PAVBLU™
(aflibercept-ayyh)
Injection 2mg

# Resource Guide

PAVBLU™ is a biosimilar to EYLEA® (aflibercept) backed by Amgen's expertise

## INDICATIONS

PAVBLU™ (aflibercept-ayyh) is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

- PAVBLU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in PAVBLU.

PAVBLU™ is not indicated for Retinopathy of Prematurity, for which Regeneron has marketing exclusivity.

Please see **full Important Safety Information** and click here for **full Prescribing Information**.

AMGEN

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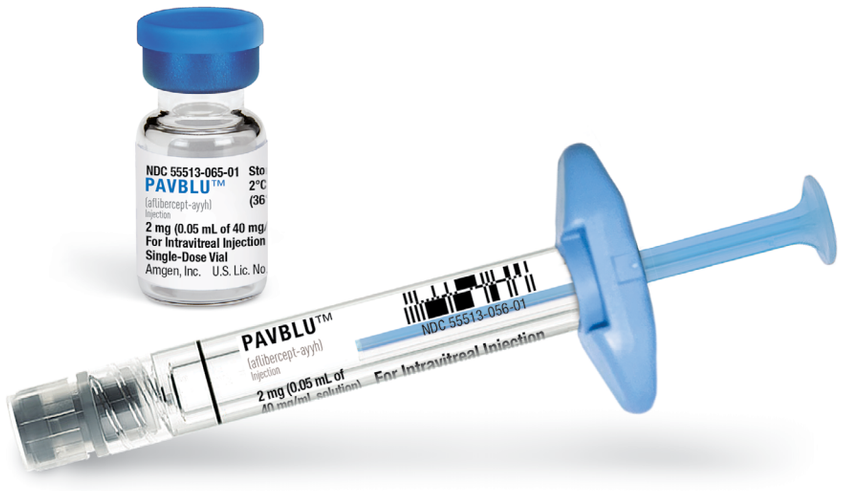
**Amgen provides access support and helpful resources for PAVBLU™**




## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with aflibercept products, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering PAVBLU. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.

 Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# HOW SUPPLIED & STORAGE AND HANDLING

## HOW SUPPLIED

PAVBLU™ is a sterile, clear to opalescent and colorless to slightly yellow solution supplied in the following presentations:

- **One blister pack** containing one 2 mg (0.05 mL of a 40-mg/mL solution) sterile, single-dose prefilled plastic syringe (NDC 55513-056-01)
- **One 2 mg** (0.05 mL of a 40-mg/mL solution) single-dose glass vial (NDC 55513-065-01)

## STORAGE AND HANDLING

- Refrigerate at 2° to 8°C (36° to 46°F) in the original carton until time of use. PAVBLU™ may be kept at room temperature (up to 30°C (86°F)) for a single-period of 3 days
- Do not freeze
- Do not use beyond the date stamped on the carton and container label
- Store in the original carton until time of use to protect from light
- Do not open sealed blister tray until time of use

# DOSAGE AND ADMINISTRATION

## IMPORTANT INJECTION INSTRUCTIONS

Administer only as an ophthalmic intravitreal injection. PAVBLU™ must only be administered by a qualified physician.

- Prefilled syringe: A 30-gauge x 1/2-inch sterile injection needle is needed but not provided
- Vial: A 5-micron sterile filter needle (18-gauge x 1 1/2-inch), a 1-mL Luer lock syringe, and a 30-gauge x 1/2-inch sterile injection needle are needed but not provided

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

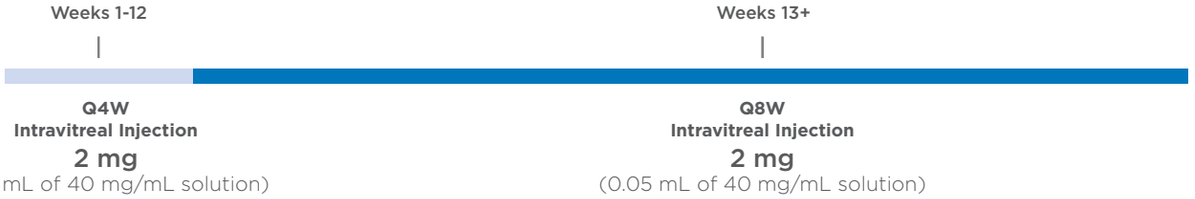
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with aflibercept products. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

PAVBLU™ (aflibercept-ayyh) Injection 2mg

Please see **full Important Safety Information** and click here for **full Prescribing Information.**

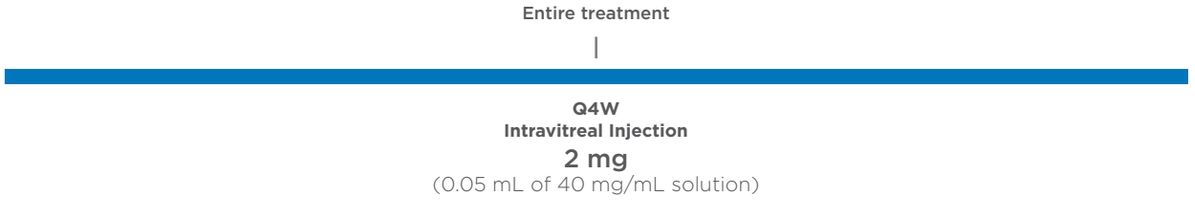
## RECOMMENDED DOSES AND SCHEDULES

### NEOVASCULAR (WET) AGE-RELATED MACULAR DEGENERATION (AMD)

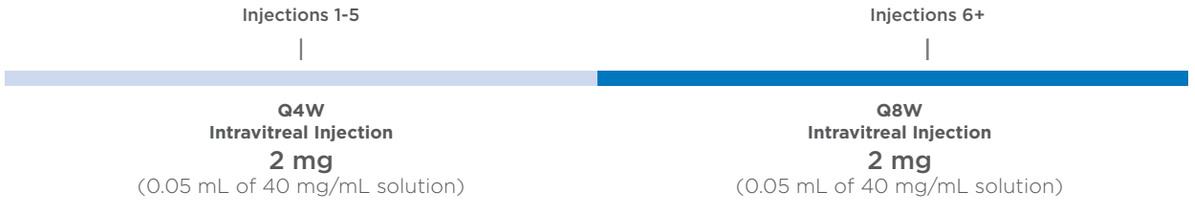



- Although PAVBLU™ may be dosed as frequently as 2 mg every 4 weeks, additional efficacy was not demonstrated in most patients when aflibercept was dosed every 4 weeks compared to every 8 weeks
- Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months)
- Although not as effective as the recommended every 8 week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy
- Patients should be assessed regularly

### MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO)

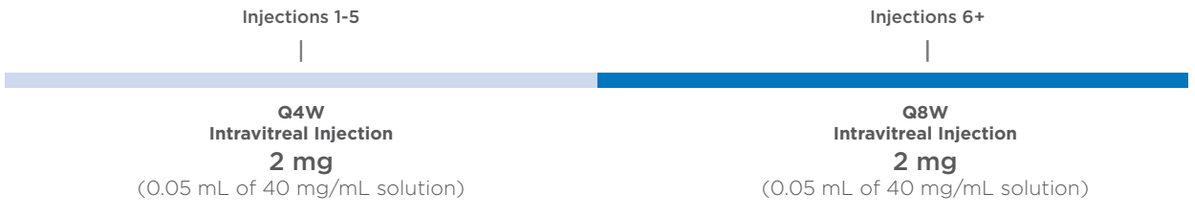



### DIABETIC MACULAR EDEMA (DME)




- Although PAVBLU™ may be dosed as frequently as 2 mg every 4 weeks, additional efficacy was not demonstrated in most patients when aflibercept was dosed every 4 weeks compared to every 8 weeks
- Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months)

### DIABETIC RETINOPATHY (DR)




- Although PAVBLU™ may be dosed as frequently as 2 mg every 4 weeks, additional efficacy was not demonstrated in most patients when aflibercept was dosed every 4 weeks compared to every 8 weeks
- Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months)

Q4W = every 4 weeks; Q8W = every 8 weeks; Q12W = every 12 weeks.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including aflibercept products. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).


Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# BILLING AND CODING

## CODING INFORMATION

| | |
|---|---|
| **NDC** | Prefilled syringe: NDC 55513-056-01<br>Single-dose vial: NDC 55513-065-01 |
| **HCPCS CODES** | Report PAVBLU™ using an appropriate unclassified code until a permanent HCPCS code has been established:<br>**J3590:** Unclassified biologics<br>**J3490:** Unclassified drugs<br>**C9399:** Unclassified drugs or biologicals (Medicare hospital outpatient claims only) |
| **CPT** | **67028:** Intravitreal injection of a pharmacologic agent (separate procedure) |
| | Modifier **LT:** left eye injection **RT:** right eye injection **50:** bilateral injection |
| **REVENUE CODES*** | **Medicare:** 0636 (Drugs requiring detailed coding)<br>**Other payers:** 0250 (General pharmacy) or 0636, if required by a given payer |
| **MODIFIERS** | **JW modifier:** Drug amount discarded/not administered to any patient |
| | **JZ modifier:** Zero drug amount discarded/not administered to any patient |

*Revenue codes are only required on the CMS 1450 claim form.

## NEOVASCULAR WET AGE-RELATED MACULAR DEGENERATION (AMD)

| | Exudative age-related macular degeneration | Right Eye | Left Eye | Bilateral | Unspecified Eye |
|---|---|---|---|---|---|
| **ICD-10-CM** | With active choroidal neovascularization | **H35.3211** | **H35.3221** | **H35.3231** | **H35.3291** |
| | With inactive choroidal neovascularization | **H35.3212** | **H35.3222** | **H35.3232** | **H35.3292** |
| | With inactive scar | **H35.3213** | **H35.3223** | **H35.3233** | **H35.3293** |
| | Stage unspecified | **H35.3210** | **H35.3220** | **H35.3230** | **H35.3290** |

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this document be considered a guarantee of coverage or reimbursement for any product or service.

NDC = national drug code; HCPCS = Healthcare Common Procedure Coding System; CPT = Current Procedural Terminology; ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification; FAR/DFARS = Federal Acquisition Regulation/Defense Federal Acquisition Regulation Supplement.



## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with aflibercept compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the aflibercept group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with aflibercept compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with aflibercept compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with aflibercept in the first six months of the RVO studies.

Please see **full Important Safety Information** and click here for **full Prescribing Information.**

PAVBLU™ (aflibercept-ayyh) Injection 2mg

# BILLING AND CODING (cont'd)

## MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO)

| | | | | | |
|---|---|---|---|---|---|
| ICD-10-CM | **Central retinal vein occlusion** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | With macular edema | **H34.8110** | **H34.8120** | **H34.8130** | **H34.8190** |
| | **Tributary (branch) retinal vein occlusion** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | With macular edema | **H34.8310** | **H34.8320** | **H34.8330** | **H34.8390** |

## DIABETIC MACULAR EDEMA (DME)

| | | | | | |
|---|---|---|---|---|---|
| ICD-10-CM | **Diabetes mellitus due to underlying condition with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy with macular edema | **E08.3211** | **E08.3212** | **E08.3213** | **E08.3219** |
| | Moderate nonproliferative diabetic retinopathy with macular edema | **E08.3311** | **E08.3312** | **E08.3313** | **E08.3319** |
| | Severe nonproliferative diabetic retinopathy with macular edema | **E08.3411** | **E08.3412** | **E08.3413** | **E08.3419** |
| | Proliferative diabetic retinopathy with macular edema | **E08.3511** | **E08.3512** | **E08.3513** | **E08.3519** |
| | Unspecified diabetic retinopathy with macular edema | **E08.311** | | | |
| | **Drug or chemical induced diabetes mellitus with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy with macular edema | **E09.3211** | **E09.3212** | **E09.3213** | **E09.3219** |
| | Moderate nonproliferative diabetic retinopathy with macular edema | **E09.3311** | **E09.3312** | **E09.3313** | **E09.3319** |
| | Severe nonproliferative diabetic retinopathy with macular edema | **E09.3411** | **E09.3412** | **E09.3413** | **E09.3419** |
| | Proliferative diabetic retinopathy with macular edema | **E09.3511** | **E09.3512** | **E09.3513** | **E09.3519** |
| | Unspecified diabetic retinopathy with macular edema | **E09.311** | | | |

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with aflibercept including endophthalmitis and retinal detachment.



Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# BILLING AND CODING (cont'd)

## DIABETIC MACULAR EDEMA (DME) (cont'd)

| | Type 1 diabetes mellitus with | Right Eye | Left Eye | Bilateral | Unspecified Eye |
|---|---|---|---|---|---|
| ICD-10-CM | Mild nonproliferative diabetic retinopathy with macular edema | E10.3211 | E10.3212 | E10.3213 | E10.3219 |
| | Moderate nonproliferative diabetic retinopathy with macular edema | E10.3311 | E10.3312 | E10.3313 | E10.3319 |
| | Severe nonproliferative diabetic retinopathy with macular edema | E10.3411 | E10.3412 | E10.3413 | E10.3419 |
| | Proliferative diabetic retinopathy with macular edema | E10.3511 | E10.3512 | E10.3513 | E10.3519 |
| | Unspecified diabetic retinopathy with macular edema | E10.311 | | | |
| | **Type 2 diabetes mellitus with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy with macular edema | E11.3211 | E11.3212 | E11.3213 | E11.3219 |
| | Moderate nonproliferative diabetic retinopathy with macular edema | E11.3311 | E11.3312 | E11.3313 | E11.3319 |
| | Severe nonproliferative diabetic retinopathy with macular edema | E11.3411 | E11.3412 | E11.3413 | E11.3419 |
| | Proliferative diabetic retinopathy with macular edema | E11.3511 | E11.3512 | E11.3513 | E11.3519 |
| | Unspecified diabetic retinopathy with macular edema | E11.311 | | | |
| | **Other specified diabetes mellitus with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy with macular edema | E13.3211 | E13.3212 | E13.3213 | E13.3219 |
| | Moderate nonproliferative diabetic retinopathy with macular edema | E13.3311 | E13.3312 | E13.3313 | E13.3319 |
| | Severe nonproliferative diabetic retinopathy with macular edema | E13.3411 | E13.3412 | E13.3413 | E13.3419 |
| | Proliferative diabetic retinopathy with macular edema | E13.3511 | E13.3512 | E13.3513 | E13.3519 |
| | Unspecified diabetic retinopathy with macular edema | E13.311 | | | |

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS (cont'd)

- The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

PAVBLU™ (aflibercept-ayyh) Injection 2mg

Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# BILLING AND CODING (cont'd)

## DIABETIC RETINOPATHY (DR)

| | Diabetes mellitus due to underlying condition with | Right Eye | Left Eye | Bilateral | Unspecified Eye |
|---|---|---|---|---|---|
| ICD-10-CM | Mild nonproliferative diabetic retinopathy without macular edema | E08.3291 | E08.3292 | E08.3293 | E08.3299 |
| | Moderate nonproliferative diabetic retinopathy without macular edema | E08.3391 | E08.3392 | E08.3393 | E08.3399 |
| | Severe nonproliferative diabetic retinopathy without macular edema | E08.3491 | E08.3492 | E08.3493 | E08.3499 |
| | Proliferative diabetic retinopathy with traction retinal detachment involving the macula | E08.3521 | E08.3522 | E08.3523 | E08.3529 |
| | Proliferative diabetic retinopathy with traction retinal detachment not involving the macula | E08.3531 | E08.3532 | E08.3533 | E08.3539 |
| | Proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment | E08.3541 | E08.3542 | E08.3543 | E08.3549 |
| | Stable proliferative diabetic retinopathy | E08.3551 | E08.3552 | E08.3553 | E08.3559 |
| | Proliferative diabetic retinopathy without macular edema | E08.3591 | E08.3592 | E08.3593 | E08.3599 |
| | Unspecified diabetic retinopathy without macular edema | E08.319 | | | |
| | **Drug or chemical induced diabetes mellitus with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy without macular edema | E09.3291 | E09.3292 | E09.3293 | E09.3299 |
| | Moderate nonproliferative diabetic retinopathy without macular edema | E09.3391 | E09.3392 | E09.3393 | E09.3399 |
| | Severe nonproliferative diabetic retinopathy without macular edema | E09.3491 | E09.3492 | E09.3493 | E09.3499 |
| | Proliferative diabetic retinopathy with traction retinal detachment involving the macula | E09.3521 | E09.3522 | E09.3523 | E09.3529 |
| | Proliferative diabetic retinopathy with traction retinal detachment not involving the macula | E09.3531 | E09.3532 | E09.3533 | E09.3539 |
| | Proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment | E09.3541 | E09.3542 | E09.3543 | E09.3549 |
| | Stable proliferative diabetic retinopathy | E09.3551 | E09.3552 | E09.3553 | E09.3559 |
| | Proliferative diabetic retinopathy without macular edema | E09.3591 | E09.3592 | E09.3593 | E09.3599 |
| | Unspecified diabetic retinopathy without macular edema | E09.319 | | | |

## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS (cont'd)

- Patients may experience temporary visual disturbances after an intravitreal injection with PAVBLU and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.



Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# BILLING AND CODING (cont'd)

## DIABETIC RETINOPATHY (DR)

| ICD-10-CM | Type 1 diabetes mellitus with | Right Eye | Left Eye | Bilateral | Unspecified Eye |
|---|---|---|---|---|---|
| | Mild nonproliferative diabetic retinopathy without macular edema | E10.3291 | E10.3292 | E10.3293 | E10.3299 |
| | Moderate nonproliferative diabetic retinopathy without macular edema | E10.3391 | E10.3392 | E10.3393 | E10.3399 |
| | Severe nonproliferative diabetic retinopathy without macular edema | E10.3491 | E10.3492 | E10.3493 | E10.3499 |
| | Proliferative diabetic retinopathy with traction retinal detachment involving the macula | E10.3521 | E10.3522 | E10.3523 | E10.3529 |
| | Proliferative diabetic retinopathy with traction retinal detachment not involving the macula | E10.3531 | E10.3532 | E10.3533 | E10.3539 |
| | Proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment | E10.3541 | E10.3542 | E10.3543 | E10.3549 |
| | Stable proliferative diabetic retinopathy | E10.3551 | E10.3552 | E10.3553 | E10.3559 |
| | Proliferative diabetic retinopathy without macular edema | E10.3591 | E10.3592 | E10.3593 | E10.3599 |
| | Unspecified diabetic retinopathy without macular edema | E10.319 | | | |
| | **Type 2 diabetes mellitus with** | **Right Eye** | **Left Eye** | **Bilateral** | **Unspecified Eye** |
| | Mild nonproliferative diabetic retinopathy without macular edema | E11.3291 | E11.3292 | E11.3293 | E11.3299 |
| | Moderate nonproliferative diabetic retinopathy without macular edema | E11.3391 | E11.3392 | E11.3393 | E11.3399 |
| | Severe nonproliferative diabetic retinopathy without macular edema | E11.3491 | E11.3492 | E11.3493 | E11.3499 |
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## IMPORTANT SAFETY INFORMATION (cont'd)

### CONTRAINDICATIONS

- PAVBLU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in PAVBLU.

PAVBLU™ (aflibercept-ayyh) Injection 2mg

Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# BILLING AND CODING (cont'd)

## DIABETIC RETINOPATHY (DR)

| | Other specified diabetes mellitus with | Right Eye | Left Eye | Bilateral | Unspecified Eye |
|---|---|---|---|---|---|
| ICD-10-CM | Mild nonproliferative diabetic retinopathy without macular edema | E13.3291 | E13.3292 | E13.3293 | E13.3299 |
| | Moderate nonproliferative diabetic retinopathy without macular edema | E13.3391 | E13.3392 | E13.3393 | E13.3399 |
| | Severe nonproliferative diabetic retinopathy without macular edema | E13.3491 | E13.3492 | E13.3493 | E13.3499 |
| | Proliferative diabetic retinopathy with traction retinal detachment involving the macula | E13.3521 | E13.3522 | E13.3523 | E13.3529 |
| | Proliferative diabetic retinopathy with traction retinal detachment not involving the macula | E13.3531 | E13.3532 | E13.3533 | E13.3539 |
| | Proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment | E13.3541 | E13.3542 | E13.3543 | E13.3549 |
| | Stable proliferative diabetic retinopathy | E13.3551 | E13.3552 | E13.3553 | E13.3559 |
| | Proliferative diabetic retinopathy without macular edema | E13.3591 | E13.3592 | E13.3593 | E13.3599 |
| | Unspecified diabetic retinopathy without macular edema | E13.319 | | | |

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with aflibercept products, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering PAVBLU. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.

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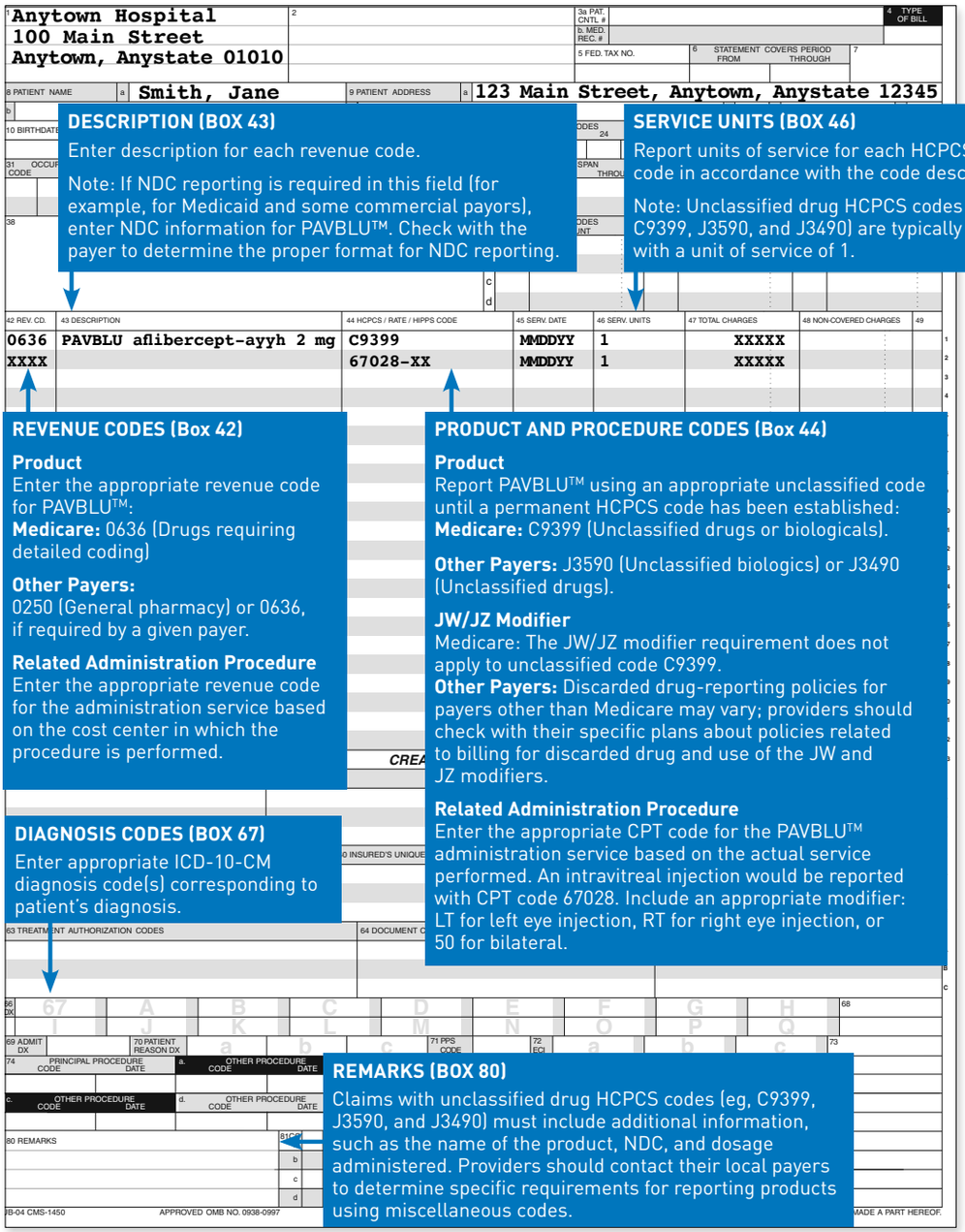
# HOSPITAL CODING FORM

## The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration




This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

CMS = Centers for Medicare & Medicaid Services.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with aflibercept products. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

PAVBLU™ (aflibercept-ayyh) Injection 2mg

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# PHYSICIAN CODING FORM

## The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration

### Box 19, Additional Claim Information

Claims with unclassified drug HCPCS codes (eg, J3590 and J3490) must include additional information, such as the name of the product, NDC, and dosage administered. Providers should contact their local payers to determine specific requirements for reporting products using miscellaneous codes.

### Box 21, Diagnosis Code

Enter the appropriate ICD-10-CM code for the patient's diagnosis/condition.

### Box 24A, Dates of Service

If NDC reporting is required in this field (for example, for Medicaid and some commercial payers), enter NDC information for PAVBLU™ in the shaded portion. Check with the payer to determine the proper format for NDC reporting.*

### Box 24D, Procedures, Services, or Supplies Product

Report PAVBLU™ using an appropriate unclassified code until a permanent HCPCS code has been established: J3590 (Unclassified biologics) or J3490 (Unclassified drugs).

**JW/JZ Modifier**

Medicare: Under Medicare's discarded drug policy, claims for drugs from single-dose containers require use of the JW modifier (Drug amount discarded/not administered to any patient) or JZ modifier (Zero drug amount discarded/not administered to any patient). When reporting a miscellaneous drug code (eg, J3590 or J3490) with a unit of service of 1, the JZ modifier would be appropriate.

**Other Payers:** Discarded drug reporting policies for payers other than Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

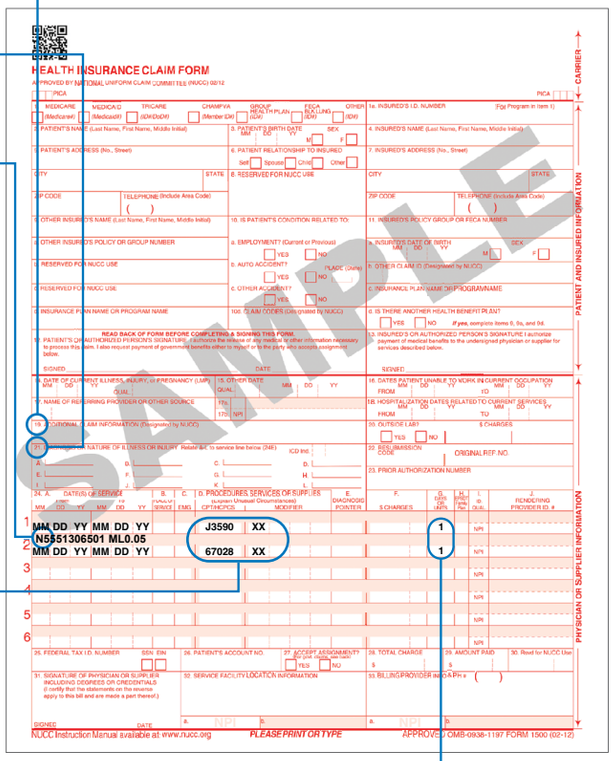
**Related Administration Procedure**

Enter the appropriate CPT code for the PAVBLU™ administration service based on the actual service performed. An intravitreal injection would be reported with CPT code 67028. Include an appropriate modifier: LT for left eye injection, RT for right eye injection, or 50 for bilateral injection.

### Box 24G, Days or Units

Report units of service for each HCPCS or CPT code in accordance with the code descriptor.

Note: Unclassified drug HCPCS codes (eg, C9399, J3590, and J3490) are typically reported with a unit of service of 1.




This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

*Some payers require the 10-digit NDC for PAVBLU™ (55513-056-01 for the prefilled syringe and 55513-065-01 for the single-dose vial).

## IMPORTANT SAFETY INFORMATION (cont'd)

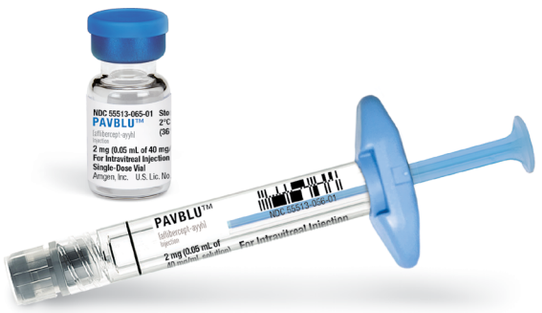
## WARNINGS AND PRECAUTIONS (cont'd)

- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including aflibercept products. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).



Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# PAVBLU™ PRODUCT FACT SHEET




## INDICATIONS

PAVBLU™ is a vascular endothelial growth factor (VEGF) inhibitor 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)

## PRODUCT INFORMATION

| NDC | Description | Quantity |
|---|---|---|
| 55513-056-01 | Blister pack containing 2 mg (0.05 mL of a 40-mg/mL solution) sterile, single-dose prefilled plastic syringe | One per carton |
| 55513-065-01 | Singe-dose glass vial containing 2 mg (0.05 mL of a 40-mg/mL solution) | One per carton |

## STORAGE AND HANDLING REQUIREMENTS

Refrigerate PAVBLU™ at 2°C to 8°C (36°F to 46°F). PAVBLU™ may be kept at room temperature (up to 30°C (86°F)) for a single-period of 3 days. Do not freeze. Do not use beyond the date stamped on the carton and container label. Store in the original carton until time of use to protect from light. Do not open sealed blister tray until time of use.

## PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

## SUPPLIED AND MARKETED BY

Amgen USA Inc.

amgen.com

PAVBLU.com

## PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

## PRODUCT INFORMATION

Medical Information: 800-77-AMGEN (800-772-6436)

## REIMBURSEMENT INFORMATION

Amgen® SupportPlus: 866-264-2778 or www.AmgenSupportPlus.com

## IMPORTANT SAFETY INFORMATION (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

- The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with aflibercept compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the aflibercept group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with aflibercept compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with aflibercept compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with aflibercept in the first six months of the RVO studies.

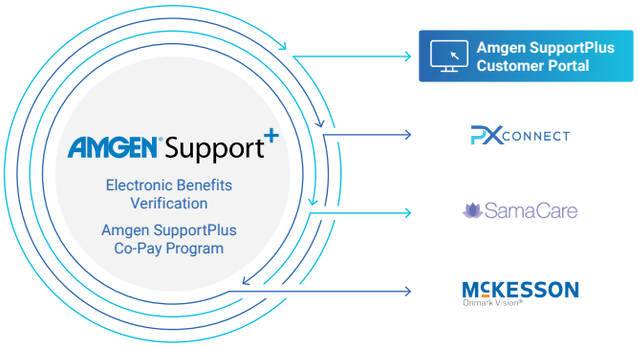
PAVBLU™ (aflibercept-ayyh) Injection 2mg

Please see **full Important Safety Information** and click here for **full Prescribing Information.**

# SUPPORT SERVICES

## AMGEN® Support+

### We're right here, right when you need us




### Integrated PAVBLU™ access support with these platforms

Our goal is to make the experience with PAVBLU™ efficient and straightforward. To do that, we have developed a program that integrates with commonly used platforms for benefits verification, enrollment, and prior authorizations with real-time status updates.

### HCP Support Center

Our Amgen® SupportPlus representatives can assist with issues around patient coverage, prior authorizations, Amgen® SupportPlus Co-Pay Program, and more.

**Benefits verification**

- Verify patient's insurance plan coverage details

**Prior authorization requirements**

- Provide payer-specific prior authorization forms

**Amgen® SupportPlus customer portal**

- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically
- Integration with commonly used platforms for real-time status regardless of platform

### Field Reimbursement Specialists

A Field Reimbursement Specialist can provide coverage and access resources to support your patients.

**Contact your Field Reimbursement Specialist for live or virtual support that includes:**

- Help with navigating prior authorization, appeals, and fulfillment processes
- Educate on payer requirements and necessary documentation for individual patient support
- Provide guidance on general reimbursement questions, including product coding and billing information
- Answer general questions about Amgen® SupportPlus programs and other available resources


### Amgen® SupportPlus Co-Pay Program

The Amgen® SupportPlus Co-Pay Program may help eligible patients with private or commercial insurance lower their out-of-pocket costs.

- Eligible patients may pay **as little as $0** out-of-pocket for each dose and receive **up to $1,000** per calendar year for in-office administration out-of-pocket costs*
- No income eligibility requirement

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions. Massachusetts and Rhode Island residents not eligible for in-office administration support.

**Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay**

CALL 866-264-2778 Monday to Friday, 9:00 am to 8:00 pm ET, or visit **AmgenSupportPlus.com.**

# IMPORTANT SAFETY INFORMATION

## INDICATIONS

PAVBLU™ (aflibercept-ayyh) is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

- PAVBLU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in PAVBLU.

### WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with aflibercept products, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering PAVBLU. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with aflibercept products. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including aflibercept products. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).
- The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with aflibercept compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the aflibercept group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with aflibercept compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with aflibercept compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with aflibercept in the first six months of the RVO studies.

### ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with aflibercept including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with PAVBLU and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

**Click here for full Prescribing Information for PAVBLU.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.**

PAVBLU™
(aflibercept-ayyh)
Injection 2mg

PAVBLU™
(aflibercept-ayyh)
Injection 2mg

**Reference:** PAVBLU™ (aflibercept) Prescribing Information. Amgen.

## Reimbursement Disclaimer

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Please see **full Important Safety Information** and click here for full **Prescribing Information.**

Please visit **PAVBLU.com** for additional information and resources.

Call **800-77-AMGEN (800-772-6436)** if you have questions about the preparation and administration of PAVBLU™.

AMGEN