

## Clinical Policy: Aflibercept (Eylea)

Reference Number: CP.PHAR.184

Effective Date: 03/16

Last Review Date: 03/17

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

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

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Eylea is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

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

1. Member has one of the following diagnoses (a, b, c, or d):
  - 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) in the presence of DME;
2. Prescribed dose of Eylea does not exceed:
  - a. AMD: 2 mg (1 vial) every four weeks for the first 3 months, then every eight weeks thereafter;
  - b. RVO, DME, and DR in the presence of DME: 2 mg (1 vial) every four weeks;
3. Eylea will not be used concomitantly with other anti-vascular endothelial growth factor (VEGF) medications;
4. At the time of request, member has none of the following contraindications:
  - a. Ocular or periocular infection;
  - b. Active intraocular inflammation.

**Approval duration: 6 months**

**B. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

#### II. Continued Approval

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

1. Previously received medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response 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. Prescribed dose does not exceed:

- a. AMD: 2 mg (1 vial) every eight weeks (*every four weeks may be approved upon submission of documentation supporting medical necessity*);
- b. RVO, DME, and DR in the presence of DME: 2 mg (1 vial) every four weeks.

**Approval duration: 6 months**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

**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

*FDA Approved Indications:*

Eylea (aflibercept) is a VEGF inhibitor/solution for intravitreal injection 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

**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
Policy converted to new template and split from CP.PHAR.39 AMD Retinal Disorder Treatments. Criteria: added age and max dose; monotherapy defined as “other anti-VEGF drugs” since Visudyne sometimes used with anti-VEGF drugs in nonresponsive cases; removed requests for documentation.	03/16	03/16
Removed age requirement. Removed hypersensitivity safety criteria. For re-auth: modified “Currently receiving...” to “Previously received...”; 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.	03/17	03/17

**References**

1. Eylea Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2016. Available at: [www.eylea.com](http://www.eylea.com). Accessed February 27, 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](http://www.aao.org/ppp). Accessed February 24, 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](http://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](http://www.aao.org/ppp). Accessed February 27, 2017.

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or

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### Aflibercept

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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