

POLICY: Ophthalmology – Vascular Endothelial Growth Factor Inhibitors – Eylea® (aflibercept intravitreal injection – Regeneron)

APPROVAL DATE: 11/06/2019

OVERVIEW

Eylea, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy.¹ The recommended dose for Eylea is 2 mg administered by intravitreal injection. Frequency of the dose does vary depending on the condition, although all conditions state some patients may need upper limit dosing of once every 4 weeks (approximately every 25 days, monthly).

Other Uses with Supportive Evidence

Overproduction of VEGF may lead to other eye conditions, including neovascular glaucoma, retinopathy of prematurity, and other retinal and choroidal neovascular conditions affecting the eye, the VEGF inhibitors also have the potential to be used off-label and reduce vision loss associated with other eye conditions related to increased VEGF production.^{2,3} The use of anti-VEGF agents have been shown to stop the angiogenic process and maintain visual acuity and improve vision in patients with certain neovascular ophthalmic conditions; therefore, research is rapidly evolving on the use of VEGF inhibitors in other neovascular ophthalmic conditions which threaten vision.^{4,5} Anti-VEGF therapy has the potential to be used off-label in other neovascular conditions affecting the eye and may prevent or slow visual impairment.^{2,4,5}

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Eylea. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis, the injection technique required, and the monitoring required for adverse events and long-term efficacy, approval requires Eylea to be prescribed by or in consultation with an ophthalmologist.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Eylea is recommended in those who meet the following criteria.

FDA-Approved Indications

1. Neovascular (Wet) Age-Related Macular Degeneration. Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the requested dosing meets the following (A and B):

- A)** The dose is ≤ 2 mg administered by intravitreal injection for each eye being treated; AND
 - B)** The dosing interval is not more frequent than once every 25 days for each eye being treated.
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- 2. Macular Edema Following Retinal Vein Occlusion.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets both criteria (A and B):

- A) The dose is ≤ 2 mg administered by intravitreal injection for each eye being treated; AND
- B) The dosing interval is not more frequent than once every 25 days for each eye being treated.

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- 3. Diabetic Macular Edema.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets both criteria (A and B):

- A) The dose is ≤ 2 mg administered by intravitreal injection for each eye being treated; AND
- B) The dosing interval is not more frequent than once every 25 days for each eye being treated.

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- 4. Diabetic Retinopathy.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets both criteria (A and B):

- A) The dose is ≤ 2 mg administered by intravitreal injection for each eye being treated; AND
- B) The dosing interval is not more frequent than once every 25 days for each eye being treated.

Other Uses with Supportive Evidence

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- 5. Other Neovascular Ophthalmic Conditions.** Approve for 1 year if administered by or under the supervision of an ophthalmologist.

Dosing. Approve if the dose meets both criteria (A and B):

- A) The dose is ≤ 2 mg administered by intravitreal injection for each eye being treated; AND
- B) The dosing interval is not more frequent than once every 25 days for each eye being treated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Eylea has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Eylea® injection [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; May 2019.
2. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs*. 2009;18(5):637-646.
3. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol*. 2011;56(2):95-113.
4. Kinnunen K, Ylä-Herttua S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med*. 2012;44(1):1-17.
5. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol*. 2010;21(2):112-117.

HISTORY

Type of Revision	Summary of Changes	Approval Date
New policy	--	11/14/2018
Selected revision	For Eylea, the condition, Diabetic retinopathy in patients with Diabetic Macular Edema, was update to include all patients with Diabetic Retinopathy. Previously the product was only indicated to treatment Diabetic Retinopathy in patients who also had DME.	5/22/2019
Annual revision	The dosing in the approval conditions for Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy, and Other Neovascular Ophthalmic Conditions was changed from “the dose is 2 mg” to “The dose is \leq 2 mg”.	11/06/2019