EYLEA 4U®

EYLEA® (aflibercept) Injection

EYLEA

ICD-10-CM Billing and Coding Guide for Retinopathy of Prematurity (ROP)

The coding material discussed in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice.

The codes listed herein may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

ICD-10-CM = *International Classification of Diseases, 10th Revision, Clinical Modification.*

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

EYLEA is indicated for the treatment of

pre-term infants with Retinopathy of Prematurity (ROP).[1]

EYLEA Is the First and Only FDA-Approved Anti-VEGF Treatment for ROP[1]

The recommended dose of EYLEA for the treatment of ROP is 0.4 mg (0.01 mL or 10 microliters of 40 mg/mL solution) administered by intravitreal injection. Treatment is initiated with a single injection per eligible eye and may be given bilaterally on the same day. Injections may be repeated in each eye. The treatment interval between doses injected into the same eye should be at least 10 days[1]

The EYLEA NDC and packaging have not changed and can be found below:

EYLEA 11-Digit NDC*	NDC Description	WAC†
61755**0**00502	**One EYLEA 2 mg (0.05 mL of a 40 mg/mL solution) single-dose glass vial kit with injection components‡**	$1850

*The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in **bold**.
†WAC is based on information listed in the National Drug Compendia.
‡**The EYLEA pre-filled syringe is not approved for use for ROP. Do not use the EYLEA pre-filled syringe for the treatment of ROP.**
FDA = US Food and Drug Administration; NDC = National Drug Code; VEGF = vascular endothelial growth factor; WAC = wholesale acquisition cost.

Please Note: WAC pricing is only to be used to determine the cost of the drug and **does not** include the administration charge.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. December 2023.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering EYLEA. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

Relevant ICD-10-CM Codes for EYLEA for ROP

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	Right eye	Left eye	Bilateral	Unspecified eye
Retinopathy of prematurity, unspecified	H35.101	H35.102	H35.103	H35.109

	Right eye	Left eye	Bilateral	Unspecified eye
Retinopathy of prematurity, stage 0	H35.111	H35.112	H35.113	H35.119
Retinopathy of prematurity, stage 1— demarcation line	H35.121	H35.122	H35.123	H35.129
Retinopathy of prematurity, stage 2— intraretinal ridge	H35.131	H35.132	H35.133	H35.139
Retinopathy of prematurity, stage 3— ridge with extraretinal fibrovascular proliferation	H35.141	H35.142	H35.143	H35.149
Retinopathy of prematurity, stage 4— subtotal retinal detachment	H35.151	H35.152	H35.153	H35.159
Retinopathy of prematurity, stage 5— total retinal detachment	H35.161	H35.162	H35.163	H35.169

The codes listed herein may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

Sample CMS-1500 Form—Physician Office

EYLEA 4U
EYLEA® (aflibercept) Injection

Note: The information presented below is based on the paper claim format; **please adopt this information to electronic equivalent fields in your software systems**. The coding information discussed in this document and sample form is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed below may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

Box 21, Diagnosis Code
Enter the appropriate ICD-10-CM code for the patient's diagnosis/condition.

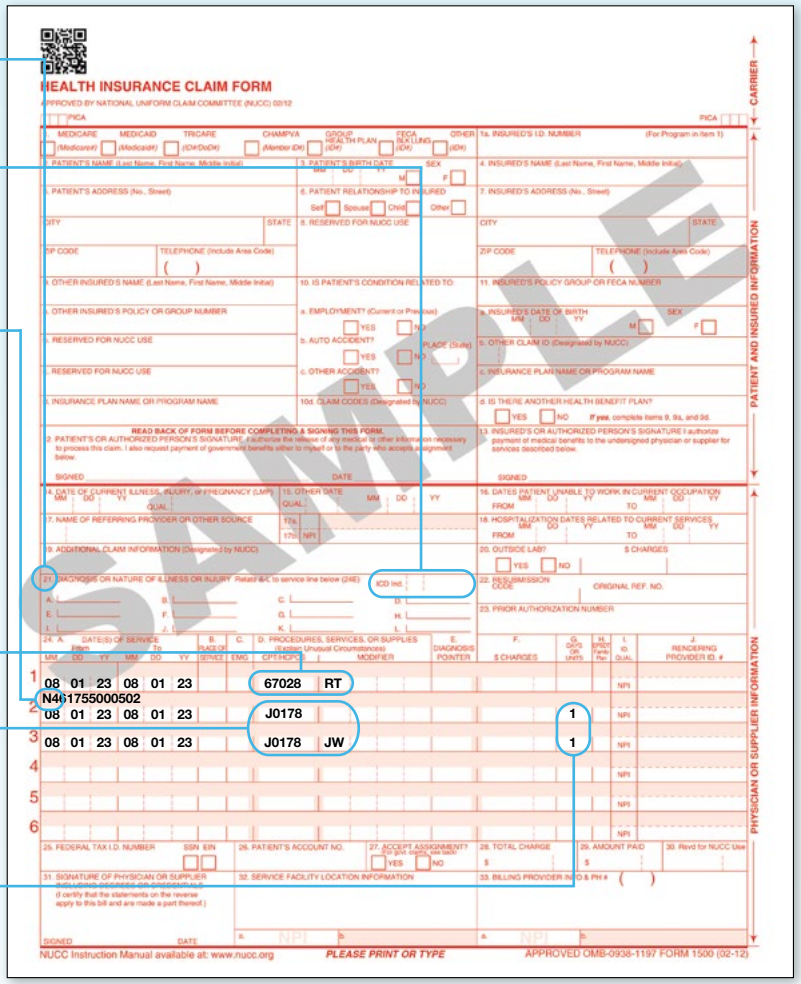
Box 21, ICD Indicator
Enter **0** to indicate the ICD code set.

Box 24A, NDC Information
In the shaded red area, the full name of the medication administered, including strength if applicable (eg, EYLEA® [aflibercept] Injection 2 mg [0.05 mL of 40 mg/mL solution]), dosage, basis of measurement (mg, mL, etc) as well as the NDC on the package used (eg, 61755000502) should be entered. **Please Note:** Payer NDC requirements and placement may vary; check with payer.*

Box 24D, Procedure Code
Enter the appropriate drug administration/CPT† code for EYLEA intravitreal injection – 67028. Enter appropriate modifiers: LT for left eye injection, RT for right eye injection, or 50 for bilateral injection.

Box 24D, Product Code
Enter HCPCS code J0178 to represent EYLEA – injection, aflibercept, 1 mg. In addition, CMS and most payers require you to record drug waste. You can record waste on a separate line with the JW modifier (ie, J0178 JW).

Box 24G, Units Administration
J0178 has a unit descriptor of 1 mg; when administering a 0.4 mg dose for ROP, 1 unit should be entered on the JW modifier claim line for indicating wastage. **Please Note:** Billing units may vary by payer; please check with payer for appropriate billable units to be used.


HEALTH INSURANCE CLAIM FORM

1	08	01	23	08	01	23		67028	RT			
	N4 61755000502											
2	08	01	23	08	01	23		J0178		1		
3	08	01	23	08	01	23		J0178	JW	1		
4												
5												
6												

*Some payers may require the 11-digit NDC for EYLEA (61755000502 for the vial kit with injection components). Payer NDC requirements and placement may vary; check with payer.

CMS = Centers for Medicare & Medicaid Services; CPT = Current Procedural Terminology; FAR/DFARS = Federal Acquisition Regulation/Defense Federal Acquisition Regulation Supplement; HCPCS = Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- In infants with ROP, reactivation of abnormal angiogenesis and tortuosity may occur following treatment with EYLEA. Infants should be monitored closely after injection with EYLEA until retinal vascularization has completed or until the examiner is assured that reactivation of ROP will not occur. Treatment with EYLEA will necessitate extended periods of ROP monitoring and additional EYLEA injections and/or laser treatments may be necessary.

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

Sample CMS-1450 Form—
Hospital Outpatient Department

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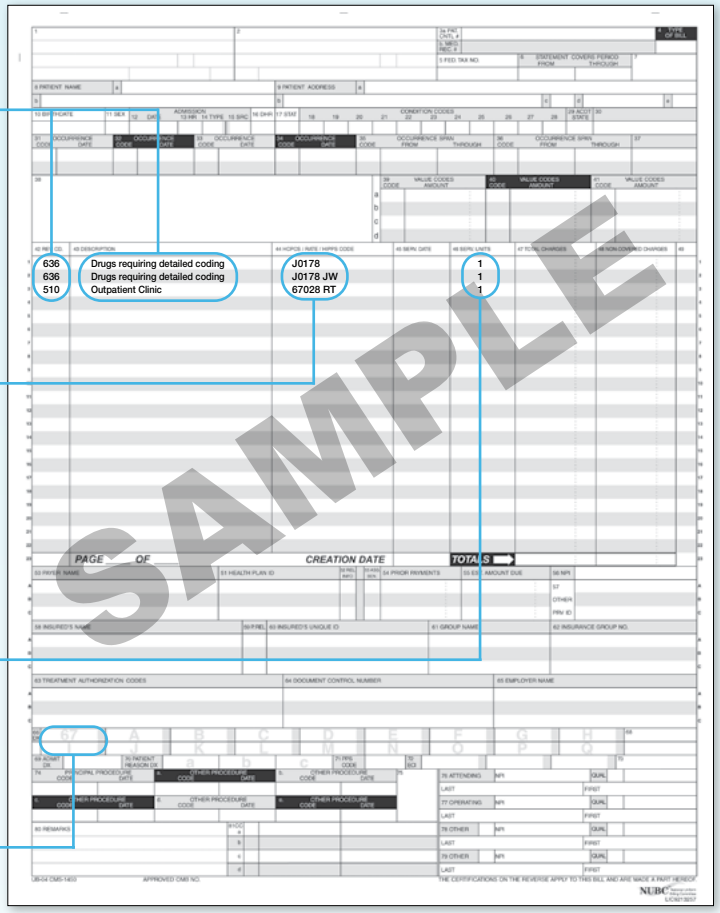
Boxes 42 and 43, Revenue Code
Enter the full name of the medication administered, including strength if applicable (eg, EYLEA® [aflibercept] Injection 2 mg [0.05 mL of 40 mg/mL solution]), dosage, basis of measurement (mg, mL, etc), as well as the NDC on the package used (eg, 61755000502). **Please Note:** Payer NDC requirements and placement may vary; check with payer.

Box 44, Procedure Code
Enter the appropriate drug administration/CPT* code for EYLEA intravitreal injection: 67028. Include appropriate modifiers: 67028 LT for left eye injection, 67028 RT for right eye injection, or 67028 50 for bilateral injection.

Product Code
Enter HCPCS code J0178 to represent EYLEA, 1 mg. In addition, CMS and most payers require you to record drug waste. You can record waste on a separate line with the JW modifier (ie, J0178 JW).

Box 46, Units - Medication Quantity
J0178 has a unit descriptor of 1 mg; when administering a 0.4 mg dose for ROP, 1 unit should be entered on the JW modifier claim line for indicating wastage. **Please Note:** Billing units may vary by payer; please check with payer for appropriate billable units to be used.

Box 67, Diagnosis Code
Enter the appropriate ICD-10-CM code for the patient's diagnosis/condition.



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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

Have a billing or reimbursement question related to EYLEA?

Reach out to your **Reimbursement Business Manager**

OR

Call **1-855-EYLEA4U** (1-855-395-3248), Option 4, Monday-Friday 9 AM-8 PM Eastern Time

IMPORTANT SAFETY INFORMATION AND INDICATIONS

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- In pre-term infants with ROP receiving EYLEA the most common adverse reactions (≥4%) reported were retinal detachment, conjunctival hemorrhage, and intraocular pressure increased. Adverse reactions established for adult indications are considered applicable to pre-term infants with ROP, though not all were observed in the clinical studies.
- Patients may experience temporary visual disturbances after an intravitreal injection with EYLEA and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg is indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Retinopathy of Prematurity (ROP) (0.4 mg).

Please see additional Important Safety Information throughout and click here for the full Prescribing Information for EYLEA.

REGENERON®

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