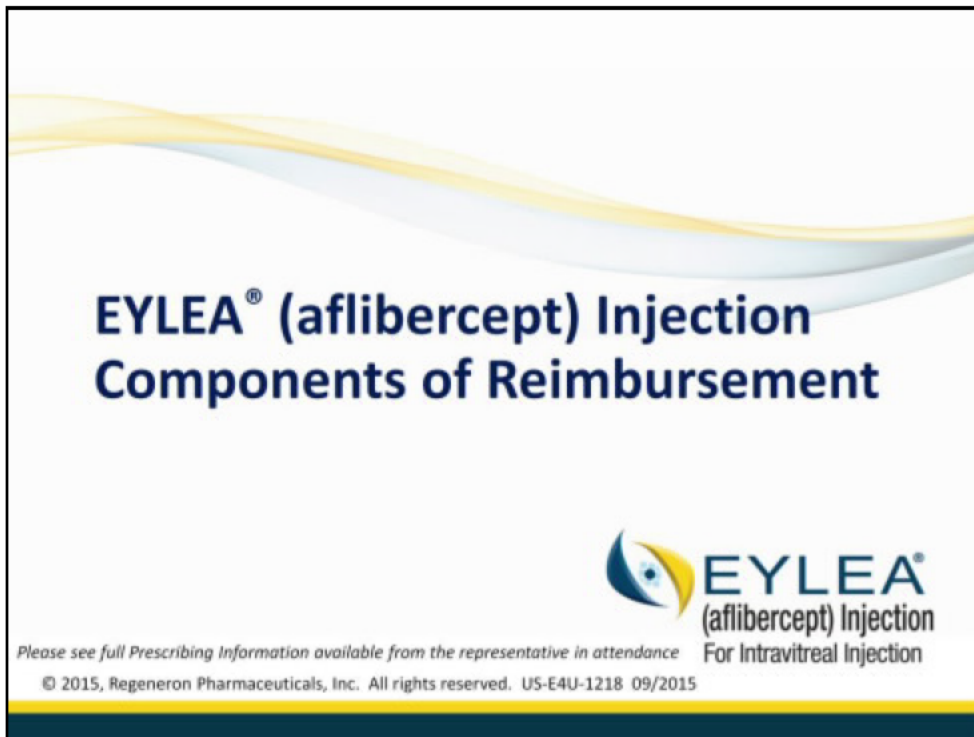




EYLEA[®] (aflibercept) Injection
Components of Reimbursement

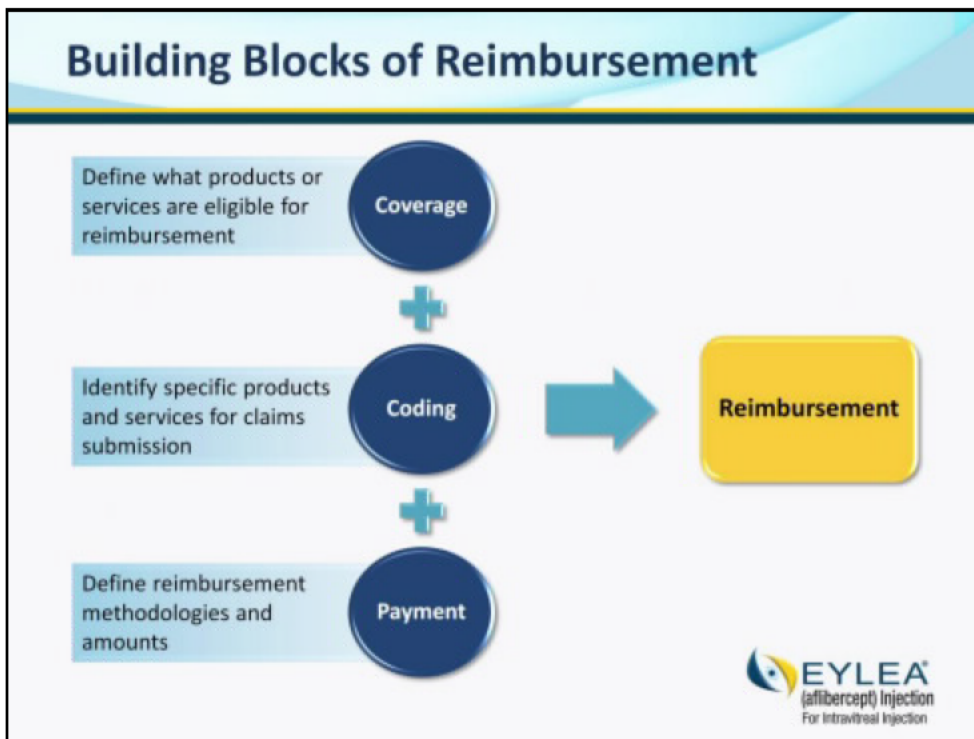


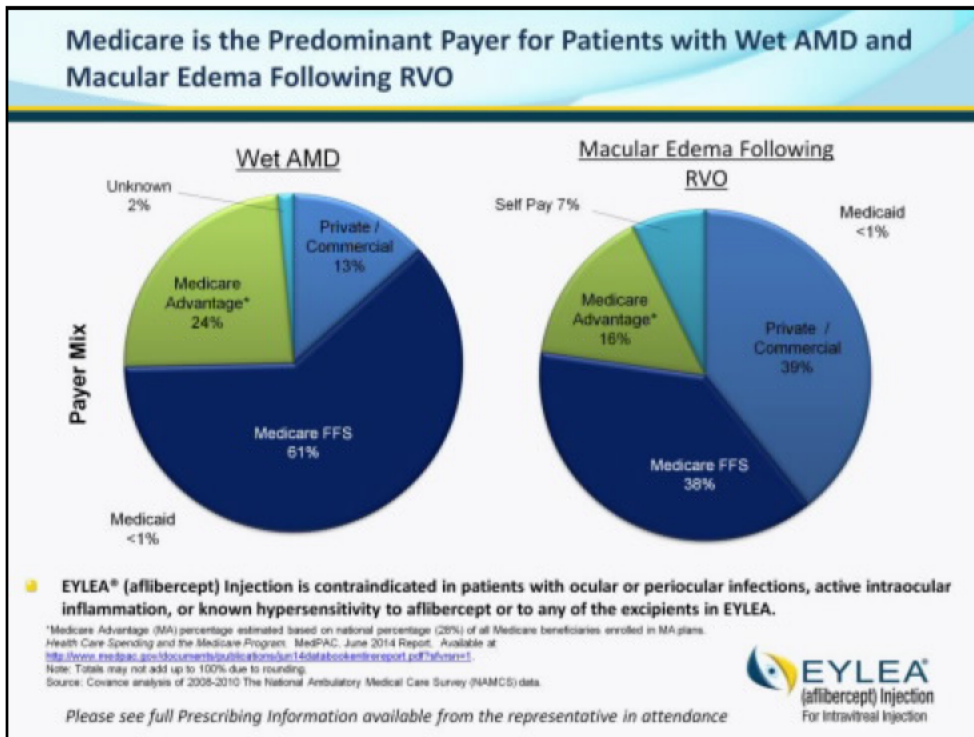
EYLEA[®]
(aflibercept) Injection
For Intravitreal Injection

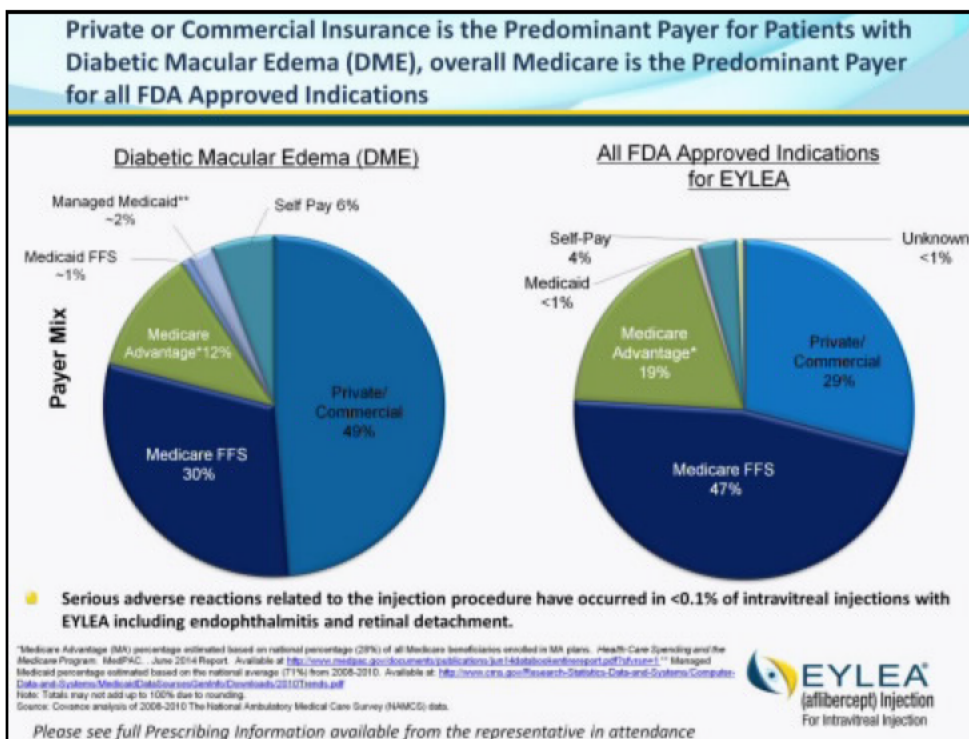
Please see full Prescribing Information available from the representative in attendance

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Coverage for EYLEA® (afibercept) Injection

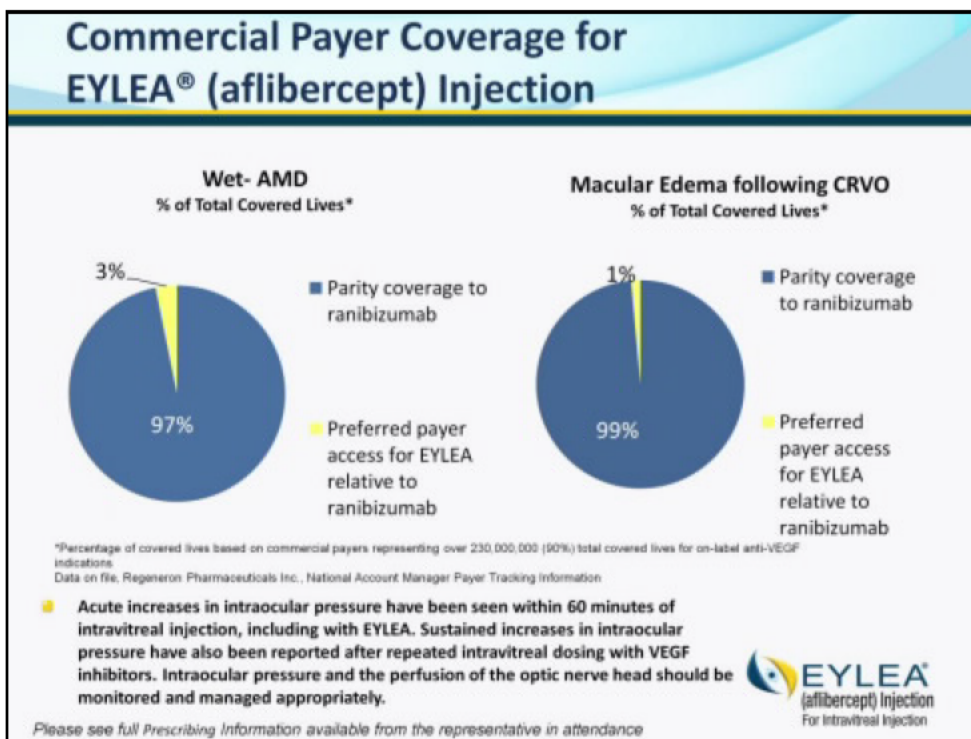
Wet Age-Related Macular Degeneration (AMD)	Macular Edema Following Retinal Vein Occlusion	Diabetic Macular Edema (DME) / Diabetic Retinopathy in patients with DME*
Medicare (Fee-for-Service)		
Covered and reimbursed by all Medicare administrative contractors		
Medicare Advantage		
Covered by Medicare Advantage plans; however, coverage guidelines, cost sharing, and benefit restrictions can differ from traditional Medicare		
Commercial Payers		
Covered by majority of commercial payers; however, coverage guidelines, cost sharing, and benefit restrictions vary from payer to payer (e.g., medical review, prior authorization, and specialty pharmacy management)		
Medicaid		
Covered in majority of states; coverage guidelines will differ state to state		

 Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

 **EYLEA®**
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*Coverage for Diabetic Retinopathy in Patients with Diabetic Macular Edema is still being established



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



EYLEA® (aflibercept) Injection Coding: Diagnosis and Procedure Coding

CPT Code and Modifiers	Description	Site of Service
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	
-LT	Left eye modifier	MDO, HOP
-RT	Right eye modifier	
-50	Bilateral injection modifier	

MDO: Medical office. HOP: Hospital outpatient.

 Select Important Safety Information

EYLEA® (afibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to afibercept or to any of the excipients in EYLEA.

The coding information discussed is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed above may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

Please see full Prescribing Information available from the representative in attendance



ICD-10 Coding for EYLEA® (aflibercept) Injection: Wet AMD

- For neovascular (wet) age-related macular degeneration (AMD)

Description	NEW ICD-10 diagnosis code
Exudative age-related macular degeneration	H35.32

- Select Important Safety Information**

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ICD-10 Coding for EYLEA® (aflibercept) Injection: Macular Edema following Retinal Vein Occlusion (RVO)

Description	NEW ICD-10 diagnosis codes
Retinal edema (Primary Diagnosis)	H35.81
Central RVO (Secondary Diagnosis)	H34.811 (Right eye) H34.812 (Left Eye) H34.813 (Bilateral) H34.819 (Unspecified Eye)
Venous tributary (branch) occlusion (Secondary Diagnosis)	H34.831 (Right Eye) H34.832 (Left Eye) H34.833 (Bilateral) H34.839 (Unspecified Eye)

Select Important Safety Information

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

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Please see full Prescribing Information available from the representative in attendance



ICD-10 Coding for EYLEA® (aflibercept) Injection: Diabetic Macular Edema (DME)

Description	NEW ICD-10 diagnosis codes
Diabetic Macular Edema: Type 1 diabetes	Type 1 diabetes with... E10.311 unspecified diabetic retinopathy [DR] with macular edema [ME] E10.321 mild nonproliferative DR with ME E10.331 moderate nonproliferative DR with ME E10.341 severe nonproliferative DR with ME E10.351 proliferative DR with ME

Note: Coding for the indication of Diabetic Retinopathy in patients with DME is consistent with coding for the indication of Diabetic Macular Edema (DME).

Select Important Safety Information
Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. 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.

The coding information discussed is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed above may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.

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EYLEA®
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ICD-10 Coding for EYLEA® (aflibercept) Injection: Diabetic Macular Edema (DME) (cont'd)

Description	NEW ICD-10 diagnostic codes
Diabetic Macular Edema: Type 2 diabetes	Type 2 diabetes with ...
Note: An additional code should be used to identify any insulin use.	E11.311 unspecified diabetic retinopathy (DR) with macular edema (ME) E11.321 mild nonproliferative DR with ME E11.331 moderate nonproliferative DR with ME E11.341 severe nonproliferative DR with ME E11.351 proliferative DR with ME

- Note: Coding for the indication of Diabetic Retinopathy in patients with DME is consistent with coding for the indication of Diabetic Macular Edema (DME).

Select Important Safety Information

There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. 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 EYLEA. 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 EYLEA 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 EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

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Please see full Prescribing Information available from the representative in attendance



ICD-10 Coding for EYLEA® (afibercept) Injection: Diabetes Caused by Another Condition or Event

Description	NEW ICD-10 diagnostic codes
Diabetic Macular Edema: Diabetes due to underlying condition The underlying conditions must be coded first: congenital rubella; Cushing's syndrome; cystic fibrosis; malignant neoplasm; malnutrition; pancreatitis and other diseases of the pancreas An additional code should be used to identify any insulin use	Diabetes due to underlying condition with... E08.311 unspecified diabetic retinopathy (DR) with macular edema (ME) E08.321 mild nonproliferative DR with ME E08.331 moderate nonproliferative DR with ME E08.341 severe nonproliferative DR with ME E08.351 proliferative DR with ME

Note: Coding for the indication of Diabetic Retinopathy in patients with DME is consistent with coding for the indication of Diabetic Macular Edema (DME).

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

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Please see full Prescribing Information available from the representative in attendance



ICD-10 Coding for EYLEA® (afibercept) Injection:
Diabetes Caused by Another Condition or Event

Description	NEW ICD-10 diagnostic codes
Diabetic Macular Edema: Drug or chemical induced diabetes	Drug or chemical induced diabetes with...
For these diabetes codes, code first poisoning due to drug or toxin, if applicable	E09.311 unspecified diabetic retinopathy (DR) with macular edema (ME) E09.321 mild nonproliferative DR with ME E09.331 moderate nonproliferative DR with ME E09.341 severe nonproliferative DR with ME E09.351 proliferative DR with ME
Use additional code for adverse effect, if applicable, to identify drug	
An additional code should be used to identify any insulin use	

Note: Coding for the indication of Diabetic Retinopathy in patients with DME is consistent with coding for the indication of Diabetic Macular Edema (DME).

Select Important Safety Information
EYLEA® (afibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to afibercept or to any of the excipients in EYLEA.

The coding information discussed is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed above may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.
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ICD-10 Coding for EYLEA® (afibercept) Injection: Other Specified Diabetes

Description	NEW ICD-10 diagnostic codes
Diabetic Macular Edema: Other Specified Diabetes	Other specified diabetes with...
These new ICD-10 diagnostic codes should be used with the following types of diabetes: diabetes due to genetic defects of beta-cell function or in insulin action; postpancreatectomy diabetes; postprocedural diabetes; secondary diabetes NEC	E13.311 (unspecified diabetic retinopathy [DR] with macular edema [ME]) E13.321 (mild nonproliferative DR with ME) E13.331 (moderate nonproliferative DR with ME) E13.341 (severe nonproliferative DR with ME) E13.351 (proliferative DR with ME)
An additional code should be used to identify any insulin use	

Note: Coding for the indication of Diabetic Retinopathy in patients with DME is consistent with coding for the indication of Diabetic Macular Edema (DME).

Select Important Safety Information
 Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

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Please see full Prescribing Information available from the representative in attendance



Coding: Product Codes for EYLEA® (aflibercept) Injection

HCP/PCS	Description	Billing Units
J0178	Injection, aflibercept, 1 mg*	2

*With the 1 mg descriptor, it is important to accurately indicate "2" billing units for each 2 mg injection on the claim form (or electronic equivalent)

10-Digit NDC	11-Digit NDC	Carton Type
61755-005-02	61755-0005-02	Single-use, sterile, 3-mL, glass vial to deliver 0.05 mL of 40 mg/mL EYLEA

- EYLEA is available in the same 2-mg, single-strength formulation for all approved indications.

The coding information discussed is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed above may not apply to all patients or to all health plans; providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient.



Please see full Prescribing Information available from the representative in attendance

Payment Terminology

- ASP**
 - Average Sales Price**
 - Weighted average of a products sales less price concessions across all purchasing channels
 - Reported to Centers for Medicare and Medicaid Services (CMS) by the manufacturer each quarter
- WAC**
 - Wholesale Acquisition Cost**
 - Manufacturer's list price for the drug or biologic to wholesalers or direct purchasers
 - Reported to CMS by the manufacturer each quarter
- Direct**
 - Direct Price**
 - The list price for a drug or biological to non-wholesaler customers



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Understanding the Average Sales Price (ASP) for EYLEA® (aflibercept) Injection

Why is the ASP for EYLEA relevant?

- Medicare reimburses based upon ASP methodology
- Commercial payers reimbursement rates are generally based off of the ASP methodology
 - 53% of physician contracts with commercial payers are based upon ASP methodology for payment ¹
 - Other reimbursement methodologies are based off of AWP or WAC +/- a percentage

What is the ASP for EYLEA?

- The ASP for EYLEA is \$1,850

1. "Zitter Health Insights Managed Care Benefit Design Index, Fall 2012 Edition"



[REDACTED]

[REDACTED]

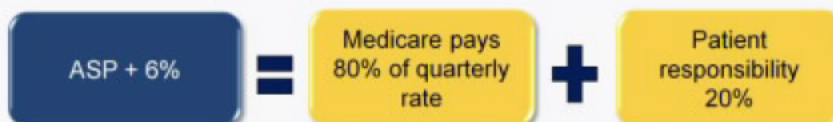
[REDACTED]

[REDACTED]

Physician Office Reimbursement by Payer for EYLEA® (aflibercept) Injection

- **Medicare (FSS)** : Reimbursement for EYLEA® (aflibercept) Injection is based upon the weighted ASP + 6%

Quarterly Medicare Allowable Rate



- **Commercial payers:** reimbursement rates vary by payer and may be based upon provider/payer contractual arrangements
- **Medicaid (FFS):** Individual States set reimbursement rates based on a maximum allowable rate or payment methodology that calculates the rate



Sequestration Impact on EYLEA® (aflibercept) Injection

Sequestration: Automatic withholding of funding for the federal budget in order to reduce the federal deficit by \$1.2 trillion dollars over 10 years from 2013-2022

HCPs receive a 2% reduction on all payments (services and drugs) received from Medicare

- 2% reduction applies to the 80% allowable that Medicare normally pays
- 20% patient co-pay responsibility is NOT affected
- Sequester reimbursement adjustment for 80% Medicare allowable = ASP + 4.3%



The logo for EYLEA (aflibercept) Injection, For Intravitreal Injection, featuring a stylized blue and yellow eye icon.

[REDACTED]

[REDACTED]

[REDACTED]

Your Payers Components of Reimbursement for EYLEA® (aflibercept) Injection	
☐	[Name of MAC, Carrier, or FI], [Jurisdiction # and States]:
	Covered: [Yes or No]
	Coding: [J0178]
	Reimbursement Methodology: [e.g. ASP+6%]
	Additional information: [e.g. PA required, Step edit, SP required, etc.]
	

[REDACTED]

[REDACTED]

Your Payers Components of Reimbursement for EYLEA® (aflibercept) Injection	
☐	Medicare Advantage: [Payer name] Covered: [Yes or No] Coding: [J0178] Reimbursement Methodology: [e.g. ASP+6%] Additional information: [e.g. PA required, Step edit, SP required, etc.]
☐	Medicare Advantage: [Payer name] Covered: [Yes or No] Coding: [J0178] Reimbursement Methodology: [e.g. ASP+6%] Additional information: [e.g. PA required, Step edit, SP required, etc.]



EYLEA®
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[REDACTED]

[REDACTED]

Your Payers Components of Reimbursement for EYLEA® (afibercept) Injection	
☐	Commercial Payer: [Payer name] Covered: [Yes or No] Coding: [J0178] Reimbursement Methodology: [e.g. ASP+6%] Additional information: [e.g. PA required, Step edit, SP required, etc.]
☐	Commercial Payer: [Payer name] Covered: [Yes or No] Coding: [J0178] Reimbursement Methodology: [e.g. ASP+6%] Additional information: [e.g. PA required, Step edit, SP required, etc.]
Note: For reimbursement methodologies using AWP, Regeneron Pharmaceuticals, Inc. has no involvement in the establishment of AWP determinations (which vary among data providers) and does not endorse the use of AWP in determining reimbursement.	
	

[REDACTED]

[REDACTED]

[REDACTED]

Your Payers Components of Reimbursement for EYLEA® (aflibercept) Injection

[State Medicaid Agency]:

Pharmacy Benefit:

Covered: [Yes or No]

Code Required: [J0178]

Reimbursement Methodology: [e.g. ASP+6%]

Additional information: [e.g. PA required, Step edit, SP required, etc.]

Medical Benefit:

Covered: [Yes or No]

Code Required: [J0178]

Reimbursement Methodology: [e.g. ASP+6%]

Additional information: [e.g. PA required, Step edit, SP required, etc.]

Crossover Benefit:

Covered: [Yes or No]

Code Required: [J0178]

Reimbursement Methodology: [e.g. ASP+6%]

Additional information: [e.g. PA required, Step edit, SP required, etc.]

 **EYLEA®**
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[REDACTED]

[REDACTED]

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