

aflibercept

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: Vascular endothelial growth factor (VEGF) inhibitor

HCPCS:

C9399 / J3490 / J3590:injection, aflibercept-ayyh (Pavblu)

J0177:Injection, aflibercept hd, 1 mg

J0178:Injection, aflibercept, 1 mg

How Supplied:

Eylea:

- 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose pre-filled syringe
- 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial

Eylea HD:

- 8 mg (0.07 mL of 114.3 mg/mL solution) in a single-dose vial

Pavblu:

- 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose prefilled syringe
- 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial

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

- [Diabetic Macular Edema \(DME\)](#)
- [Diabetic Retinopathy \(DR\)](#)
- [Macular Edema \(ME\) following Central or Branch Retinal Vein Occlusion \(RVO\)](#)
- [Neovascular \(WET\) Age-Related Macular Degeneration \(AMD\)](#)
- [Retinopathy of Prematurity \(ROP\)](#)

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

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

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Effective: 03/01/2025

Y0118_24_675A1_C 10162024

H2819_24_675A1_C Accepted 10212024

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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:

Covered Doses:

Eylea or Pavblu: 2 mg (0.05 ml) given by intravitreal injection every 25 days

Eylea HD: 8 mg given by intravitreal injection every 3–5 weeks for the first three doses, followed by 8 mg once every 7 to 17 weeks

Coverage Period:

Yearly

ICD-10:

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

Diabetic Retinopathy (DR)

Meets medical necessity if all the following are met:

Covered Doses:

Eylea or Pavblu: 2 mg (0.05 ml) given by intravitreal injection every 25 days

Eylea HD: 8 mg given by intravitreal injection every 3–5 weeks for the first three doses, followed by 8 mg once every 7 to 13 weeks

Coverage Period:

Yearly

ICD-10:

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

Macular Edema (ME) following Central or Branch Retinal Vein Occlusion (RVO)

Meets medical necessity if all the following are met:

1. Request is for Eylea or Pavblu (Not FDA approved for Eylea HD)

Covered Doses:

Eylea or Pavblu: 2 mg (0.05 ml) given by intravitreal injection every 25 days

Coverage Period:

Yearly

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:

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Covered Doses:

Eylea or Pavblu: 2 mg (0.05 ml) given by intravitreal injection every 25 days

Eylea HD: 8 mg given by intravitreal injection every 3 - 5 weeks for the first three doses, followed by 8 mg once every 7 to 17 weeks

Coverage Period:

Yearly

ICD-10:

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

Retinopathy of Prematurity (ROP)**Meets medical necessity if all the following are met:**

1. Request is for Eylea (Not FDA approved for Eylea HD or Pavblu)

Covered Doses:

Eylea: 0.4 mg (0.01 ml) given by intravitreal injection every 10 days

Coverage Period:

Yearly

ICD-10:

H35.109

Additional Information**Summary of Evidence**

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

1. The prescribing information for Eylea, Eylea HD, and Pavblu
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

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. Eylea (aflibercept) Prescribing Information. Regeneron Pharmaceuticals, Inc., Tarrytown, NY: 10/2024.

7. Eylea HD (aflibercept) Prescribing Information. Regeneron Pharmaceuticals, Inc., Tarrytown, NY: 10/2024.
8. Pavblu (aflibercept-ayyh) Prescribing information. Amgen, Inc., Thousand Oaks, CA. 8/2024.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- Added Pavblu (aflibercept-ayyh), biosimilar to Eylea. Pavblu is FDA approved for the following:
 - Neovascular (Wet) Age-Related Macular Degeneration (AMD)
 - Macular Edema following retinal vein occlusion (RVO)
 - Diabetic Macular Edema (DME)
 - Diabetic Retinopathy (DR)

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

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