

# PHARMACY POLICY STATEMENT

## Ohio Medicaid

<b>DRUG NAME</b>	<b>Eylea and Eylea HD (aflibercept)</b>
<b>BENEFIT TYPE</b>	Medical
<b>STATUS</b>	Prior Authorization Required

Eylea was originally approved by the FDA in 2011. It is indicated for the treatment of several different ophthalmic conditions. Eylea is a vascular endothelial growth factor (VEGF) inhibitor for intravitreal use. VEGF inhibitors suppress endothelial cell proliferation, neovascularization, and vascular permeability. Eylea HD, approved in 2023, is a high-dose, extended-interval version of Eylea, but with fewer indications.

There are 2 forms of age-related macular degeneration (AMD), dry and wet (neovascular). Eylea is approved for the treatment of Wet AMD which is less common but progresses more quickly. Neovascular in the context of AMD means growth of new blood vessels under the macula which can lead to loss of central vision.

Diabetic eye disease includes diabetic retinopathy (DR) and diabetic macular edema (DME). DR affects blood vessels in the retina at the back of the eye. DME is a consequence of DR that occurs in about half of DR patients. It causes fluid build-up in the macula part of the retina.

Retinal Vein Occlusion (RVO) occurs when there is a partial or complete obstruction of a retinal vein. Macular edema is a complication of RVO and can lead to vision loss. It is treated first-line with anti-VEGF drugs.

Retinopathy of prematurity (ROP) is a neovascular disorder of the developing retinal blood vessels in preterm infants. The standard treatment has been laser coagulation.

Eylea and Eylea HD (aflibercept) will be considered for coverage when the following criteria are met:

### Retinal Disease (adults)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of one of the following conditions:
  - a) Neovascular (Wet) Age-Related Macular Degeneration (AMD)
  - b) Macular Edema Following Retinal Vein Occlusion (RVO) – Eylea Only
  - c) Diabetic Macular Edema (DME)
  - d) Diabetic Retinopathy (DR); AND
4. Member has tried and failed bevacizumab intravitreal injection (Exception: not required for diagnosis of DME when visual acuity is worse than 20/50); AND
5. Documentation of best-corrected visual acuity (BCVA); AND
6. Member does NOT have active infection or inflammation in or around the eye(s) to be treated.
7. **Dosage allowed/Quantity limit:**

Eylea:

AMD: 2 mg every 4 weeks for 3 months, then 2 mg every 8 weeks.

RVO: 2 mg every 4 weeks.

DME or DR: 2 mg every 4 weeks for the first 5 injections, then 2 mg every 8 weeks.

Note: Eylea is supplied as a 2 mg/0.05 mL single-dose vial or pre-filled syringe.

Eylea HD:

AMD or DME: 8 mg every 4 weeks for 3 months, then 8 mg every 8 to 16 weeks.



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4. Holekamp, Nanvy M. Review of Neovascular Age-Related Macular Degeneration Treatment Options. *Am J Manag Care*. July 2019; 25:-S0
5. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(2):P288-P320. doi:10.1016/j.optha.2019.09.029
6. Shalchi Z, Mahroo O, Bunce C, Mitry D. Anti-vascular endothelial growth factor for macular oedema secondary to branch retinal vein occlusion. *Cochrane Database Syst Rev*. 2020;7(7):CD009510. Published 2020 Jul 7. doi:10.1002/14651858.CD009510.pub3
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8. Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth( )-25(r)26(e)18(c)-37(t)-2