GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

EYLEA® *(aflibercept)* injection, for intravitreal use
EYLEA HD® *(aflibercept)* injection, for intravitreal use
PAVBLU *(aflibercept-ayyh)* injection, for intravitreal use

PA Criteria	Criteria Details
Description	Aflibercept is a vascular endothelial growth factor (VEGF) inhibitor.
Covered Uses (FDA approved indication)	**EYLEA/PAVBLU** (biosimilar) are indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (nAMD) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Macular Edema Following Retinal Vein Occlusion (RVO) **EYLEA** is also indicated for treatment of Retinopathy of Prematurity (ROP) **EYLEA HD** is indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (nAMD) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Macular Edema Following Retinal Vein Occlusion (RVO)
Dosing and Administration	**Neovascular (Wet) Age-Related Macular Degeneration (nAMD)** **EYLEA/PAVBLU:** • 2 mg via intravitreal injection every four weeks (approximately every 28 days, monthly) for the first three months, followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every eight weeks (two months) • Some patients may need every four-week (monthly) dosing after the first 12 weeks (three months) • Patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly **EYLEA HD:** • 8 mg via intravitreal injection every four weeks (approximately every 28 days +/- seven days) for the first three doses, followed by 8 mg via intravitreal injection once every eight to 16 weeks, +/- one week. • Some patients did not maintain a response with extended dosing intervals after successful response to the three initial monthly doses. These patients may benefit from resuming every four-week dosing (approximately every 28 days +/- seven days). **Macular Edema Following Retinal Vein Occlusion (RVO)** **EYLEA/PAVBLU:** • 2 mg (0.05 mL of 40 mg/mL solution) intravitreal injection once every four weeks (approximately every 25 days, monthly) **EYLEA HD:** • 8 mg via intravitreal injection every four weeks (approximately every 28 days +/- seven days) for the first three to five doses, followed by 8 mg via intravitreal injection once every eight weeks, +/- one week • 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 four-week dosing (approximately every 28 days +/- seven days).

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

EYLEA/PAVBLU:

- 2 mg via intravitreal injection every four weeks (approximately every 28 days, monthly) for the first five injections followed by 2 mg via intravitreal injection once every eight weeks (two months).
- EYLEA HD:
- DME: 8 mg via intravitreal injection every four weeks (approximately every 28 days +/- 7 days) for the first three doses, followed by 8 mg via intravitreal injection once every 8 to 16 weeks, +/- 1 week
- DR: 8 mg via intravitreal injection every 4 weeks (approximately every 28 days +/- 7 days) for the first 3 doses, followed by 8 mg via intravitreal injection once every 8 to 12 weeks, +/- 1 week
- Some patients did not maintain a response with extended dosing intervals after successful response to the 3 initial monthly doses. These patients may benefit from resuming every 4-week dosing (approximately every 28 days +/- 7 days).

Retinopathy of Prematurity (ROP)

EYLEA only:

- 0.4 mg via intravitreal injection. Treatment may be given bilaterally on the same day. Injections may be repeated in each eye. The treatment interval between doses injected into the same eye should be at least 10 days.
- In infants with ROP, treatment with EYLEA will necessitate extended periods of ROP monitoring.

Billing and Coding Information

	10-digit NDC	11-digit NDC
EYLEA SDV	61755-005-02	61755-0005-02
EYLEA PF syringe	61755-005-01	61755-0005-01
EYLEA HD	61755-050-01	61755-0050-01
PAVBLU SDV	55513-065-01	55513-0065-01
PAVBLU PF syringe	55513-056-01	55513-0056-01

	HCPCS Code	Description
EYLEA	J0178	Injection, aflibercept, 1 mg
PAVBLU	Q5147	Injection, aflibercept-ayyh, biosimilar, 1 mg
EYLEA HD	J0177	Injection, aflibercept HD, 1 mg

CPT Procedural Codes	Description
67028	Intravitreal injection of a pharmacologic agent (separate procedure)

Product Availability

EYLEA:

- Single-dose vial: 2 mg (0.05 mL of 40 mg/mL) solution for intravitreal injection
- Single-dose Prefilled Syringe: 2 mg (0.05 mL of 40 mg/mL) solution for intravitreal injection

EYLEA HD:

- Single-dose vial -- 8 mg (0.07 mL of 114.3 mg/mL) solution for intravitreal injection

PAVBLU:

- Single-dose vial: 2 mg/0.05 mL solution for intravitreal injection
- Single-dose Prefilled Syringe: 2 mg/0.05 mL solution for intravitreal injection

	• Prolia: 60 mg/mL (1 mL) • Stoboclo: Denosumab-bmwo 60 mg/mL (1 mL)
Contraindications	• Ocular or periocular infection • Active intraocular inflammation • Hypersensitivity
Recommended Medical Monitoring	EYLEA, PAVBLU and EYLEA HD have been associated with: • Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion • Increases in intraocular pressure within 60 minutes of intravitreal injection • Potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.
Approval Criteria	**EYLEA/PAVBLU** a. Physician administered intravitreal injection; in-office or HOPD i. Cannot be self-administered b. Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (must meet all): i. Diagnosis of nAMD ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 2 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 25 days for each eye being treated c. Macular Edema Following Retinal Vein Occlusion (RVO) (must meet all): i. Diagnosis of RVO ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 2 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 25 days for each eye being treated. d. Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR) (must meet all): i. Diagnosis of DME or DR ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 2 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 25 days for each eye being treated. **EYLEA ONLY** a. Physician administered intravitreal injection; in-office or HOPD i. Cannot be self-administered b. b. Retinopathy of Prematurity (ROP) (must meet all) i. Diagnosis of RVO ii. Prescribed by or in consultation with a pediatric ophthalmologist iii. The dose is 0.4 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 10 days for each eye being treated

	EYLEA HD a. Physician administered intravitreal injection; in-office or HOPD i. Cannot be self-administered b. Neovascular (Wet) Age-Related Macular Degeneration (nAMD) (must meet all): i. Diagnosis of nAMD ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 8 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 21 days for three doses, followed by not more frequent than once every 7 weeks for each eye being treated c. Macular Edema Following Retinal Vein Occlusion (RVO) (must meet all): i. Diagnosis of RVO ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 8 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 21 days for three doses, followed by not more frequent than once every 7 weeks for each eye being treated. d. Diabetic Macular Edema (DME) or Diabetic Retinopathy (DR) (must meet all): i. Diagnosis of DME or DR ii. Prescribed by or in consultation with an ophthalmologist iii. The dose is 8 mg administered by intravitreal injection for each eye being treated iv. The dosing interval is not more frequent than once every 21 days for three doses, followed by not more frequent than once every 7 weeks for each eye being treated.
Age Restriction	Adults ≥ 18 years old • Neovascular (Wet) Age-Related Macular Degeneration (nAMD) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Macular Edema Following Retinal Vein Occlusion (RVO) Infants born before 31 weeks gestation or weighing < 3.3 lbs: • Retinopathy of Prematurity (ROP)
Coverage Duration	**Initial**: six months. **Reauthorization**: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/20/26	1/20/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26