

faricimab-svoa (Vabysmo)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

Drug Details

USP Category: OPHTHALMIC AGENTS

Mechanism of Action: Inhibits vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2)

HCPCS:

J2777:Injection, faricimab-svoa, 0.1 mg

How Supplied:

- 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose prefilled syringe
- 6 mg (0.05 mL of 120 mg/mL solution) in a single-dose vial

Condition(s) listed in policy (see coverage criteria for details)

- Diabetic Macular Edema (DME)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Neovascular (WET) Age-Related Macular Degeneration (AMD)

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Diabetic Macular Edema (DME)

Meets medical necessity if all the following are met:

1. Diagnosis only

Covered Doses:

Blue Shield of California is an independent member of the Blue Shield Association

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Effective: 12/01/2024

Y0118_24_675A1_C 10162024

H2819_24_675A1_C Accepted 10212024

6 mg administered by intravitreal injection given as often as every 3 weeks for the first 4 doses, followed by every 4 weeks thereafter

Coverage Period:

Yearly

ICD-10: (X= 0-9)

E08.3XXX, E09.3XXX, E10.3XXX, E11.3XXX, E13.3XXX

Macular Edema following Retinal Vein Occlusion (RVO)

Meets medical necessity if all the following are met:

1. Diagnosis only

Covered Doses:

6 mg administered by intravitreal injection every 3-5 weeks

Coverage Period:

6 months total

No reauthorization

ICD-10:

H34.8110-8112, H34.8120-8122, H34.8130- 8132, H34.8190-8192, H34.8310-8312, H34.8320-8322, H34.8330-8332, H34.8390-8392

Neovascular (WET) Age-Related Macular Degeneration (AMD)

Meets medical necessity if all the following are met:

1. Diagnosis only

Covered Doses:

6 mg administered by intravitreal injection every 3-5 weeks for the first 4 doses followed by every 4 weeks thereafter

Coverage Period:

Yearly

ICD-10:

H35.3210-3213, H35.3220-3223, H35.3230-3233, H35.3290-3293

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Vabysmo
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
 - a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
 - b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text

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Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer’s prescribing information.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at <http://www.lexi.com>
5. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
6. Vabysmo (faricimab-svoa) Prescribing Information. Genentech, Inc., South San Francisco, CA; 7/2024.

Review History

Date of Last Annual Review: 1Q2024

Changes from previous policy version:

- New Part B policy

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee

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