EYLEA®
(aflibercept) Injection
For Intravitreal Injection

Established Anti-VEGF Agents Provide Proven Treatment for Several Retinal Diseases

INDICATIONS

EYLEA® (aflibercept) Injection 2 mg (0.05 mL) 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), and Diabetic Retinopathy (DR).

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.

This material is intended for use by payers, formulary committees, or other similar entities for purposes of population-based drug selection, coverage, and/or reimbursement decision making, pursuant to FD&C Act Section 502(a).

ANTI-VEGF AGENTS ARE THE STANDARD OF CARE FOR SEVERAL RETINAL DISEASES PER THE AMERICAN ACADEMY OF OPHTHALMOLOGY

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There are several established anti-VEGF agents **approved by the FDA** already available to treat a broad range of retinal conditions, including Wet AMD, DME, DR, and MEfRVO.[1-3]

	Neovascular (Wet) AMD	DME	DR	MEfRVO	mCNV
EYLEA® (aflibercept) Injection For Intravitreal Injection	✓	✓	✓	✓	—
Lucentis® (ranibizumab injection)[2]	✓	✓	✓	✓	✓
Beovu® (brolucizumab-dbll) injection[3]	✓	—	—	—	—
Avastin® (bevacizumab) injection[4] compounded, off-label	—	—	—	—	—

» Intravitreal anti-VEGF therapy has also demonstrated **proven results in DME and MEfRVO**[1,5,6]

FDA = US Food and Drug Administration; mCNV = myopic choroidal neovascularization; VEGF = vascular endothelial growth factor.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- 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.

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WORLD'S LARGEST ORGANIZATION OF RETINA SPECIALISTS ADVOCATES FOR OPEN ACCESS TO ANTI-VEGF AGENTS

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The American Society of Retina Specialists advocates for physicians' ability to choose the appropriate anti-VEGF medication for individual patients, contending that treatment decisions need to be based on each patient's unique risk factors, clinical presentation, availability of compounded drugs, and economic requirements.[7]

EYLEA® (aflibercept) Injection provides flexible dosing to help address the clinical needs of patients with several retinal diseases

- Given the complexities of retinal diseases, HCPs are **personalizing currently available treatment options and dosing intervals for patients**[8,9]
- Real-world data show that HCPs are choosing approved dosing options with EYLEA that are **tailored to the needs of patients across multiple indications**,* including Q12W dosing for Wet AMD after 1 year of effective therapy[1,10,11]
  - The recommended dose for EYLEA for Wet AMD is 2 mg administered by intravitreal injection Q4W for the first 3 months, followed by 2 mg via intravitreal injection Q8W[1]
  - Although not as effective as the recommended Q8W dosing regimen, patients may also be treated with 1 dose every 12 weeks (Q12W) after 1 year of effective therapy. Patients should be assessed regularly[1]
- **Flexible dosing regimens with anti-VEGF agents**, including EYLEA, for **diabetic eye diseases** have also been shown to be effective[1]

*Wet Age-related Macular Degeneration (AMD): The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, 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). Although not as effective as the recommended every-8-week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly. Diabetic Macular Edema (DME) and DR: The recommended dose of EYLEA is 2 mg administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg via intravitreal injection once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, 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).

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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IMPORTANT SAFETY INFORMATION (CONT'D)

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.
- 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.

References

1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc.
2. Lucentis® (ranibizumab injection) full U.S. Prescribing Information. Genentech, Inc. March 2018.
3. Beovu® (brolucizumab-dbll) injection full U.S. Prescribing Information. Novartis Pharmaceuticals Corporation. June 2020.
4. Holekamp NM. Review of neovascular age-related macular degeneration treatment options. *Am J Manag Care*. 2019;25(suppl 10):S172-S181.
5. Adamis AP, Brittain CJ, Dandekar A, Hopkins JJ. Building on the success of anti-vascular endothelial growth factor therapy: a vision for the next decade. *Eye (Lond)*. 2020;34(11):1966-1972.
6. Bahrami B, Hong T, Giles MC, Chang A. Anti-VEGF therapy for diabetic eye diseases. *Asia Pac J Ophthalmol (Phila)*. 2017;6(6):535-545.
7. American Society of Retina Specialists. Physician choice of medication. Accessed May 26, 2021. https://www.asrs.org/advocacy/physician-choice-of-medication
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9. Volkmann I, Knoll K, Wiezorrek M, Greb O, Framme C. Individualized treat-and-extend regime for optimization of real-world vision outcome and improved patients' persistence. *BMC Ophthalmol*. 2020;20(1):122.
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11. Khurana RN, Rahimy E, Joseph WA, et al. Extended (every 12 weeks or longer) dosing interval with intravitreal aflibercept and ranibizumab in neovascular age-related macular degeneration: post hoc analysis of VIEW trials. *Am J Ophthalmol*. 2019;200:161-168.

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REGENERON

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