

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Eylea (aflibercept)
BILLING CODE	J0178
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
STATUS	Prior Authorization Required

Eylea was approved by the FDA in 2011. It is indicated for the treatment of 4 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.

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.

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

Retinal Disease

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)
 - 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:**
 - 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.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must include documentation of improved or stabilized visual acuity.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Eylea (aflibercept) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/22/2021	New policy for Eylea created.

References:

1. Eylea [prescribing information]. Regeneron Pharmaceuticals, Inc.; 2021.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024
3. Holekamp, Nanvy M. Review of Neovascular Age-Related Macular Degeneration Treatment Options. *Am J Manag Care*. July 2019; 25:-S0
4. 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.ophtha.2019.09.029
5. 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
6. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in *Ophthalmology*. 2020 Sep;127(9):1279]. *Ophthalmology*. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025
7. Virgili G, Parravano M, Evans JR, Gordon I, Lucenteforte E. Anti-vascular endothelial growth factor for diabetic macular oedema: a network meta-analysis. *Cochrane Database Syst Rev*. 2018;10(10):CD007419. Published 2018 Oct 16. doi:10.1002/14651858.CD007419.pub6
8. Diabetic Retinopathy Clinical Research Network, Wells JA, Glassman AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. *N Engl J Med*. 2015;372(13):1193-1203. doi:10.1056/NEJMoa1414264

Effective date: 04/01/2022

Revised date: 10/22/2021