Policy Title:	Vabysmo (faricimab-svoa)		
		Department:	PHA
Effective Date:	06/01/2022		
Review Date:	05/12/2022, 6/16/2022, 7/27/2023, 12/07/2023, 01/10/2024, 02/26/2025, 01/27/2026		

Purpose: To support safe, effective and appropriate use of Vabysmo (faricimab-svoa) in patients with neovascular (wet) age related macular degeneration (nAMD),diabetic macular edema (DME), and macular edema following retinal vein occlusion (RVO).

Scope: Medicaid, Commercial, Medicare

Policy Statement:

Vabysmo (faricimab-svoa) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Vabysmo (faricimab-svoa) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Vabysmo (faricimab) is an intravitreal vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with neovascular age-related macular degeneration (nAMD),diabetic macular edema (DME), and macular edema following retinal vein occlusion (RVO). Vabysmo was studied in four phase 3 randomized clinical trials, 2 for nAMD and 2 for DME, and demonstrated non-inferiority compared against Eylea (aflibercept) in regard to average change in best-corrected visual acuity (BCVA) score at 1 year. For macular edema following RVO, the safety and efficacy of Vabysmo was evaluated in two randomized, multicenter, double-masked studies. Patients received either Vabysmo 6 mg every 4 weeks or aflibercept 2 mg every 4 weeks for 6 injections. At week 24, Vabysmo demonstrated non-inferiority to aflibercept for the primary endpoint of mean change in BCVA from baseline. Results showed comparable visual gains between treatment arms, confirming Vabysmo's efficacy in this population.

Initial Criteria:

- Member is at least 18 years of age or older; AND
- Prescribed by or in consultation with Retina Specialist; AND

- Must have a diagnosis of one of the following:
    - Neovascular (wet) age related macular degeneration (AMD)
    - Diabetic macular edema (DME)
    - Macular edema due to retinal vein occlusion (RVO); AND
- Member's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; AND
- The member meets one of the following:
    - For neovascular AMD, or RVO the member must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab and Byooviz (ranibizumab) or Lucentis (ranibizumab); OR
    - For members with DME and baseline visual acuity of 20/50 or worse, they must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab or Lucentis(ranibizumab) ; OR
    - For members with DME and baseline visual acuity better than 20/50, the patient must have an inadequate treatment response, intolerance or contraindication to treatment with bevacizumab; AND
- Member is free of ocular and periocular infections; AND
- Member does not have active intraocular inflammation; AND
- Therapy will not be used concurrently with other ophthalmic VEGF inhibitors (e.g., aflibercept, bevacizumab, brolucizumab, ranibizumab) in the absence of documentation indicating that individual products are to be used in different eyes; AND
- Members requesting therapy with Vabysmo for RVO, cannot exceed 6 months of treatment
- For members that are currently on treatment with Vabysmo (faricimab-svoa), they can remain on treatment OR Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; AND

  * Additional efficacy was not demonstrated in most patients when Vabysmo was dosed every 4 weeks compared to every 8 weeks during the maintenance phase. Some patients may need every 4 week (approximately monthly) dosing after the first four doses (16 weeks or 4 months) of the initiation phase.

Continuation of Therapy Criteria:

- Member continues to meet all initial criteria; AND
- Member is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments, increase in intraocular pressure, and arterial thromboembolic events; AND
- Member has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition; AND
- Members requesting therapy with Vabysmo for RVO, cannot be renewed

Coverage Durations:

- AMD & DME
  - Initial coverage: 6 months
  - Continuation of therapy coverage: 12 months

- RVO
  - Initial coverage: 6 months
  - Continuation of therapy coverage: cannot be renewed

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Vabysmo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Vabysmo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Quantity Limit/ Maximum Dose (1 billable unit = 0.1 mg)
nAMD	Initiation: • 6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days ±7 days, monthly) for the first four doses (16 weeks or 4 months) Maintenance: • Follow the initial four doses with optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to ascertain whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: – Weeks 28 and 44 (every 16 weeks); or – Weeks 24, 36 and 48 (every 12 weeks); or – Weeks 20, 28, 36 and 44 (every 8 weeks) Note: 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 (approximately monthly) dosing after the first four doses (16 weeks or 4 months).	12mg or 120 units* every 28 days
DME	• 6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days ±7 days, monthly) for at least four 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 • 6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days ±7 days, monthly) for the first six doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks. Note: 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 four doses.	12mg or 120 units* every 28 days

RVO	6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 ± 7 days, monthly) for 6 months	12mg or 120 units* every 28 days

*based on administration to both eyes

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2777	Injection, faricimab-svoa, 0.1mg

References:

1. Vabysmo [package insert]. South San Francisco, CA; Genentech, Inc.; December 2025. Accessed January 2026.
2. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Diabetic Retinopathy PPP – Update 2017. Nov 2017.
3. American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2017. Nov 2017.
4. Heier JS, Khanani AM, Quezada et al; TENAYA and LUCERNE Investigators. 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 Jan 21. pii: S0140-6736(22)00010-1. doi: 10.1016/S0140-6736(22)00010-1.
5. Wykoff CC, Abreu F, Adamis AP, et al; YOSEMITE and RHINE Investigators. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. Lancet. 2022 Jan 21. pii: S0140-6736(22)00018-6. doi: 10.1016/S0140-6736(22)00018-6.