

# Local Coverage Article: Billing and Coding: Aflibercept (EYLEA®) (A53387)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

## Article Information

### General Information

<b>Article ID</b> A53387	<b>Original Effective Date</b> 10/01/2015
<b>Article Title</b> Billing and Coding: Aflibercept (EYLEA®)	<b>Revision Effective Date</b> 10/24/2019
<b>Article Type</b> Billing and Coding	<b>Revision Ending Date</b> N/A
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## **CMS National Coverage Policy**

N/A

## **Article Guidance**

### **Article Text:**

Effective November 18, 2011, September 21, 2012, July 29, 2014, October 6, 2014, March 25, 2015, and May 13, 2019 respectively, Aflibercept (EYLEA<sup>®</sup>) was approved by the Food and Drug Administration (FDA) for the treatment of patients with:

- Neovascular (Wet) Aged-related Macular Degeneration (AMD)
- Macular Edema following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

For AMD the recommended dose is 2 mg (0.05 mL) administered by intravitreal injection every four weeks for the first 12 weeks (3 months), followed by 2 mg (0.05 mL) once every 8 weeks (2 months) by intravitreal injection. Although EYLEA<sup>®</sup> may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA<sup>®</sup> was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months).

For Macular Edema following RVO the recommended dose is 2 mg (0.05 mL) administered by intravitreal injection once every 4 weeks (monthly).

For DME the recommended dose is 2 mg (0.05 mL) once every 4 weeks (monthly) for the first 5 injections, and then 2 mg (0.05 mL) every 2 months (8 weeks) by intravitreal injection. Although EYLEA<sup>®</sup> may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA<sup>®</sup>

was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).

For Diabetic retinopathy (DR) the recommended dose is 2 mg (0.05 mL) once every 4 weeks (monthly) for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks (every 2 months). Although may be administered every 4 weeks, additional efficacy has not been demonstrated (compared with every 8 week administration); some patients may require every 4 week (monthly) dosing after the first 20 weeks of therapy (5 months).

To bill aflibercept services, submit the following claim information on CMS Form 1500:

- J0178 - Injection, aflibercept, 1 mg
- 67028 – Intravitreal injection of a pharmacologic agent (separate procedure)

**Note:** Quantity to be billed 67028 is 1 as this is a bilateral procedure.

**Note:** It is not reasonable and necessary to inject more than one anti-vascular endothelial growth factor (VEGF) medication (bevacizumab, ranibizumab, aflibercept) 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 DOS, the rationale for this therapy must be documented in the medical record and the billing modifier (RT/LT) 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.

## Coding Information

<b>CPT/HCPCS Codes</b>	
<b>Group 1 Paragraph:</b>	
N/A	
<b>Group 1 Codes:</b>	
CODE	DESCRIPTION
67028	INTRAVITREAL INJECTION OF A PHARMACOLOGIC AGENT (SEPARATE PROCEDURE)
J0178	INJECTION, AFLIBERCEPT, 1 MG

<b>CPT/HCPCS Modifiers</b>
<b>Group 1 Paragraph:</b>
LT

RT

**Group 1 Codes:**

N/A

**ICD-10 Codes that Support Medical Necessity**

N/A

**ICD-10 Codes that DO NOT Support Medical Necessity**

N/A

**Additional ICD-10 Information**

N/A

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**Other Coding Information**

N/A

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/24/2019	R12	This article is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs and incorporate into related Billing and Coding Articles. Under <b>Article Title</b> changed the title to "Billing and Coding: Aflibercept (EYLEA®)". Under <b>CPT/HCPCS Modifiers</b> added modifiers RT and LT. Formatting, punctuation and typographical errors were corrected throughout the article.
07/04/2019	R11	Under <b>Article Text</b> added the verbiage "and May 13, 2019" to the first paragraph, removed the verbiage "in patients with Diabetic Macular Edema (DME)" from the fourth bullet, and replaced the fifth paragraph with the verbiage "For Diabetic retinopathy (DR) the recommended dose is 2 mg (0.05 mL) once every 4 weeks (monthly) for the first 5 injections, followed by 2 mg (0.05 mL) once every 8 weeks (every 2 months). Although may be administered every 4 weeks, additional efficacy has not been demonstrated (compared with every 8 week administration); some patients may require every 4 week (monthly) dosing after the first 20 weeks of therapy (5 months)". Formatting, punctuation and typographical errors were corrected throughout the article.
05/17/2018	R10	<p>Under <b>Article Text</b> in the fifth paragraph added the verbiage "Although EYLEA® may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when Eylea® was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months)".</p> <p><i>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>
02/26/2018	R9	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.
02/01/2018	R8	Under <b>Article Text</b> corrected capitalization errors, added the registered trademark symbol, deleted the "s" from weeks in the second and fourth paragraph and added "monthly" to the fourth and fifth paragraph. Under <b>CPT/HCPCS Codes</b>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		added J0178 and 67028.
08/04/2016	R7	Under <b>Article Text</b> for Age-related Macular Degeneration (AMD) added the verbiage "Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 12 weeks (3 months)" to the end of the second sentence. For Diabetic Macular Edema (DME) added the verbiage "Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 20 weeks (5 months)" to the end of the fourth sentence. In the second <b>Note:</b> added the verbiage "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 two weeks will not be covered". The additional verbiage is effective for dates of service on or after May 26, 2016.
02/04/2016	R6	Under Article Text removed CRVO and BRVO information as they are not relevant to the current package insert, revised dosing instructions for Macular Edema following RVO and DME and revised the code description for CPT code 67028.
10/01/2015	R5	Under Article Text added FDA approved indication for Eylea, Diabetic Retinopathy (DR) with Diabetic Macular Edema (DME). Added FDA dosing instructions for DR with DME.
10/01/2015	R4	Under Article Text added FDA approved indication for Eylea, Diabetic Macular Edema (DME). Added FDA dosing instructions for DME.
10/01/2015	R3	Added to CMS Manual Explanations under Associated Documents Publication 100-02, Ch. 15, §50, Drugs and Biological.
10/01/2015	R2	Under Article Text added addition coverage for BRVO per FDA. Added dosing instructions for BRVO.
10/01/2015	R1	Added HCPCS codes from body of Article Text to <b>HCPCS Coding</b> .

## Associated Documents

### Related Local Coverage Document(s)

N/A

### Related National Coverage Document(s)

N/A

### Statutory Requirements URL(s)

Title XVIII Social Security Act 1862(a)(1)

**Rules and Regulations URL(s)**

N/A

**CMS Manual Explanations URL(s)**

Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, §50

**Other URL(s)**

N/A

**Public Version(s)**

Updated on 10/14/2019 with effective dates 10/24/2019 - N/A

Updated on 06/05/2019 with effective dates 07/04/2019 - N/A

Updated on 05/10/2018 with effective dates 05/17/2018 - N/A

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## Keywords

- Aflibercept
- EYLEA®
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