CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Eylea and Eylea HD (aflibercept)
BENEFIT TYPE	Medical
STATUS	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 (Avastin) 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.
DR: 8 mg every 4 weeks for 3 months, then 8 mg every 8 to 12 weeks.

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.

Retinopathy of Prematurity (ROP) – Eylea Only

For **initial** authorization:
1. Member's gestational age at birth was 32 weeks or fewer, or birth weight 1500 g or less; AND
2. Medication must be prescribed by or in consultation with an ophthalmologist; AND
3. Member has a confirmed diagnosis of Type 1 ROP (specify one or both eye(s)) defined by any of the following:
   a) Zone I ROP: any stage with plus disease
   b) Zone I or posterior zone II ROP: stage 3 without plus disease
   c) Zone II ROP: stage 2 or 3 with plus disease; AND
4. Member does NOT have any of the following:
   a) Advanced stages of ROP with partial or complete retinal detachment (stage 4 or 5)
   b) ROP involving only Zone III
5. **Dosage allowed/Quantity limit:** 0.4 mg. May be given bilaterally on same day. May repeat after an interval of at least 10 days.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Member continues to have active ROP; AND
2. Member has not experienced retinal detachment, macular dragging, macular fold, or retrolental opacity.

If all the above requirements are met, the medication will be approved for an additional 3 months.

CareSource considers Eylea and Eylea HD (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.
04/04/2023	Added new indication for ROP.
10/02/2023	Added Eylea HD to policy name. Incorporated Eylea HD into policy. Noted that ROP and RVO indications are exclusive to Eylea (not HD).
11/08/2024	Annual review; no updates.

References:

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