PART B DRUG MEDICAL/PHARMACY	ASPIRE HEALTH	Effective Date January 1, 2024	
	VABYSMO (FARICIMAB-SVOA)	**Policy #** Vabysmo (faricimab-svoa)	
		Review Date 09/27/2023	**Applicable to:** ☑ Medicare Advantage ☐ Commercial ☐ Elevance Health HMO ☐ Blue Shield Trio
	Approver's Name & Title QI & UM Drug Subcommittee		

Aspire Health Plan applies medical drug clinical criteria as a reference for medical policy information only. Federal and state laws or requirements, contract language, and Plan benefit may take precedence over the application of these clinical criteria. Please consult the applicable certificate or contract for benefit details. This policy is subject to revision at the discretion of the Plan and is therefore subject to change. Refer to the disclaimer section below for more information.

POLICY

This policy addresses the coverage of Vabysmo (faricimab-svoa) for ophthalmic use.

APPLICABLE HCPCS

J2777: Injection, faricimab-svoa, 0.1 mg; 1 billable unit = 0.1 mg *(Effective 10/01/2022)*

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

CLINICAL CRITERIA

A. INITIAL CRITERIA

Vabysmo (faricimab-svoa) may be authorized when **ALL** of the following are met and submitted with clinical documentation:

1. Clinical diagnosis of **ONE** of the following:
    a. Diabetic macular edema
    b. Neovascular (wet, or exudative) age-related macular degeneration.

AND

2. No active intraocular inflammation; **AND**
3. No concurrent ocular or periocular infection; **AND**

4. Vabysmo (faricimab-svoa) is being prescribed as monotherapy: Member is not on additional ophthalmic vascular endothelial growth factor (VEGF) inhibitors (i.e., aflibercept, ranibizumab, pegaptanib, bevacizumab).

B. REAUTHORIZATION / CONTINUATION OF THERAPY CRITERIA

Vabysmo (faricimab-svoa) may be authorized for continuation of thereapy when **ALL** of the following are met:

1. Member continues to meet the initial therapy criteria (as stated above); **AND**

2. Absence of adverse events from intravitreal injections of Vabysmo (faricimab-svoa) (e.g., endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events); **AND**

3. Positive response to therapy (e.g., improvement or maintenance in best corrected visual acuity or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss) and continued administration is necessary for the maintenance treatment of the condition; **AND**

4. Documentation of administration records showing dates and eye(s) administered, along with documentation of member compliance with treatment plan.

STEP THERAPY

Step therapy criteria do not apply for members who are currently being treated with the requested medications. Step therapy is only applied for members that are new to therapy (have not received the requested drug in the last 365 days.

A. **PREFERRED PRODUCT(S): AVASTIN (no step therapy required)**

B. Vabysmo (faricimab-svoa) may be authorized when all of the clinical criteria above are met **AND** the member meets the following criteria for a non-preferred intravitreal VEGF antagonist:

   1. Inadequate response to a trial of the *preferred agent, bevacizumab (Avastin); **or**

   2. History of contraindication or adverse event(s) to Avastin (bevacizumab); **or**

   3. Member has been on the requested agent within the past 365 days.

DOSAGE AND AUTHORIZATION TIMEFRAMES

Indication	Initial and Maintenance Dosing	Maximum Dosing
Age-related macular degeneration, neovascular (wet)	Initial: 6 mg every month (approximately every 28 +/- 7 days) for 4 doses. Maintenance: After optical coherence tomography and visual acuity evaluations are completed, one of the following three regimens: 6 mg at Weeks 28 and 44; 6 mg at Weeks 24, 36 and 48; **OR** 6 mg Weeks 20, 28, 36 and 44	6 mg every 4 weeks: 1 vial per eye every month

Diabetic Macular Edema (DME)	Initial: 6 mg every month (approximately every 28 +/- 7 days) for 4 doses Maintenance: 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: 6 mg interval of dosing may be modified based on CST and visual acuity evaluations through week 52 **OR** 6 mg dose every month for the first 6 doses, followed by 6 mg dose every 2 months over the next 28 weeks.	6 mg injection: 1 vial per eye every month

2. Authorization Period: May be authorized for 12 months and reauthorized with continuation of therapy criteria.

3. Limitations

    a. It is not reasonable and necessary to inject more than one anti-VEGF medication (e.g., aflibercept, pegaptanib, brolucizumab, bevacizumab, ranibizumab, faricimab-svoa, etc.) in the same eye during the same treatment session. It is not typical to inject one anti-VEGF medication in one eye and another in the other eye. If different medications are injected into each eye during the same date of service, the rationale for this therapy must be documented in the medical record and the billing modifier [right (RT) and left (LT) modifiers] must be appended to the correct drug. Intravitreal injection for the treatment of macular edema more frequently than every 4 weeks regardless of which drug is used for any given injection i.e. alternating drugs every 2 weeks will not be covered.

    b. Concurrent use of more than one VEGF inhibitor in the same eye: The safety and effectiveness of combinational use of VEGF inhibitors for ocular indications has not been established and is currently not the standard of care according to clinical evidence and guidelines.

DRUG INFORMATION

PHARMACOLOGIC CATEGORY: Ophthalmic Agent; Vascular Endothelial Growth Factor (VEGF) Inhibitor

ROUTE OF ADMINISTRATION: Intravitreal Injection

FDA-APPROVED INDICATIONS
1. Neovascular (wet) AMD
2. Diabetic Macular Edema

COMPENDIAL APPROVED (OFF-LABELED) USES: NONE

CONTRAINDICATIONS:
Hypersensitivity (e.g., rash, pruritus, urticaria, erythema, severe intraocular inflammation) to faricimab or any component of the formulation; ocular or periocular infections; active intraocular inflammation.

OTHER CONSIDERATIONS

1. Monitoring Parameters**:**
   Intraocular pressure (via tonometry) and optic nerve head perfusion immediately following administration; symptoms of endophthalmitis and retinal detachment (e.g., eye redness/pain, photophobia, blurred vision, other vision changes).

2. General dosing considerations: 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)**.** Patients should be assessed regularly (FDA Label).

CLINICAL SUMMARY / APPENDIX

Faricimab-svoa is indicated for the treatment of nAMD and DME. Faricimab-svoa is administered by intravitreal injection by a qualified physician. The recommended dosage is dependent on the indication. Endophthalmitis and retinal detachments may occur following intravitreal injections of faricimab-svoa. The most common adverse reaction with faricimab-svoa is conjunctival hemorrhage. In pivotal studies, faricimab-svoa was noninferior to aflibercept for the treatment of nAMD (TENAYA and LUCERNE) and DME (YOSEMITE and RHINE).

REFERENCES

Government Agency

Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified; no applicable LCD identified). Available from CMS.

Prescribing Information

Vabysmo (faricimab) [prescribing information]. South San Francisco, CA: Genentech Inc; January 2023.

Peer-reviewed Literature, Guidelines, and Consensus

Milliman Care Guidelines (MCG). Ambulatory Care 27th Edition. ACG: A-1051 (AC). 2023.

1. Heier JS, Khanani AM, Quezada Ruiz C, Basu K, 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 Feb 19;399(10326):729-740.
2. Petri AS, Boysen K, Cehofski LJ, et al. Intravitreal injections with vascular endothelial growth factor inhibitors: a practical approach. OphthalmolTher. 2020;9(1):191-203. doi:10.1007/s40123-020-00230-4.
3. Wykoff CC, Abreu F, Adamis AP, Basu K, 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 Feb 19;399(10326):741-755.

IMPORTANT REMINDER

This Medicare Part B Step Therapy Medical Necessity Guideline is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers are solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage

provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

Aspire Health Plan (AHP) adheres to Medicare guidelines, including National Coverage Determination (NCD), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant Medicare manuals established by CMS. Compliance with these guidelines is required when applicable. Refer to the CMS website at http://www.cms.hhs.gov. For the most up-to-date Medicare policies and coverage, please search the Medicare Coverage Database. All LCDS are the same for each state within a Jurisdiction. Medicare Part B Administrative Contractor (MAC) for CA [Jurisdiction E (1)]: Active LCDs - JE Part B – Noridian (noridianmedicare.com). In the event of a discrepancy between this policy and the Medicare NCD or LCD, the Medicare NCD/LCD will govern.

This policy is utilized by AHP to determine coverage in the absence of applicable CMS Medicare guidelines. Please refer to the links provided in the References section to access the Medicare source materials that were used for developing this resource document. This document does not serve as a substitute for the official Medicare source materials that provide detailed information on Medicare coverage requirements. In the event of a conflict between this document and Medicare source materials, the Medicare source materials will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested in order to support coverage.

POLICY HISTORY

Version	Date	Revision Author/Title	Summary of Changes
1	9/27/2023		New Policy