Clinical Policy: Aflibercept (Eylea)

Reference Number: PA.CP.PHAR.184
Effective Date: 01/18
Last Review Date: 07/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for aflibercept (Eylea®).

FDA Approved Indication(s)
Eylea is indicated for the treatment of patients with:

- 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
It is the policy of Pennsylvania Health and Wellness that Eylea is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ophthalmic Disease (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. Prescribed by or in consultation with an ophthalmologist;
3. Age ≥ 18 years;
4. For all indications except for DME in members with baseline visual acuity worse than 20/50: Failure of a trial of bevacizumab unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed:
   a. AMD: 2 mg (1 vial) via intravitreal injection every 4 weeks for the first 3 months, then every 8 weeks thereafter;
   b. DME, and DR in the presence of DME: 2 mg (1 vial) via intravitreal injection every 4 weeks for the first 5 injections, then every 8 weeks thereafter;
   c. RVO: 2 mg (1 vial) via intravitreal injection every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Ophthalmic Disease (must meet all)**:**

1. Previously received medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by one of the following (a, b, c, or d):
   a. Detained neovascularization;
   b. Improvement/stabilization in visual acuity;
   c. Maintenance of corrected visual acuity from prior treatment;
   d. Supportive findings from optical coherence tomography or fluorescein angiography;
3. If request is for a dose increase, new dose does not exceed:
   a. AMD, DME, and DR in the presence of DME: 2 mg (1 vial) via intravitreal injection every 8 weeks;
   b. RVO: 2 mg (1 vial) via intravitreal injection every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or

III. Refer to PA.CP.PMN.53 **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 policies – PA.CP.PMN.53 evidence of coverage document;

B. Concomitant use with other anti-vascular endothelial growth factor (VEGF) medications.

Background

Description/Mechanism of Action:

Eylea (aflibercept) is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PlGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PlGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors.

Formulations:
Single-use vial: 40 mg/mL solution

Appendices

Appendix A: Abbreviation Key

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

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0178	Injection, aflibercept, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Added bevacizumab redirection except for members with baseline visual acuity worse than 20/50 due to clinical superiority of Eylea. Moved initial and continued therapy criterion "not used concomitantly with other VEGF therapies" to section III. Diagnoses/indications NOT authorized. Added specialist requirement. Removed criteria checking for contraindications (ocular infections) due to its ophthalmic nature and addition of specialist requirement. Added age limit following safety guidance endorsed by Medical Affairs. References reviewed and updated.		

References

1. Eylea Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; May 2017. Available at: www.eylea.com. Accessed November 10, 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 November 10, 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 November 10, 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 November 10, 2017.
5. Wells JA, Glassman AR, Ayala AR, et al. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema. N Engl J Med. 2015 Mar 26;372(13):1193-203. doi: 10.1056/NEJMoa1414264