Clinical Policy: Faricimab-svoa (Vabysmo)

Reference Number: ERX.SPA.473
Effective Date: 06.01.22
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

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)

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 or b):
   a. nAMD;
   b. DME;
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 or b):
   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)*.

Approval duration:
nAMD – 4 months (first 4 doses)
DME – 6 months (up to 6 doses)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

B. Ophthalmic Disease (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

Ang-2: angiopoietin-2
BCVA: best-correct 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
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bevacizumab (Avastatin®)	**nAMD** 1.25 to 2.5 mg administered by intravitreal injection every 4 weeks	2.5 mg/month
	DME 1.25 mg administrated by intravitreal injection every 4 weeks	1.25 mg/6 weeks

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 meeting 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 wills 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 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.*	6 mg every 4 weeks

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

VI. Product Availability

Single-dose vial: 6 mg/0.05 mL solution (120 mg/mL)

VII. References

1. Vabysmo Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2022. Available at: www.vabysmo.com. Accessed February 17, 2022.
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 February 18, 2022.
3. Faricimab Drug Monograph. Clinical Pharmacology. Available at http://www.clinicalpharmacology-ip.com/. Accessed February 18, 2022
4. 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.
5. 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 February 18, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.03.22	05.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.