EYLEA® (aflibercept) Injection: First and Only FDA-Approved Anti-VEGF Treatment for Retinopathy of Prematurity (ROP)

EYLEA is indicated for the treatment of pre-term infants with ROP[1]

Dosage and Administration in ROP[1]

- The recommended dose for EYLEA 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

How supplied[1]

- Injection: 2 mg (0.05 mL of a 40 mg/mL solution) in a single-dose glass vial*

Storage[1]

Refrigerate EYLEA at 2°C to 8°C (36°F to 46°F). Do not freeze. Do not use beyond the date stamped on the carton and container label. Store in the original carton until time of use to protect from light. Do not open sealed blister tray until time of use.

*__Do not__ use the EYLEA pre-filled syringe for the treatment of ROP. **Note:** If the contralateral eye requires treatment, a new sterile vial should be used.[1]

J-Code

Injection, aflibercept, 1 mg	**J0178**

With the 1-mg descriptor, when administering a 0.4 mg dosage for ROP, 1 unit should be entered along with a separate claim line of 1 unit with the JW modifier for indicating wastage.[2]

10-digit NDC

One EYLEA 2 mg (0.05 mL of a 40 mg/mL solution) single-dose glass vial	**6175500502**[1]

11-digit NDC

One EYLEA 2 mg (0.05 mL of a 40 mg/mL solution) single-dose glass vial	**61755000502**

The coding information 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.

FDA = US Food and Drug Administration; NDC = National Drug Code; VEGF = vascular endothelial growth factor.

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 full Prescribing Information.

Accessing EYLEA® (aflibercept) Injection

If EYLEA is not currently on your hospital's formulary, EYLEA may be acquired by working with your appropriate NICU contact or Hospital Pharmacy Director to request a hospital formulary change or by requesting EYLEA through a nonformulary exception pathway.

Authorized specialty distributors

Contact one of our **authorized distributors** below and receive EYLEA on the next business day.*

Besse Medical

Phone: 1-800-543-2111 | besse.com

CuraScript SD Specialty Distribution

Phone: 1-877-599-7748 | curascriptsd.com

McKesson Specialty Health

Phone: 1-855-477-9800 | mscs.mckesson.com

McKesson Plasma & Biologics for Hospitals

Phone: 1-877-625-2566 | connect.mckesson.com

Metro Medical (A Cardinal Health Company)

Phone: 1-800-768-2002 | metromedicalorder.com

Cardinal Health Specialty Pharmaceutical Distribution for Hospitals

Phone: 1-866-300-3838

specialtyonline.cardinalhealth.com

Regeneron does not recommend the use of any particular listed distributor.
Subject to distributor qualification.

*Orders received prior to 7 PM Eastern Time Monday–Thursday are typically processed on the same day and scheduled for delivery the next business day. Orders received on Friday will typically be delivered the following Monday.

NICU = neonatal intensive care unit.

IMPORTANT SAFETY INFORMATION (cont'd)

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.
- 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 full Prescribing Information.

Accessing EYLEA® (aflibercept) Injection (cont'd)

Specialty pharmacy providers

As an option, or if instructed by the patient's payer, EYLEA may be obtained through our broad network of **specialty pharmacy providers**.

Accredo Health Group
Phone: 1-866-759-1557 | accredo.com

AllianceRx Walgreens Pharmacy
Phone: 1-855-244-2555 | alliancerxwp.com

CVS Specialty
Phone: 1-800-237-2767 | cvsspecialty.com

CenterWell Specialty Pharmacy
Phone: 1-800-486-2668
centerwellspecialtypharmacy.com

Optum
Phone: 1-877-409-9347 | specialty.optumrx.com

RelianceRx
Phone: 1-800-809-4763 | reliancerxsp.com

Special Care Pharmacy Services (Puerto Rico Only)
Phone: 1-888-727-1727 | specialcarepr.com/en
Local Phone: 787-781-4585

Regeneron does not recommend the use of any particular specialty pharmacy.
List is subject to change.

IMPORTANT SAFETY INFORMATION (cont'd)

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.
- 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 full Prescribing Information.

EYLEA® (aflibercept) Injection Product Return Procedure

If EYLEA is rendered unusable after purchase, it may be returned to Regeneron and replaced under certain circumstances. Returns are subject to adherence to Regeneron policies and procedures regarding the return of product and Regeneron's right, at its sole discretion, to deny replacement when misuse is suspected.

Information about returning EYLEA

- As a condition of replacement, **product should be returned**, when possible
- Note the condition of the vial:
  - **If vial is intact:** Return to the address provided when you contact the patient support program
  - **If the vial is broken*:** Submit pictures documenting the damage
- **Contact your distributor or specialty pharmacy** if you believe EYLEA expired or was damaged in shipment
- For product complaints and/or product returns, or to obtain appropriate forms and a list of required documents, **call EYLEA4U® at 1-855-EYLEA4U (1-855-395-3248), Option 3**, or visit the **Trade Service Center at http://tsc.regeneron.com**

*Broken vials do not have to be returned, but pictures documenting the damage should be submitted.

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 full Prescribing Information.

References: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. December 2023. **2.** Billing and coding: JW modifier billing guidelines. Centers for Medicare & Medicaid Services. Revised January 10, 2023. Accessed January 7, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55932

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REGENERON

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