Article - Billing and Coding: Aflibercept (EYLEA®) (A53387)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
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

Article ID A53387

Article Title

Billing and Coding: Aflibercept (EYLEA®)

Article Type Billing and Coding

Original Effective Date 10/01/2015

Revision Effective Date 04/22/2021

Revision Ending Date N/A

Retirement Date N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Current Dental Terminology $\textcircled{\sc c}$ 2020 American Dental Association. All rights reserved.

Copyright © 2013 - 2021, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the American Hospital Association (AHA) copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816. You may also contact us at ub04@aha.org.

Mylan v. Regeneron, IPR2021-00881

Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

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[®]) 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[®] 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 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 $EYLEA^{(R)}$ may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when $EYLEA^{(R)}$ 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

DOCKE.

• 67028 – Intravitreal injection of a pharmacologic agent (separate 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

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION	
67028	INTRAVITREAL INJECTION OF A PHARMACOLOGIC AGENT (SEPARATE PROCEDURE)	
J0178	INJECTION, AFLIBERCEPT, 1 MG	

CPT/HCPCS Modifiers
Group 1 Paragraph:

LT

RT

Group 1 Codes:

N/A

ICD-10-CM Codes that Support Medical Necessity

N/A

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

N/A

Additional ICD-10 Information

RM

N/A

DOCKE.

Α

Bill Type Codes

Find authenticated court documents without watermarks at docketalarm.com.

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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

N/A

DOCKET

RM

Δ

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/22/2021	R13	Under Article Text removed the verbiage " Note: Quantity to be billed 67028 is 1 as this is a bilateral procedure."
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 Article Title changed the title to "Billing and Coding: Aflibercept (EYLEA®)". Under CPT/HCPCS Modifiers added modifiers RT and LT. Formatting, punctuation and typographical errors were corrected throughout the article.
07/04/2019	R11	Under Article Text 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)".

Find authenticated court documents without watermarks at docketalarm.com.

REVISION HISTORY DATE			
		punctuation and typographical errors were corrected throughout the article.	
05/17/2018	R10	Under Article Text 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)".	
		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.	
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 Article Text 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 CPT/HCPCS Codes added J0178 and 67028.	
08/04/2016	R7	Under Article Text 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 Note: 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	

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

DOCKET A L A R M



Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.