Clinical Policy: Aflibercept (Eylea)

Reference Number: ERX.SPA.203
Effective Date: 01.11.17
Last Review Date: 11.17 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Aflibercept (Eylea®) is a vascular endothelial growth factor (VEGF) inhibitor.

FDA Approved Indication(s)
Eylea is indicated for the treatment of:
- Neovascular (wet) age-related macular degeneration (AMD)
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR) in patients with DME

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Eylea is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Macular Degeneration and Edema (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
   a. Neovascular (wet) AMD;
   b. Macular edema following RVO;
   c. DME;
   d. DR in the presence of DME;
2. Age ≥ 18 years;
3. Eylea will not be used concomitantly with other anti-VEGF medications;
4. Dose does not exceed (a or b):
   a. AMD: 2 mg (1 vial) every 4 weeks for the first 12 weeks, then every 8 weeks thereafter;
   b. DME and DR in the presence of DME: 2 mg (1 vial) every 4 weeks for the first 20 weeks, then every 8 weeks thereafter;
   c. RVO: 2 mg (1 vial) every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Macular Degeneration and Edema (must meet all)**:**

1. Previously received medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., detained neovascularization, improvement/stabilization of visual acuity, supportive findings on optical coherence tomography or fluorescein angiography);
3. Eylea is not being used concomitantly with other anti-VEGF medications;
4. If request is for a dose increase, new dose does not exceed (a or b):
   a. AMD, DME, and DR in the presence of DME: 2 mg (1 vial) every 8 weeks (*every 4 weeks may be approved upon submission of documentation supporting medical necessity*);

b. RVO: 2 mg (1 vial) every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AMD: age-related macular degeneration
DME: diabetic macular edema
DR: diabetic retinopathy
FDA: Food and Drug Administration
RVO: retinal vein occlusion
VEGF: vascular endothelial growth factor

Appendix B: Therapeutic Alternatives

N/A

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AMD	2 mg administered by intravitreal injection every 4 weeks for the first 12 weeks (3 months), followed by 2 mg every 8 weeks thereafter; some patients may need every 4 week dosing after the first 12 weeks (*caveat*: additional efficacy with every 4 week vs every 8 week dosing was not demonstrated in most patients)	2 mg/4 weeks
DME, DR in the presence of DME	2 mg administered by intravitreal injection every 4 weeks for the first 20 weeks (5 months), followed by 2 mg every 8 weeks thereafter; some patients may need every 4 week dosing after the first 20 weeks (*caveat*: additional efficacy with every 4 week vs every 8 week dosing was not demonstrated in most patients)	2 mg/4 weeks
RVO	2 mg administered by intravitreal injection every 4 weeks	2 mg/4 weeks

VI. Product Availability

Single-use vial for injection: 40 mg/mL

VII. References

1. Eylea Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; May 2017. Available at: www.eylea.com. Accessed September 12, 2017.
2. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; January 2015. Available at www.aao.org/ppp. Accessed February 27, 2017.
3. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; November 2015. Available at www.aao.org/ppp. Accessed February 27, 2017.
4. American Academy of Ophthalmology Retina/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; February 2016. Available at www.aao.org/ppp. Accessed February 27, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.16	01.17
4Q17 Annual Review Converted to new template. Specified max dosing by indication. For initial: Added age requirement. For re-auth: Modified "Currently receiving…" to "Previously received…" to account for as needed dosing; modified documentation of positive response criterion to be open-ended; added criterion to verify that Eylea is not being used with other anti-VEGF therapies.	09.21.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.