

PRODUCT PROFILE

EYLEA HD *Aflibercept injection, solution*

Manufacturer

Regeneron Pharmaceuticals, Inc

Indication

- Eylea HD is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:
 - neovascular (wet) age-related macular degeneration (nAMD);
 - diabetic macular edema (DME); and
 - diabetic retinopathy (DR).¹

Dosing and Administration

- Eylea HD is an ophthalmic intravitreal injection; it must be administered only by a qualified physician.¹
- The recommended dose for Eylea HD is 8 mg administered by intravitreal injection every 4 weeks for the first 3 doses, followed by 8 mg via intravitreal injection once every 8 to 16 weeks (± 1 week for nAMD and DME) or once every 8 to 12 weeks (± 1 week for DR).¹

Storage and Handling

- Eylea HD is supplied as a kit with the following components: 1 single-dose vial of EYLEA HD, 8 mg; 1 filter needle for withdrawal of the vial contents; 1 needle for intravitreal injection; and one 1-mL syringe for administration.¹
- Refrigerate EYLEA HD at 2 to 8 °C (36-46 °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.¹

Safety/Warnings

- Eylea HD 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 HD.¹
- Intravitreal injections, including those involving aflibercept, have been associated with endophthalmitis, retinal detachments, and, more rarely, retinal vasculitis with or without occlusion.¹
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with administration of Eylea HD.¹
- There is a potential risk of arterial thromboembolic events (defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death [including deaths of unknown cause]) following intravitreal use of VEGF inhibitors, including Eylea HD.¹
- The most common adverse events reported in at least 3% of patients treated with Eylea HD were cataract, conjunctival hemorrhage, increased intraocular pressure, ocular discomfort/eye pain/eye irritation, vision blurred, vitreous floaters, vitreous detachment, corneal epithelium defect, and retinal hemorrhage.¹

Disease State Background

- AMD is a leading cause of vision loss in people 60 years and older.² An estimated 20 million people in the United States have some form of AMD.³ Wet AMD, 1 of 2 types of MD, involves the abnormal formation of blood vessels growing under the retina and leaking fluid and blood.² This leakage may lead to swelling and macular damage; this, in turn, can severely affect a patient's vision.² Wet AMD accounts for approximately 10% of cases of AMD but results in 90% of legal blindness.⁴
- DR is the most common diabetic eye disease and is the leading cause of blindness in working-age adults.⁵ DR is caused by changes in blood vessels in the retina.⁵ DME can occur at any stage of DR and can develop without any evident symptoms.⁵ If DME is not treated in a timely manner, it can lead to severe vision loss or blindness.⁵ The CDC estimates that 90% of blindness caused by diabetes is preventable.⁶

Place in Therapy

- According to the American Academy of Ophthalmology, intravitreal injection of anti-VEGF agents is the most effective way to manage wet AMD.⁷ Similarly, anti-VEGF agents are effective in the management of center-involved DME with vision loss.⁸ Available anti-VEGF agents

include aflibercept, bevacizumab, brolocizumab, faricimab, and ranibizumab.⁹ Individualized continuous, variable anti-VEGF dosing regimens, referred to as *treat-and-extend* approaches, are commonly used in clinical practice as an alternative to fixed continuous regimens or as-needed dosing regimens.⁷

Managed Care Considerations

- Loss of vision from wet AMD, DME, and DR can cause substantial economic burden on patients, families, and society.^{7,8} Early detection of these diseases coupled with individualized management with anti-VEGF agents may help preserve patients' vision, quality of life, and independence.^{7,8}

Market Insights

- Eylea HD is the first anti-VEGF treatment approved in wet AMD and DME for immediate dosing at intervals of every 8 weeks and up to every 16 weeks following 3 initial monthly doses.
- Eylea HD offers an 8-mg intravitreal injection of aflibercept, whereas the original Eylea product contains a 2-mg dose.¹⁰ The higher dose of Eylea HD enables longer treatment intervals between injections (wet AMD: Eylea HD, 8-16 weeks; Eylea, 4 weeks).¹⁰ In the PULSAR trial (NCT04423718) of Eylea HD, for wet AMD, 83% of treated patients maintained dosing intervals of 12 weeks or longer.¹¹ Similarly, in the PHOTON trial (NCT04429503) of aflibercept for DME, 93% of patients given Eylea HD, maintained dosing intervals of 12 weeks or longer.¹²

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