**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:** Aflibercept is a recombinant fusion protein that acts as a soluble decoy receptor that binds VEGF-A and PGF, thereby inhibiting the binding and activation of these cognate VEGF receptors

**HCPCS:**

J0177:Injection, aflibercept hd, 1 mg

J0178:Injection, aflibercept, 1 mg

**How Supplied:**

Eylea:

- 2 mg/0.05 mL solution in a single-dose pre-filled syringe
- 2 mg/0.05 mL solution in a single-dose vial

Vial Kit contains the following Components:

- one Eylea 2 mg/0.05 mL single-dose glass vial
- one 19-gauge × 1½-inch, 5-micron, filter needle for withdrawal of the vial contents
- one 30-gauge × ½-inch injection needle for intravitreal injection
- one 1-mL syringe for administration

Eylea HD:

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

61755-050-01: Vial Kit with Injection Components

- 8 mg single-dose glass vial
- one 18-gauge × 1½-inch, 5-micron, filter needle for withdrawal of the vial contents
- one 30-gauge × ½-inch injection needle for intravitreal injection
- one 1-mL syringe for administration

61755-051-01: Vial Only

- 8 mg single-dose glass vial

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

- Diabetic Macular Edema (DME)
- Diabetic Retinopathy
- 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**

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:**

Eylea: 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**

**Meets medical necessity if all the following are met:**

1. Diagnosis only

**Covered Doses:**

Eylea: 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 (not Eylea HD)

**Covered Doses:**

Eylea: 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:**

1. Diagnosis only

**Covered Doses:**

Eylea: 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 Eylea HD)

**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 and Eylea HD
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. 12/2023.
7. Eylea HD (aflibercept) Prescribing information. Regeneron Pharmaceuticals, Inc., Tarrytown, NY. 12/2023.


**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*