

## Aflibercept (Eylea<sup>®</sup>, Eylea HD<sup>®</sup>, Pavblu<sup>™</sup>, Yesafili<sup>™</sup>) Injection

When requesting an aflibercept product, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines for the covered indication.

### FDA-Approved Indications

Eylea, Pavblu, and Yesafili are 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)
- Retinopathy of prematurity (ROP)

Eylea HD is indicated for the treatment of patients with:

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

### Approved Off-Label Compendial Uses

#### Eylea, Eylea HD, Pavblu, and Yesafili

- Other neovascular ophthalmic conditions (e.g., angioid streaks, iris neovascularization, neovascular glaucoma, pachychoroid neovascularopathy, polypoidal choroidal vasculopathy, and presumed ocular histoplasmosis syndrome)

### Coverage Guidelines

#### Eylea, Pavblu, and Yesafili

For all approved indications the individual must meet the following criteria for approval:

- Administered by or under the supervision of an ophthalmologist.

#### Eylea HD

For all approved indications the individual must meet the following criteria for approval:

- Administered by or under the supervision of an ophthalmologist.

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Approval duration (Eylea, Eylea HD, Pavblu, and Yesafili): 12 months

## Dosing Recommendations

### Eylea, Pavblu, and Yesafili

#### Neovascular (Wet) Age-Related Macular Degeneration (AMD)

The recommended dose is 2 mg administered by intravitreal injection every 4 weeks for the first 3 months, followed by 2 mg via intravitreal injection once every 8 weeks.

#### Macular Edema Following Retinal Vein Occlusion (RVO)

The recommended dose is 2 mg administered by intravitreal injection once every 4 weeks.

#### Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

The recommended dose is 2 mg administered by intravitreal injection every 4 weeks for the first 5 injections followed by 2 mg via intravitreal injection once every 8 weeks.

#### Retinopathy of Prematurity (ROP)

The recommended dose is 0.4 mg administered by intravitreal injection. The treatment interval between doses injected into the same eye should be at least 10 days.

### Eylea HD

#### Neovascular (Wet) Age-related Macular Degeneration (nAMD)

- The recommended dose is 8 mg administered by intravitreal injection every 4 weeks for the first 3 doses, followed by 8 mg via intravitreal injection once every 8 to 16 weeks.
- Some patients did not maintain a response with 8mg once every 8 to 16 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).
- Extended dosing intervals (8mg once every 20 weeks, +/- 1 week) may be considered after one year of successful response based on visual and anatomic outcomes.

#### Diabetic Macular Edema

- The recommended dose is 8 mg administered by intravitreal injection every 4 weeks for the first 3 doses, followed by 8 mg via intravitreal injection once every 8 to 16 weeks.
- Some patients did not maintain a response with 8mg once every 8 to 16 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

- Extended dosing intervals (8mg once every 20 weeks, +/- 1 week) may be considered after one year of successful response based on visual and anatomic outcomes.

#### Diabetic Retinopathy

- The recommended dose is 8 mg administered by intravitreal injection every 4 weeks for first 3 doses, followed by 8 mg via intravitreal injection once every 8 to 12 weeks.
- Some patients did not maintain a response with 8mg once every 8 to 12 weeks, +/- 1 week, after successful response to the three initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

#### Macular Edema following Retinal Vein Occlusion (RVO)

- The recommended dose is 8 mg administered by intravitreal injection every 4 weeks for first 3 to 5 doses, followed by 8 mg via intravitreal injection once every 8 weeks.
- Some patients did not maintain a response with extended dosing intervals after successful response to the first three to five initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

### References

1. Eylea® injection [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2024.
2. Eylea® HD intravitreal injection [prescribing information]. Tarrytown, NY: Regeneron; April 2026.
3. Pavblu™ intravitreal injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2026.
4. Yesafili™ intravitreal injection [prescribing information]. Cambridge, MA: Biocon Biologics; January 2026.
5. Hang A, Feldman S, Amin AP, et al. Intravitreal anti-vascular endothelial growth factor therapies for retinal disorders. *Pharmaceuticals*. 2023;16:1140. Doi.org/10.3390/ph16081140.