Clinical Policy: Faricimab-svoa (Vabysmo)

Reference Number: CP.PHAR.581
Effective Date: 06.01.22
Last Review Date: 10.23
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Faricimab-svoa (Vabysmo®) 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 health plans affiliated with Centene Corporation® 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 ≥ 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) 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) every 4 weeks for the first 6 doses, then 6 mg every 8 weeks thereafter;
      ii. Variable dosing regimen: 6 mg (1 vial) every 4 weeks for at least 4 doses and until a central subfield thickness (CST) of < 325 µM is achieved, then one of the following (1 or 2):

1) 6 mg (1 vial) every 8 to 16 weeks;
2) 6 mg (1 vial) 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 ≤ 20% with an associated ≥ 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 ≥ 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 ≥ 10-letter BCVA decrease from the reference value (*see Appendix D)*;

c. RVO: 6 mg (1 vial) 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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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. Currently meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*

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;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;
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) every 16 weeks;
      ii. 6 mg (1 vial) every 12 weeks if member has documented active disease (*see Appendix D*) at week 24;
      iii. 6 mg (1 vial) 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) every 8 weeks;
      ii. Variable dosing regimen: 6 mg (1 vial) every 4 weeks until a CST of < 325 µM is achieved, then one of the following (1 or 2):
         1) 6 mg (1 vial) every 8 to 16 weeks;
         2) 6 mg (1 vial) 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 ≤ 20% with an associated ≥ 5- to < 10-letter BCVA decrease from the reference values (*see Appendix D)*;
               ii) CST has increased by > 20% without an associated ≥ 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 ≥ 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 one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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
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 not be a formulary agent for all relevant lines of business and may require prior authorization.

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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
nAMD	6 mg (1 vial) 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: 1) Weeks 28 and 44 2) Weeks 24, 36 and 48 or 3) Weeks 20, 28, 36, and 44 *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.*	6 mg every 4 weeks*
DME	Administered using one of the following dosing regimens: 1) 6 mg (1 vial) 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	6 mg every 4 weeks

Indication	Dosing Regimen	Maximum Dose
	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 2) 6 mg (1 vial) administer by intravitreal injection every 4 weeks for the first 6 doses, followed by 6 mg every 8 weeks over the next 28 weeks. *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.*	
RVO	6 mg (1 vial) 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-dose vial: 6 mg/0.05 mL (120 mg/mL)

VII. References

1. Vabysmo Prescribing Information. South San Francisco, CA: Genentech, Inc.; October 2023. Available at: www.vabysmo.com. Accessed October 31, 2023.
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. Accessed January 25, 2023.
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. Accessed December 8, 2023.
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
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.

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-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	P&T Approval Date
Policy created.	03.03.22	05.22
Added HCPCS code [C9097].	06.30.22	
Added HCPCS code [J2777]. Template changes applied to other diagnoses/indications and continued therapy section.	09.29.22	
2Q 2023 annual review: no significant changes, removed inactive HCPCS codes J3590 and C9097; references reviewed and updated.	01.25.23	05.23
RT4: added newly FDA-approved indication of macular edema following retinal vein occlusion.	10.31.23	

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.