

Standard Medicare Part B Management

Eylea-Eylea HD

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Eylea	aflibercept
Eylea HD	aflibercept
Ahzantive	aflibercept-mrbb
Enzeevu	aflibercept-abzv
Opuviz	aflibercept-yszy
Pavblu	aflibercept-ayyh
Yesafili	aflibercept-jbvf

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

Eylea is indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion
- Diabetic macular edema
- Diabetic retinopathy
- Retinopathy of Prematurity

Reference number(s)
2507-A

Eylea HD

Eylea HD is indicated for the treatment of:

- Diabetic macular edema
- Diabetic retinopathy
- Neovascular (wet) age-related macular degeneration

Ahzantive, Opuviz, Pavblu, Yesafili

Ahzantive, Opuviz, Pavblu and Yesafili are indicated for the treatment of:

- Diabetic macular edema
- Diabetic retinopathy
- Neovascular (wet) age-related macular degeneration
- Macular edema following retinal vein occlusion

Enzeevu

Enzeevu is indicated for the treatment of:

- Neovascular (wet) age-related macular degeneration

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Diabetic Macular Edema

Authorization of 12 months may be granted for treatment of diabetic macular edema.

Diabetic Retinopathy

Authorization of 12 months may be granted for treatment of diabetic retinopathy.

Neovascular (Wet) Age-Related Macular Degeneration

Authorization of 12 months may be granted for treatment of neovascular (wet) age-related macular degeneration.

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

Authorization of 12 months may be granted for treatment of macular edema following retinal vein occlusion.

Retinopathy of Prematurity (Eylea and Biosimilars Only)

Authorization of 12 months may be granted for treatment of retinopathy of prematurity.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when ALL of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or vision field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Eylea, Eylea HD, Ahzantive, Enzeevu, Opuviz, Pavblu and Yesafili.
- The available compendium
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - Micromedex DrugDex
 - American Hospital Formulary Service- Drug Information (AHFS-DI)
 - Lexi-Drugs
 - Clinical Pharmacology
- American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Diabetic Retinopathy.
- American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration.
- American Academy of Ophthalmology Retinal/Vitreous Panel. Preferred Practice Pattern® Guidelines. Retinal Vein Occlusions.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Eylea, Eylea HD, Ahzantive, Enzeevu, Opuviz, Pavblu and Yesafili.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Reference number(s)
2507-A

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.
8. Ahzantive [package insert]. Martinsried/Planegg, Germany: Formycon AG; June 2024.
9. Enzeevu [package insert]. Princeton, NJ: Sandoz Inc.; August 2024.
10. Pavblu [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2024.