

SPECIALTY GUIDELINE MANAGEMENT

EYLEA (aflibercept)
EYLEA HD (aflibercept)
OPUVIZ (aflibercept-yszy)
YESAFILI (aflibercept-jbvf)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Eylea is indicated for the treatment of:

- A. Diabetic macular edema
- B. Diabetic retinopathy
- C. Neovascular (wet) age-related macular degeneration
- D. Macular edema following retinal vein occlusion
- E. Retinopathy of Prematurity

Eylea HD is indicated for the treatment of:

- A. Diabetic macular edema
- B. Diabetic retinopathy
- C. Neovascular (wet) age-related macular degeneration

Opuviz and Yesafili are indicated for the treatment of:

- A. Diabetic macular edema
- B. Diabetic retinopathy
- C. Neovascular (wet) age-related macular degeneration
- D. Macular edema following retinal vein occlusion

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Diabetic Macular Edema

Authorization of 6 months may be granted for treatment of diabetic macular edema.

B. Diabetic Retinopathy

Authorization of 6 months may be granted for treatment of diabetic retinopathy.

C. Neovascular (Wet) Age-Related Macular Degeneration

Authorization of 6 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

D. Macular Edema Following Retinal Vein Occlusion (Eylea and Biosimilars Only)

Reference number(s)
2024-A

Authorization of 6 months may be granted for treatment of macular edema following retinal vein occlusion.

E. Retinopathy of Prematurity (Eylea and Biosimilars Only)

Authorization of 6 months may be granted for treatment of retinopathy of prematurity.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when the member has demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

IV. REFERENCES

1. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
2. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
3. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp>.
4. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp>.
5. American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions. San Francisco, CA: American Academy of Ophthalmology; 2019. Available at: <https://www.aao.org/preferred-practice-pattern/retinal-vein-occlusions-ppp>.
6. Opuviz [package insert]. Cambridge, MA: Biogen MA Inc.; May 2024.
7. Yesafili [package insert]. Cambridge, MA: Biocon Biologics Inc.; May 2024.