and LUCERNE study results. Presented at the Angiogenesis in February 12-13, 2021. Oral presentation. Available at: <https://medically.gene.com/global/en/unrestricted/ophthalmology/ANGIOGENESIS-2021/angiogenesis-2021-presentation-heier-phase-3-namd-tenay.html>. Accessed January 25, 2023.~~
5. Hattenbach LO, Abreu F, Arrisi P, et al. BALATON and COMINO: Phase III randomized clinical trials of faricimab for retinal vein occlusion: study design and rationale. *Ophthalmol Sci*. 2023 Mar 27;3(3):100302. doi: [10.1016/j.xops.2023.100302](https://doi.org/10.1016/j.xops.2023.100302).

### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

## CLINICAL POLICY

### Faricimab-svoa

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created.	05.01.23	09.25.23
Annual Review - Added newly FDA-approved indication of macular edema following retinal vein occlusion; references reviewed and updated.	05.06.24	<u>07.29.24</u>
<u>Annual review; added newly approved prefilled syringe formulation; in Appendix D, added RVO clinical trial duration details; references reviewed and updated.</u>	<u>02.23.25</u>	

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.



## CLINICAL POLICY

### Faricimab-svoa

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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