

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**AN OPHTHALMOLOGY CLINIC IN  
CALIFORNIA: AUDIT OF MEDICARE  
PAYMENTS FOR EYE INJECTIONS OF  
EYLEA AND LUCENTIS**

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## Report in Brief

Date: March 2021

Report No. A-09-19-03022

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

Prior OIG work found that Medicare inappropriately paid for services that were billed as being distinct or significant and separately identifiable from other services provided on the same day. Our analysis showed that in 2018, an ophthalmology clinic in California (the Clinic) frequently billed for other services as being unrelated to, distinct from, or significant and separately identifiable from intravitreal (inside the eye) injections of the drugs Eylea and Lucentis.

Our objective was to determine whether the Clinic complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis and for other services provided on the same day as the injections.

### How OIG Did This Audit

Our audit covered Medicare Part B payments of \$4.3 million for intravitreal injections of Eylea and Lucentis (and for other services provided on the same day as the injections) that the Clinic provided in 2018. We reviewed a stratified random sample of 100 beneficiary days, consisting of 627 services and drugs. (A beneficiary day consisted of all services and drugs provided on a date of service to a beneficiary in which intravitreal injections of Eylea or Lucentis were administered.) For each sampled beneficiary day, we provided copies of the medical records to an independent medical review contractor to determine whether the services and drugs were properly billed.

## An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea and Lucentis

### What OIG Found

The Clinic generally complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis, which accounted for 88 percent of the total payments in our sample. (All of these injections complied with Medicare requirements except for three injections of Eylea.) However, the Clinic did not always comply with Medicare requirements when billing for other services provided on the same day as the intravitreal injections (e.g., injections of an anesthesia drug). For 326 of the 627 services and drugs associated with the 100 sampled beneficiary days, the Clinic complied with the requirements. However, for the remaining 301 services and drugs, the Clinic did not comply with the requirements: 195 services were not separately payable, and 106 services and drugs were not reasonable and necessary.

Because the Clinic's medical director was unfamiliar with Medicare's billing requirements, the Clinic did not have policies and procedures to ensure that services and drugs billed to Medicare were correctly billed or reasonable and necessary. On the basis of our sample results, we estimated that at least \$398,625 of the \$4.3 million paid to the Clinic for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis was unallowable for Medicare reimbursement.

### What OIG Recommends and the Clinic's Comments

We recommend that the Clinic: (1) refund to the Medicare contractor \$398,625 in estimated overpayments for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis and (2) based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. We also make two procedural recommendations on implementing policies and procedures to ensure that the Clinic complies with Medicare requirements. The full text of our recommendations is shown in the report.

The Clinic expressed concern over two of our findings and disagreed with our finding on the three injections of Eylea. The Clinic concurred in part with our first recommendation and stated that it will repay overpayments for services that will not be subject to an appeal. The Clinic concurred with our remaining recommendations and provided information on actions that it planned to take to address our recommendations. After reviewing the Clinic's comments, we maintain that our findings and recommendations remain valid.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Medicare Part B reimburses physicians for injections of the drugs Eylea and Lucentis into the eye (called intravitreal injections) that are reasonable and necessary to treat beneficiaries' conditions, such as wet age-related macular degeneration (wet AMD).<sup>1</sup> In addition to receiving reimbursement for the intravitreal injection procedures and the drugs, physicians may be eligible for additional payments for other services provided on the same day as the injections if the services are unrelated to, distinct from, or significant and separately identifiable from the intravitreal injections.

Medicare paid approximately \$270 million for intravitreal injections and an additional \$2.9 billion for Eylea and Lucentis provided to Medicare beneficiaries nationwide in calendar year 2018 (audit period). Prior Office of Inspector General (OIG) audits and evaluations found that Medicare made inappropriate or potentially inappropriate payments for: (1) evaluation and management (E&M) services<sup>2</sup> that were billed on the same day as intravitreal injections but were not significant and separately identifiable from the injections, (2) services that were billed as being distinct from other services provided on the same day, and (3) Lucentis injections that were provided sooner than 28 days from a prior Lucentis injection in the same eye.<sup>3</sup> (See Appendix B for a list of related OIG reports.)

This audit is part of a series of audits of intravitreal injections and related services. Using data analysis techniques, we identified providers at risk for noncompliance with Medicare billing requirements. An ophthalmology clinic in California (the Clinic) was one of those providers identified for audit.<sup>4</sup> Our analysis showed that during our audit period, the Clinic frequently billed for other services as being unrelated to, distinct from, or significant and separately identifiable from intravitreal injections of Eylea and Lucentis.<sup>5</sup> Additionally, 50 percent of the intravitreal injections that the Clinic billed were provided sooner than 28 days from the prior injection.

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<sup>1</sup> An intravitreal injection is a procedure to place medication directly into the space in the back of the eye, called the vitreous cavity. The procedure is usually performed by a trained retina specialist in an office setting. Wet AMD occurs when abnormal blood vessels begin to grow underneath the retina and leak blood or fluid that blurs central vision.

<sup>2</sup> Physicians and nonphysician practitioners perform E&M services to assess and manage a beneficiary's health.

<sup>3</sup> The Food and Drug Administration's (FDA's) approved dosing guidelines for Eylea and Lucentis state that injections of these drugs should generally be administered no more than once every 4 weeks (approximately every 28 days) per eye followed by less frequent dosing depending on the diagnosis.

<sup>4</sup> We plan to issue a separate report for each provider.

<sup>5</sup> The generic names for Eylea and Lucentis are aflibercept and ranibizumab, respectively.

## OBJECTIVE

Our objective was to determine whether the Clinic complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis and for other services provided on the same day as the injections.

## BACKGROUND

### The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Medicare Part B provides supplementary medical insurance for medical and other health services. CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Part B claims. During our audit period, Noridian Healthcare Solutions, LLC (Noridian), was the MAC that processed and paid the Clinic's Medicare claims.

### Ophthalmology Services and Intravitreal Injections

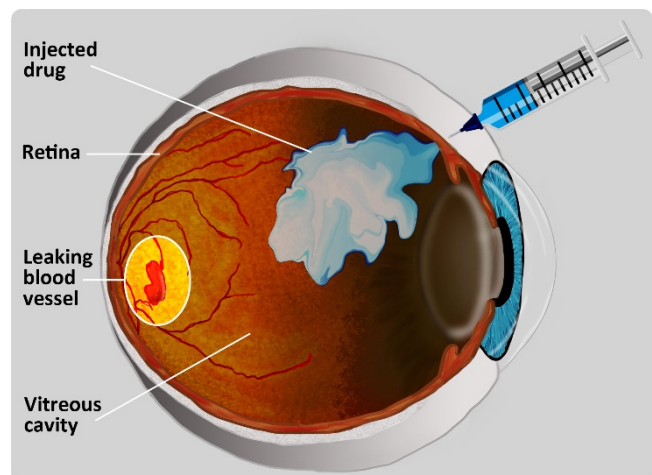
Ophthalmology is the branch of medicine concerned with the study and treatment of disorders and diseases of the eye. Ophthalmology services include intravitreal injections of Eylea and Lucentis, which are drugs approved by the Food and Drug Administration (FDA) to treat eye diseases such as wet AMD, the more advanced and damaging form of AMD.

Wet AMD occurs when abnormal blood vessels begin to grow underneath the retina and leak blood or fluid that blurs central vision. Eylea and Lucentis reduce the abnormal growth and leakage, which helps stabilize vision loss and, in some cases, can improve sight. Figure 1 shows an intravitreal injection to treat wet AMD.

The recommended frequency of intravitreal injections varies from every few weeks to every few months, and duration of treatment varies by case. Beneficiaries often require multiple doses over many months, and repeat treatments are often needed for continued benefit.

The FDA-approved dosing guidelines for Eylea and Lucentis state that injections of these drugs should generally be administered once every 4 weeks (approximately 28 days) per eye followed

**Figure 1: Intravitreal Injection for Wet AMD**





by less frequent dosing depending on the diagnosis. (See Appendix C for the FDA-approved dosing guidelines for Eylea and Lucentis for different diagnoses.)

## Medicare Coverage of Intravitreal Injections of Eylea and Lucentis


Medicare Part B covers ophthalmology services, such as intravitreal injections, that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.<sup>6</sup>

Medicare pays for an intravitreal injection (which is considered minor surgery) as part of a global surgery payment that includes the preoperative, intraoperative, and postoperative services provided by the physician (Figure 2).<sup>7</sup>

Generally, E&M services provided on the same day as intravitreal injections are included in the payment for the intravitreal injections. The beneficiary's initial consultation with the physician or the physician's evaluation of the problem to determine the need for surgery is always included in the payment for an intravitreal injection.<sup>8</sup> Additionally, Medicare does not allow separate payment for an injection of an anesthesia drug when billed with an intravitreal injection.<sup>9</sup>

Medicare Part B pays for Eylea and Lucentis separately from the global surgery payment for intravitreal injections.<sup>10</sup> In addition, Medicare may make a separate payment for other services (e.g., diagnostic imaging services) provided by the same physician on the same day as the surgery if the services are unrelated to, distinct from, or significant and separately identifiable

**Figure 2: The Global Surgery Payment Includes Services Related to the Surgery**



**The Global Surgery Payment for an Intravitreal Injection Includes:**

- **Preoperative Services**  
The initial consultation or evaluation of the problem by the physician to determine the need for surgery
- **Intraoperative Services**  
Services that are normally a usual and necessary part of a surgical procedure
- **Postoperative Services**  
Followup services during the postoperative period of the surgery that are related to the recovery from the surgery

<sup>6</sup> Social Security Act (the Act) § 1862(a)(1)(A).

<sup>7</sup> The Act § 1848(c)(1)(A)(ii); 42 CFR §§ 410.20(a) and 414.40(b)(1). The Medicare Physician Fee Schedule indicates that the procedure code for an intravitreal injection is considered a minor surgical procedure.

<sup>8</sup> The Act § 1848(c)(1)(A)(ii); 42 CFR § 414.40(b)(1); *National Correct Coding Initiative Policy Manual for Medicare Services* (NCCI Policy Manual), chapter I, § D. See also, *CMS's Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 12, §§ 40.1(A), 40.1(B), and 40.1(C).

<sup>9</sup> 42 CFR § 414.40(b)(1); NCCI Policy Manual, chapter I, § G, and chapter VIII, § D(11).

<sup>10</sup> The Act §§ 1832(a)(1), 1861(s)(2)(A), and 1861(t). See also, *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 50.

from the surgery.<sup>11</sup> (We refer to these services as “separately payable services.”) To identify such services, Medicare requires that certain “bypass modifiers” be included on claims.<sup>12</sup>

Two examples of modifiers are the following:

- **Modifier 25** indicates that a service was for a significant, separately identifiable E&M service that was above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure.<sup>13</sup>
- **Modifier 59** indicates that a service was distinct or independent from other non-E&M services provided on the same day.<sup>14</sup>

A modifier may be appended to a procedure code only if the clinical circumstances justify the use of the modifier. A modifier may not be appended to a procedure code solely to bypass an edit if the clinical circumstances do not justify its use.<sup>15</sup> The intravitreal injection and the separately payable services must be appropriately and sufficiently documented in the beneficiary’s medical record to support the claim for these services.<sup>16</sup>

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<sup>11</sup> The Act § 1848(c)(1)(A)(ii); 42 CFR § 414.40(b)(1); NCCI Policy Manual, chapter I, § E. See also, CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 12, §§ 40.1(A), 40.1(B), and 40.1(C).

<sup>12</sup> A modifier is a two-character code reported with a procedure code and is used to give Medicare additional information needed to process a claim. (Procedure codes are used on claims to report medical items, supplies, and services provided to Medicare beneficiaries.) The modifiers that we refer to as “bypass modifiers” allow Medicare claims to bypass automated prepayment edits in a MAC’s claims processing system. These edits were designed to prevent improper payment when certain procedure codes are submitted together. For example, an edit would identify and disallow services that are generally included in the global surgery payment (NCCI Policy Manual, chapter I, § E(1)).

<sup>13</sup> American Medical Association (AMA), *Current Procedural Terminology (CPT) 2018 Professional*; NCCI Policy Manual, chapter I, § D, § E(1)(b). According to Noridian, a significant, separately identifiable E&M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E&M service to be reported.

<sup>14</sup> For modifier 59, the supporting documentation must support a different session, different procedure or surgery, different anatomical site or organ system, separate incision or excision, separate lesion, or separate injury (or area of injury in extensive injuries). AMA, *CPT 2018 Professional*; NCCI Policy Manual, chapter I, § D, § E(1)(d).

<sup>15</sup> NCCI Policy Manual, chapter I, § E(1).

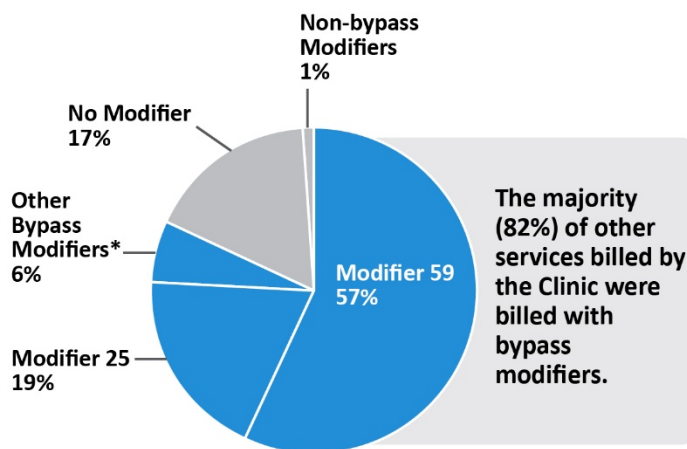
<sup>16</sup> The Act § 1833(e).

## An Ophthalmology Clinic in California

The Clinic is located in Newport Beach, California, and was established in 2008. The medical director of the Clinic provides treatment for retinal and macular diseases.

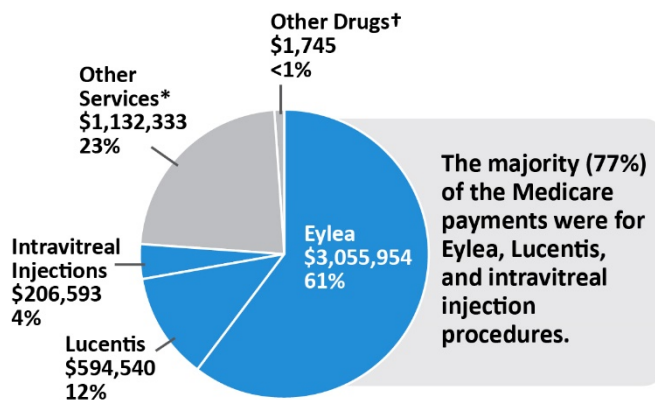
For our audit period, Medicare paid the Clinic approximately \$5 million. Our analysis of Medicare claim data indicated that the majority (77 percent) of these payments were for Eylea, Lucentis, and intravitreal injections (Figure 3). The remaining 23 percent of the Medicare payments were for other services (e.g., diagnostic imaging and E&M services) and other drugs (e.g., Avastin).<sup>17</sup>

**Figure 4: Modifiers Billed With Other Services**



\* Other bypass modifiers include modifiers 24, 79, and XS.

**Figure 3: Medicare Payments to the Clinic**



\* Other services include diagnostic imaging services, detailed examinations, injections of medication, laser treatments, and E&M services.

† Other drugs include Avastin, alteplase recombinant, vancomycin HCL, dexamethasone sodium phosphate, and lidocaine.

Our data analysis also showed that 82 percent of these other services (i.e., services other than intravitreal injections of Eylea and Lucentis) were billed by the Clinic with bypass modifiers, indicating that the services were unrelated to, distinct from, or significant and separately identifiable from services billed on the same day. Figure 4 shows the modifiers billed with other services and the corresponding percentages of the total other services billed.<sup>18</sup>

In addition, our data analysis showed that 50 percent of intravitreal injections that the Clinic billed were provided sooner than 28 days from the prior injection.<sup>19</sup>

<sup>17</sup> Avastin, a drug used to treat certain cancers, may be prescribed “off-label” to treat eye diseases. (“Off-label” prescribing occurs when a physician uses a drug to treat a medical condition for which the FDA has not approved the drug for treatment of that condition.) Avastin’s generic name is bevacizumab.

<sup>18</sup> Modifiers 24, 79, and XS (in addition to 25 and 59) are also used to identify distinct or unrelated services.

<sup>19</sup> Because 96 percent of the intravitreal injections did not include a modifier to indicate whether an injection was for the left or right eye, our data analysis did not show whether an injection was provided on the same eye as the prior injection.

## Medicare Requirements for Providers To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>20</sup>

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>21</sup>

### HOW WE CONDUCTED THIS AUDIT

Our audit covered Medicare Part B payments for intravitreal injections of Eylea and Lucentis (and for other services provided on the same day as the injections) that the Clinic provided during our audit period (January 1 through December 31, 2018). Our sampling frame consisted of 2,305 beneficiary days, with payments totaling \$4.3 million.<sup>22</sup> We selected a stratified random sample of 100 beneficiary days, totaling \$191,527 and consisting of the following 627 services and drugs:<sup>23</sup>

- 132 diagnostic imaging services,
- 100 intravitreal injections,
- 100 extended ophthalmoscopies (detailed examinations of the part of the eye that includes the retina),
- 100 injections of medication (for the anesthesia drug lidocaine),
- 95 E&M services,

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<sup>20</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>21</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

<sup>22</sup> A beneficiary day consisted of all Medicare Part B services and drugs provided on a specific date of service to a specific beneficiary in which intravitreal injections of Eylea or Lucentis were administered. We excluded from our sampling frame beneficiary days that did not contain the procedure codes for an intravitreal injection of either Eylea or Lucentis.

<sup>23</sup> Each sampled beneficiary day consisted of at least four services, including the intravitreal injection procedure, and one drug. Most of the beneficiary days included the intravitreal injection, the drug (Eylea or Lucentis), and these other services: a diagnostic imaging service, an extended ophthalmoscopy, an injection of an anesthesia drug (lidocaine), and an E&M service.

- 81 doses of Eylea,<sup>24</sup> and
- 19 doses of Lucentis (0.5-milligram (mg) doses).

The Clinic provided us with supporting documentation for the beneficiary days in our sample. The supporting documentation included the medical records for 6 months before and 1 month after each sampled beneficiary day. We submitted the supporting documentation to an independent medical review contractor to determine whether the intravitreal injections of Eylea and Lucentis and other services provided on the same day as the injections were reasonable and necessary and met Medicare requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology, Appendix D describes our statistical sampling methodology, and Appendix E contains our sample results and estimates.

## FINDINGS

The Clinic generally complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis.<sup>25</sup> However, the Clinic did not always comply with Medicare requirements when billing for other services provided on the same day as the intravitreal injections.

All 100 sampled beneficiary days included at least 1 service or drug that did not comply with Medicare requirements.<sup>26</sup> For 326 of the 627 services and drugs associated with the 100 sampled beneficiary days, the Clinic complied with Medicare requirements. However, for the remaining 301 services and drugs, the Clinic did not comply with the requirements: 195 services were not separately payable, and 106 services and drugs were not reasonable and necessary. Table 1 on the following page shows the breakdown of the allowable and unallowable services and drugs in the sample and the related payments.

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<sup>24</sup> For 75 of the 81 doses of Eylea, the Clinic billed 2 units of Eylea, for a total of 2 milligrams (mg). For the remaining 6 doses, the Clinic billed 2 units of Eylea for each eye, for a total of 4 mg.

<sup>25</sup> Of the 81 intravitreal injections of Eylea and the related doses of the drug, 78 complied with Medicare requirements. Of the 19 intravitreal injections of Lucentis and the related doses of the drug, all of them complied with the requirements. The injections of Eylea and Lucentis and the related doses of the drugs accounted for 88 percent of the total payments in our sample.

<sup>26</sup> For each beneficiary day, we disallowed only the amounts paid for the services and drugs that were not allowable in accordance with Medicare requirements.

**Table 1: Allowable and Unallowable Services and Drugs and Related Payments in the Sample**

Services and Drugs in Sample	No. of Services and Drugs in Sample	No. of Allowable Services and Drugs	No. of Unallowable Services and Drugs	Payment for Services and Drugs in Sample	Payment for Allowable Services and Drugs	Payment for Unallowable Services and Drugs
Diagnostic imaging services	132	132	0	\$5,473	\$5,473	\$0
Intravitreal injections	100	97	3	8,814	8,553	261
Extended ophthalmoscopies	100	0	100	2,156	0	2,156
Injections of an anesthesia drug	100	0	100	4,399	0	4,399
E&M services	95	0	95	10,305	0	10,305
Doses of Eylea	81	78	3	132,210	127,650	4,560
Doses of Lucentis	19	19	0	28,170	28,170	0
<b>Total</b>	<b>627</b>	<b>326</b>	<b>301</b>	<b>\$191,527</b>	<b>\$169,846</b>	<b>\$21,681</b>

Because the Clinic’s medical director was unfamiliar with Medicare’s requirements, the Clinic did not have policies and procedures to ensure that services and drugs billed to Medicare were correctly billed or reasonable and necessary. As a result, the Clinic received \$21,681 in unallowable Medicare payments. On the basis of our sample results, we estimated that at least \$398,625 of the \$4.3 million paid to the Clinic for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis was unallowable for Medicare reimbursement.

**THE CLINIC BILLED FOR SERVICES THAT WERE NOT SEPARATELY PAYABLE**

On the same day that the Clinic provided intravitreal injections, it also provided and billed for 195 services that were not separately payable. Specifically, 100 injections of an anesthesia drug (lidocaine) were not distinct or independent from the intravitreal injections, and 95 E&M services were not significant and separately identifiable from the intravitreal injections.

**Injections of an Anesthesia Drug Were Not Distinct or Independent From the Intravitreal Injections**

*Medicare Requirements*

With limited exceptions, Medicare does not allow separate payment for anesthesia services provided by the physician who also furnishes the medical or surgical service. In this case, payment for the anesthesia service is included in the payment for the medical or surgical procedure (*National Correct Coding Initiative Policy Manual for Medicare Services* (NCCI Policy Manual), chapter I, § G).

Medicare anesthesia rules prohibit the physician who is performing an operative procedure from separately reporting anesthesia for that procedure except for moderate conscious sedation for some procedures. Procedure codes describing ophthalmic injections (e.g., injections of medication) must not be reported separately with other ophthalmic procedure codes (e.g., intravitreal injections) when the injected substance is an anesthetic agent (NCCI Policy Manual, chapter VIII, § D(11)).

Modifier 59 is used to identify procedures and services, other than E&M services, that are distinct or independent from other non-E&M services provided on the same day.

“Documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual” (American Medical Association (AMA), *Current Procedural Terminology (CPT) 2018 Professional*; NCCI Policy Manual, chapter I, § E(1)(d)).

#### *Lidocaine Injections Were Not Distinct or Independent From Intravitreal Injections Provided on the Same Day*

For 100 services, the Clinic billed for injections of lidocaine (an anesthesia drug) provided on the same day as the intravitreal injections and added modifier 59 to the claims to indicate that the lidocaine injections were distinct or independent from the intravitreal injections. However, the independent medical review contractor stated that injections of lidocaine are considered anesthesia and are included in the injection procedures. Therefore, the lidocaine injections were not distinct or independent from the intravitreal injections, and separate payments for the lidocaine injections were unallowable.

#### Example of an Injection of an Anesthesia Drug That Was Not Distinct or Independent From the Intravitreal Injection

On April 23, 2018, the Clinic billed Medicare for lidocaine injections in addition to intravitreal injections of Eylea into both eyes of a beneficiary. Medicare paid the Clinic \$124 for the lidocaine injections, \$43 for the intravitreal injections, \$3,038 for the drug Eylea, and \$167 for other services (an E&M service, a diagnostic imaging service, and an extended ophthalmoscopy). According to the independent medical review contractor, the administration of lidocaine for pain control is considered anesthesia and is included in the intravitreal injection procedure. The medical review contractor stated: “Coding rules do not allow anesthesia to be reported separately. Therefore, use of bypass modifier 59 is not supported.” As a result, the \$124 for the lidocaine injections was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable Medicare requirements, we also disallowed \$131 for the E&M service and the extended ophthalmoscopy.)

## **Evaluation and Management Services Were Not Significant and Separately Identifiable From the Intravitreal Injections**

### *Medicare Requirements*

Payment must not be made to a provider for a service unless “there has been furnished such information as may be necessary in order to determine the amounts due such provider” (Social Security Act (the Act) § 1833(e)).

In general, E&M services provided on the same date of service as a minor surgical procedure are included in the payment for the procedure. However, a significant and separately identifiable E&M service unrelated to the decision to perform the minor surgical procedure is separately reportable with modifier 25 (NCCI Policy Manual, chapter I, § D).

Because minor surgical procedures include preprocedure, intraprocedure, and postprocedure work inherent in the procedure, the provider must not report an E&M service for this work. Furthermore, Medicare Global Surgery rules prevent the reporting of a separate E&M service for the work associated with the decision to perform a minor surgical procedure whether the patient is a new or an established patient (NCCI Policy Manual, chapter I, § E(1)(b)).

AMA’s *CPT 2018 Professional* states:

It may be necessary to indicate that on the day a procedure or service . . . was performed, the patient’s condition required a significant, separately identifiable E[&]M service above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure that was performed . . . . This circumstance may be reported by adding modifier 25 to the appropriate level of E[&]M service.

### *Ophthalmological Medical Examinations and Evaluations Were Not Significant and Separately Identifiable From Intravitreal Injections Provided on the Same Day*

For 95 services, the Clinic billed for E&M services (i.e., ophthalmological medical examinations and evaluations) provided on the same day as the intravitreal injections and added modifier 25 to the claims to indicate that the E&M services were significant and separately identifiable from the intravitreal injections. However, the medical records did not contain evidence that the ophthalmological medical examinations and evaluations were significant and separately identifiable from the intravitreal injections. According to the independent medical review contractor, the medical records showed that the components of the physician evaluation were related to and included in the intravitreal injection procedures. Because minor surgical procedures, such as intravitreal injections, include preprocedural, intraprocedural, and postprocedural work inherent in the procedure, the provider must not report an E&M service for this work.



### Example of an Evaluation and Management Service That Was Not Significant and Separately Identifiable From the Intravitreal Injection

On November 26, 2018, the Clinic billed Medicare for an E&M service (i.e., an ophthalmological medical examination and evaluation) in addition to intravitreal injections of Eylea into both eyes of a beneficiary. Medicare paid the Clinic \$109 for the E&M service, \$130 for the intravitreal injections, \$3,034 for Eylea, and \$120 for other services (injections of lidocaine, a diagnostic imaging service, and an extended ophthalmoscopy).

According to the independent medical review contractor, the E&M service was not separately identifiable and distinct from the pre- and postoperative work for the intravitreal injection. The contractor stated: "The [medical] record does not contain evidence that the E&M was warranted by the patient's condition as separately identifiable and unrelated to the minor procedure also performed. The record shows that the components of the physician evaluation are related to and included in the injection procedure. Therefore, use of bypass modifier 25 is not supported." As a result, the \$109 for the E&M service was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$84 for the lidocaine injections and the extended ophthalmoscopy.)

### THE CLINIC BILLED FOR SERVICES AND DRUGS THAT WERE NOT REASONABLE AND NECESSARY

The Clinic billed for 106 services and drugs that were not reasonable and necessary. Specifically, 100 extended ophthalmoscopies and the frequency of 3 intravitreal injections of Eylea (including the 3 doses of the drug) were not reasonable and necessary.<sup>27</sup>

#### Extended Ophthalmoscopies Were Not Reasonable and Necessary

##### *Medicare Requirements*

Payment must not be made under Medicare Part A or Part B for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

##### *Extended Ophthalmoscopies Provided on the Same Day as the Intravitreal Injections Were Not Reasonable and Necessary*

For 100 services, the Clinic billed for extended ophthalmoscopies provided on the same day as the intravitreal injections. These extended ophthalmoscopies were not reasonable and necessary. According to the independent medical review contractor, the Clinic provided other

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<sup>27</sup> For three sampled beneficiary days, the frequency of intravitreal injections was not reasonable and necessary. As a result, we disallowed three intravitreal injections and the three doses of Eylea that were injected, for a total of six services and drugs.

approved diagnostic imaging procedures that provided the same results as the extended ophthalmoscopies, and the extended ophthalmoscopies were not required.

For all 100 services, the medical records showed that extended ophthalmoscopies were performed at previous visits. According to the independent medical review contractor, the medical records did not contain evidence that it was necessary to perform an extended ophthalmoscopy at each visit or that a treatment plan was developed based on the extended ophthalmoscopy results. Therefore, the extended ophthalmoscopies were not supported as medically necessary.

#### Example of an Extended Ophthalmoscopy That Was Not Reasonable and Necessary

On March 7, 2018, the Clinic billed Medicare for an extended ophthalmoscopy in addition to an intravitreal injection of Eylea into a beneficiary's right eye. Medicare paid the Clinic \$22 for the extended ophthalmoscopy, \$87 for the intravitreal injection, \$1,524 for Eylea, and \$237 for other services (an E&M service, two diagnostic imaging services, and an injection of lidocaine).

According to the independent medical review contractor, the extended ophthalmoscopy was not reasonable and necessary. The medical review contractor stated that "another approved diagnostic imaging procedure was performed that provided results that included and exceeded the results available with an extended ophthalmoscopy" and that the other diagnostic imaging procedure provided enough information to visualize and treat the retina. The medical review contractor explained that the "findings in [the extended ophthalmoscopy] interpretations [were] visible through [the other diagnostic imaging procedure]" and the addition of an extended ophthalmoscopy was not necessary.

Additionally, the medical records showed that in the 6 months before the sampled date of service, the Clinic treated the beneficiary on five different visits and performed an extended ophthalmoscopy at each visit. The medical review contractor stated:

[T]he [medical] record [did] not contain evidence that it was necessary to perform the extended ophthalmoscopy at each visit. Generally, it is appropriate to perform extended ophthalmoscopy once to twice annually. There [was] also no evidence that the [beneficiary] benefitted from having this examination performed with the frequency at which it was performed. . . . There [was] also no evidence of a treatment plan being developed based on the extended ophthalmoscopy results.

Therefore, the extended ophthalmoscopy was not medically reasonable and necessary. As a result, the \$22 for the extended ophthalmoscopy was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$201 for the E&M service, a diagnostic imaging service, and the lidocaine injection.)

## The Frequency of Intravitreal Injections of Eylea Was Not Reasonable and Necessary

### *Medicare Requirements*

Payment must be not made under Medicare Part A or Part B for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)).

Generally, the FDA-recommended dosage of Eylea is 2 mg administered every 4 weeks (monthly). For wet AMD, the FDA-recommended dosage of Eylea after the first 3 months is 2 mg once every 8 weeks (2 months); however, some patients may continue to need monthly dosing after the first 3 months. (FDA, *Eylea (aflibercept injection) Intravitreal Injection*, Initial U.S. Approval: 2011. US BLA (BL125387) Aflibercept Injection.)<sup>28</sup>

### *The Medical Records Did Not Support the Need To Provide Eylea Injections More Frequently Than the FDA-Recommended Frequency*

For six services and drugs, the Clinic billed for intravitreal injections of Eylea at a frequency that was not reasonable and necessary.<sup>29</sup> According to the independent medical review contractor, the medical records did not contain clinical evidence to support the need to provide intravitreal injections more frequently than the FDA-recommended frequency of once every 4 weeks (28 days). The medical records showed that for three beneficiaries, the Clinic had provided intravitreal injections on the same eyes 11, 25, and 26 days before the respective sampled beneficiary days, and the medical records did not include clinical justifications for providing the intravitreal injections more frequently than once every 28 days. Two of the three beneficiaries were treated for wet AMD, and the remaining beneficiary was treated for macular edema.<sup>30</sup>

See the following page for an example of an intravitreal injection at a frequency that was not reasonable and necessary.

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<sup>28</sup> See Appendix C for the FDA-approved dosing guidelines of Eylea for different diagnoses.

<sup>29</sup> For three sampled beneficiary days, the frequency of intravitreal injections was not reasonable and necessary. As a result, we disallowed three intravitreal injections and the three doses of Eylea that were injected, for a total of six services and drugs. Our sample included 31 beneficiary days for intravitreal injections that were administered sooner than 28 days from the prior injection for the same eye; however, the independent medical review contractor determined that the intravitreal injections for 28 sampled beneficiary days were allowable.

<sup>30</sup> Macular edema occurs when fluid builds up in the macula (the functional center of the retina), causing swelling.

### Example of an Intravitreal Injection of Eylea at a Frequency That Was Not Reasonable and Necessary

On September 10, 2018, the Clinic billed Medicare for an intravitreal injection of Eylea into a beneficiary's left eye. Medicare paid the Clinic \$87 for the intravitreal injection, \$1,517 for Eylea, and \$341 for other services (an E&M service, three diagnostic imaging services, an extended ophthalmoscopy, and an injection of lidocaine). The date of the last intravitreal injection before this Eylea injection on the same eye was August 30, 2018 (11 days before the sampled beneficiary day).

According to the independent medical review contractor, the frequency of the Eylea injections was not medically reasonable and necessary. The medical review contractor stated: "The [FDA] guideline for Eylea is 28 days between injections. In this case, the medical record states that the injection was given early due to the patient going out of town. This is not a clinical indication for performing the Eylea injection at an earlier than recommended frequency (11 days). Therefore, the frequency for this Eylea injection is not medically reasonable and necessary." As a result, the \$1,604 for the intravitreal injection and Eylea was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$172 for the E&M service, the extended ophthalmoscopy, and the lidocaine injection.)

### **THE CLINIC DID NOT HAVE POLICIES AND PROCEDURES TO ENSURE THAT SERVICES AND DRUGS PROVIDED WERE CORRECTLY BILLED OR WERE REASONABLE AND NECESSARY**

The Clinic's medical director, who was also its only physician, stated that he was unfamiliar with Medicare's billing requirements. As a result, the Clinic did not have written policies and procedures to ensure that the separately payable services it billed were in accordance with Medicare requirements and the services and drugs it provided were reasonable and necessary.

### **The Clinic Did Not Have Policies and Procedures To Correctly Bill Separately Payable Services**

Because the Clinic's medical director was unfamiliar with Medicare's billing requirements, the Clinic did not have written policies and procedures to ensure that the services it billed as being separately payable from intravitreal injections of Eylea and Lucentis met Medicare's billing requirements. The Clinic paid a billing company to prepare and submit Medicare claims on the basis of information contained in a record referred to as a "superbill."<sup>31</sup> The superbill templates included a list of services and modifiers. The Clinic's medical director (who was the only physician in the Clinic) completed a superbill for each beneficiary and marked the services that he provided. He also marked modifier 59 to indicate that services were "distinct procedural services"; however, the superbill did not indicate which service should include

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<sup>31</sup> A superbill is an itemized form that some health care providers use to show which services were provided. A superbill is the main data source for creating a health care claim.

modifier 59. He stated that he used modifier 59 when billing for injections of anesthesia because the procedure required additional time and effort.

For all 100 sampled beneficiary days, the superbills indicated that an E&M service was provided but did not indicate that modifier 25 should be used.<sup>32</sup> The Clinic's medical director informed us that the billing company added modifier 25 to E&M services before submitting claims to Medicare.

The Clinic's medical director stated that he was unaware that he was using modifiers 59 and 25 incorrectly and that certain services could not be billed as being separately payable. He said that he relied on the billing company to determine how each service should be billed. According to the billing company, it did not review the medical records before submitting claims to Medicare.

### **The Clinic Did Not Have Policies and Procedures To Ensure That Services and Drugs Provided Were Reasonable and Necessary**

Because the Clinic's medical director was unfamiliar with Medicare's billing requirements, the Clinic did not have written policies and procedures to ensure that the services and drugs it provided were reasonable and necessary. The medical director explained that he was not aware of the billing guidelines for extended ophthalmoscopies. The medical director stated that he usually provides an extended ophthalmoscopy at every patient visit because it allows him to look at everything within the eye in detail to ensure that he does not miss anything that could have been detected by an extended ophthalmoscopy.

The Clinic did not have written policies and procedures for documenting the frequency of intravitreal injections in beneficiaries' medical records. The Clinic's medical director stated that he determined their frequency based on his clinical experience and the beneficiaries' conditions. However, no one at the Clinic reviewed the medical records to ensure that the Clinic had documented that the services and drugs provided to Medicare beneficiaries were reasonable and necessary.

### **THE CLINIC RECEIVED UNALLOWABLE MEDICARE PAYMENTS**

The Clinic received \$21,681 in Medicare payments for the 301 services and drugs that did not meet Medicare requirements. On the basis of our sample results, we estimated that at least \$398,625 of the \$4.3 million paid to the Clinic for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis was unallowable for Medicare reimbursement.

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<sup>32</sup> For all 100 sampled beneficiary days, the Clinic indicated on the superbills that an E&M service should be billed. However, based on our review of the Medicare claims data, the Clinic was not paid for the E&M services for five sampled beneficiary days.

## RECOMMENDATIONS

We recommend that the Clinic:

- refund to Noridian \$398,625 in estimated overpayments for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis;<sup>33</sup>
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule<sup>34</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation;
- implement policies and procedures to ensure that it does not bill for services that are not separately payable from intravitreal injections of Eylea and Lucentis; and
- implement policies and procedures to ensure that it documents in the medical records that the intravitreal injections of Eylea and Lucentis and other services provided on the same day as the injections are reasonable and necessary.

### THE CLINIC'S COMMENTS AND OFFICE OF INSPECTOR GENERAL'S RESPONSE

In written comments on our draft report, the Clinic expressed concern over our findings on E&M services and extended ophthalmoscopies and disagreed with our finding on the frequency of intravitreal injections. The Clinic concurred in part with our first recommendation and stated that it will repay overpayments for services that will not be subject to an appeal. The Clinic concurred with our second, third, and fourth recommendations and provided information on actions that it planned to take to address our recommendations. The Clinic's comments are included in their entirety as Appendix F.

After reviewing the Clinic's comments, we maintain that our findings and recommendations remain valid.

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<sup>33</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>34</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

## THE CLINIC'S COMMENTS

### *Findings on E&M Services and Extended Ophthalmoscopies*

The Clinic stated that because there is no “standard course of treatment,” the frequency of injections, the need for diagnostic testing, and the necessity for complete eye examinations must be evaluated in the context of a particular patient. The Clinic stated that, therefore, our findings that 100 percent of its E&M services and extended ophthalmoscopies furnished on the same day as intravitreal injections were not allowable “is concerning to the Clinic,” particularly where the medical record indicated such information as a new patient complaint, disease progression, or a threatening finding in the fellow eye requiring assessment.<sup>35</sup>

Regarding Medicare’s requirement that an E&M service must be significant and separately identifiable to be billed separately from an intravitreal injection, the Clinic stated that there is no definitive guidance as to how a health care provider is to interpret “this subjective standard” in the context of intravitreal injections and management of patients with chronic disease. The Clinic also stated that an interpretation that results in the ongoing evaluation and management of patients being done through preprocedure checks is not consistent with standards of care. Regarding footnote 13, which includes Noridian’s definition of a “significant, separately identifiable E&M service,” the Clinic stated that our report “does not provide particular guidance as to how this was applied.” The Clinic stated that it respects the concern addressed by OIG and, consistent with OIG’s recommendations, will take steps to determine the extent of any overpayments related to these services.

### *Finding on the Frequency of Intravitreal Injections of Eylea*

The Clinic stated that it believes the three Eylea injections we found to be unallowable were medically necessary and warranted payment. The Clinic stated that two of the three patients “presented to the Clinic on their own accord at days 25 and 26 since their previous injections,” and one of those patients complained of worsening vision. The Clinic stated that the third patient had a difficult-to-manage disease often requiring treatment at intervals less than 28 days. (This was the patient for which the Clinic had provided intravitreal injections on the same eye 11 days before the sampled beneficiary day.) The Clinic also stated that because this patient was scheduled to be out of town for several weeks, it was determined that the safest clinical course based on the patient’s documented history was to treat this patient early as opposed to risking serious deterioration.

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<sup>35</sup> The fellow eye is the eye that did not receive an intravitreal injection.

## *Recommendations*

The Clinic's comments on our recommendations were as follows:

- Regarding our first recommendation, the Clinic concurred in part and stated that repayments will be made reflecting overpayments for services that will not be subject to an appeal.
- Regarding our second recommendation, the Clinic concurred and stated that it will exercise diligence to comply with the 60-day rule.
- Regarding our third and fourth recommendations, the Clinic concurred and stated that it will implement policies and procedures to properly educate the Clinic's employees on Medicare requirements for intravitreal injections and other services furnished to these patients so that bills submitted to Medicare are correct and to assure that medical records include required documentation to support that services furnished are reasonable and necessary.

## **OFFICE OF INSPECTOR GENERAL'S RESPONSE**

We maintain that our findings and recommendations remain valid.

### *Findings on E&M Services and Extended Ophthalmoscopies*

Regarding our finding on E&M services, the independent medical review contractor concluded that the E&M services were not separately payable because the medical records did not support that the criteria for the E&M services were met and that the services billed were significant and separately identifiable from the intravitreal injection procedures. The majority of the E&M services billed separately by the Clinic were for comprehensive ophthalmological medical examinations and evaluations, which include an evaluation of the complete visual system (i.e., both eyes) and the "initiation of diagnostic and treatment programs." According to the independent medical review contractor, the medical records showed that the components of the physician evaluation were related to and included in the intravitreal injection procedures; therefore, the E&M services were not separately payable from the intravitreal injection procedures.<sup>36</sup>

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<sup>36</sup> The components of E&M services (physician evaluations) include patient history (e.g., chief complaint and history of present illness), patient examination, and medical decision making.



Regarding our finding on extended ophthalmoscopies, the medical records showed that scanning computerized ophthalmic diagnostic imaging (SCODI) services for the retina were also provided on the same day and were allowable.<sup>37</sup> According to the independent medical review contractor, the SCODI services provided the same results as the extended ophthalmoscopies, and the extended ophthalmoscopies were not required.

*Finding on the Frequency of Intravitreal Injections of Eylea*

Regarding our finding on the frequency of intravitreal injections of Eylea, for the three injections of Eylea, the independent medical review contractor reviewed the medical records for these services twice and stated that the medical records did not include documentation of the clinical justifications for providing the intravitreal injections more frequently than once every 28 days.<sup>38</sup>

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<sup>37</sup> SCODI is a diagnostic imaging service that involves shining a narrow beam of light into the eye and using computers to construct cross-sectional tomographic images of structures in the eye, including the retina. It can be used to assess the presence and progression of glaucoma and retinal disorders, as well as certain disorders of the anterior eye.

<sup>38</sup> The independent medical review contractor reviewed these services twice before the draft report was issued to the Clinic.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered Medicare Part B payments for intravitreal injections of Eylea and Lucentis (and other services provided on the same day as the injections) that the Clinic provided from January 1 through December 31, 2018. Our sampling frame consisted of 2,305 beneficiary days, with payments totaling \$4,344,096.<sup>39</sup> We selected a stratified random sample of 100 beneficiary days, totaling \$191,527 and consisting of the following 627 services and drugs:<sup>40</sup>

- 132 diagnostic imaging services,
- 100 intravitreal injections,
- 100 extended ophthalmoscopies (detailed examinations of the part of the eye that includes the retina),
- 100 injections of medication (for the anesthesia drug lidocaine);
- 95 E&M services,
- 81 doses of Eylea,<sup>41</sup> and
- 19 doses of Lucentis (0.5-mg doses).

The Clinic provided us with supporting documentation for the beneficiary days in our sample. The supporting documentation included the medical records for 6 months before and 1 month after each sampled beneficiary day. We submitted the supporting documentation to an independent medical review contractor to determine whether the intravitreal injections of Eylea and Lucentis and other services provided on the same day as the injections were reasonable and necessary and met Medicare requirements.

We did not review the Clinic's overall internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective. Specifically, our review of internal controls focused on the Clinic's control activities for documenting and billing Medicare for intravitreal injections and for other services provided on the same day as the injections. We assessed whether the Clinic designed the entity's information system and control activities to

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<sup>39</sup> A beneficiary day consisted of all Medicare Part B services and drugs provided on a specific date of service to a specific beneficiary in which intravitreal injections of Eylea or Lucentis were administered. We excluded from our sampling frame beneficiary days that did not contain the procedure codes for an intravitreal injection of either Eylea or Lucentis.

<sup>40</sup> Each sampled beneficiary day consisted of at least four services, including the intravitreal injection procedure, and one drug. Most of the beneficiary days included the intravitreal injection, the drug (Eylea or Lucentis), and these other services: a diagnostic imaging service, an extended ophthalmoscopy, an injection of an anesthesia drug (lidocaine), and an E&M service.

<sup>41</sup> For 75 of the 81 doses of Eylea, the Clinic billed 2 units of Eylea, for a total of 2 mg. For the remaining 6 doses of Eylea, the Clinic billed 2 units of Eylea for each eye, for a total of 4 mg.

achieve objectives and respond to risks. We also assessed whether the Clinic implemented control activities through policies.

To assess the Clinic's control activities, we interviewed Clinic officials and the Clinic's biller to obtain an understanding of the Clinic's policies and procedures for documenting and billing intravitreal injections and other services provided on the same day as the injections. We also requested the Clinic's written policies and procedures for documenting and billing the services and drugs it provided.

We conducted our audit from July 2019 to January 2021, which included fieldwork performed at the Clinic, which is located in Newport Beach, California.

## **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and coding guidance, as well as AMA's *CPT 2018 Professional* and FDA-approved dosing guidelines;
- interviewed Noridian officials to obtain an understanding of Medicare reimbursement requirements for intravitreal injections and other services provided on the same day as the injections;
- interviewed Clinic officials and the Clinic's biller to obtain an understanding of the Clinic's policies and procedures for providing, documenting, and billing intravitreal injections and other services provided on the same day as the injections;
- obtained from CMS's National Claims History (NCH) file the paid Medicare Part B claims for services and drugs that the Clinic provided to Medicare beneficiaries during our audit period;<sup>42</sup>
- created a sampling frame of 2,305 beneficiary days for intravitreal injections of Eylea and Lucentis and for other services provided on the same day as the injections and selected a stratified random sample of 100 beneficiary days (Appendix D);
- reviewed data from CMS's Common Working File for the claims included in the sampled beneficiary days to determine whether the claims had been canceled or adjusted;
- obtained from the Clinic the supporting documentation for the sampled beneficiary days and submitted the documentation to an independent medical review contractor to

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<sup>42</sup> Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

determine whether the intravitreal injections and other services provided on the same day as the injections were reasonable and necessary and met Medicare requirements;

- obtained from the Clinic additional information for certain services and drugs related to 13 sampled beneficiary days and submitted the additional information to the independent medical review contractor to re-review and determine whether the services and drugs were reasonable and necessary and met Medicare requirements;
- estimated the amount overpaid to the Clinic for services that did not comply with Medicare requirements (Appendix E); and
- shared the results of our audit with the Clinic’s medical director.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>The Medicare Contractor for Jurisdiction 1 Overpaid a Provider That Incorrectly Billed for Aflibercept</i>	<a href="#"><u>A-06-14-00055</u></a>	6/30/2015
<i>Wisconsin Physicians Service Insurance Corporation Overpaid a Provider That Incorrectly Billed for Aflibercept</i>	<a href="#"><u>A-06-14-00051</u></a>	6/22/2015
<i>CGS Administrators, LLC, Overpaid Providers That Incorrectly Billed for Aflibercept</i>	<a href="#"><u>A-06-14-00053</u></a>	5/14/2015
<i>Medicare Paid \$22 Million in 2012 for Potentially Inappropriate Ophthalmology Claims</i>	<a href="#"><u>OEI-04-12-00281</u></a>	12/22/2014
<i>Fletcher Allen Health Care Did Not Always Bill Correctly for Evaluation and Management Services Related to Eye Injection Procedures</i>	<a href="#"><u>A-01-11-00515</u></a>	5/21/2012
<i>Medicare Payments for Drugs Used to Treat Wet Age Related Macular Degeneration</i>	<a href="#"><u>OEI-03-10-00360</u></a>	4/20/2012
<i>Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration</i>	<a href="#"><u>A-01-10-00514</u></a>	9/6/2011
<i>Use of Modifier 59 to Bypass Medicare's National Correct Coding Initiative Edits</i>	<a href="#"><u>OEI-03-02-00771</u></a>	11/25/2005

**APPENDIX C: FDA-APPROVED DOSING GUIDELINES FOR EYLEA AND LUCENTIS  
FOR DIFFERENT DIAGNOSES**

	<b>Eylea<sup>43</sup></b>	<b>Lucentis<sup>44</sup></b>
<b>Wet AMD</b>	2 mg administered every 4 weeks (monthly) for the first 3 months, followed by 2 mg once every 8 weeks (2 months). Although Eylea may be dosed as frequently as 2 mg monthly, additional efficacy was not demonstrated in most patients when Eylea was dosed monthly compared to every 8 weeks. Some patients may need monthly dosing after the first 12 weeks (3 months).	0.5 mg administered once a month (approximately 28 days). Although not as effective, patients may be treated with three monthly doses followed by less frequent dosing with regular assessment. Although not as effective, patients may also be treated with one dose every 3 months after four monthly doses. Patients should be assessed regularly.
<b>Macular Edema Following Retinal Vein Occlusion</b>	2 mg administered once every 4 weeks (monthly).	0.5 mg administered once a month (approximately 28 days).
<b>Diabetic Macular Edema and Diabetic Retinopathy</b>	2 mg administered every 4 weeks (monthly) for the first five injections, followed by 2 mg once every 8 weeks (2 months). Although Eylea may be dosed as frequently as 2 mg monthly, additional efficacy was not demonstrated in most patients when Eylea was dosed every month compared to every 8 weeks. Some patients may need monthly dosing after the first 20 weeks (5 months).	0.3 mg administered once a month (approximately 28 days).
<b>Myopic Choroidal Neovascularization</b>	NA	0.5 mg initially administered once a month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.

<sup>43</sup> FDA, *Eylea (aflibercept injection) Intravitreal Injection*, Initial U.S. Approval: 2011. US BLA (BL125387) Aflibercept Injection.

<sup>44</sup> FDA, *Lucentis (ranibizumab injection) Intravitreal Injection*, Initial U.S. Approval: 2006. US BLA (BL125156) Ranibizumab Injection.

## APPENDIX D: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

We obtained Medicare Part B claims data for intravitreal injections of Eylea and Lucentis and for other services and drugs that the Clinic provided during our audit period, representing 26,607 line items totaling \$4,991,165. (Each line item represented a billed service or drug on a claim.) We grouped the line items by beneficiary Health Insurance Claim Number and date of service to identify the beneficiary days. The total beneficiary days for the Clinic during our audit period were 4,396. We excluded 2,091 beneficiary days that did not contain the procedure codes for an intravitreal injection of either Eylea or Lucentis. As a result, the sampling frame consisted of 2,305 beneficiary days, which had 14,742 line items totaling \$4,344,096.

### SAMPLE UNIT

The sample unit was a beneficiary day for which Medicare paid for services and drugs provided by the Clinic.

### SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. We divided the sampling frame into two strata (Table 2).

**Table 2: Strata in Sampling Frame**

Stratum	Description	No. of Beneficiary Days in Sampling Frame	Sample Size	Value of Beneficiary Days in Sampling Frame
1	Greater than or equal to 28 days from previous beneficiary day	1,124	50	\$2,136,735
2	Less than 28 days from previous beneficiary day <sup>45</sup>	1,181	50	2,207,361
<b>Total</b>		<b>2,305</b>	<b>100</b>	<b>\$4,344,096</b>

### SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

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<sup>45</sup> Because 96 percent of the intravitreal injections did not include a modifier to indicate whether an injection was for the left or right eye, our data analysis did not show whether an injection was provided on the same eye as the prior injection. Of the 50 sampled beneficiary days in this stratum, 31 were for injections that were administered sooner than 28 days from the prior injection for the same eye.

## **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in each stratum of the sampling frame. After generating 50 random numbers for stratum 1 and 50 random numbers for stratum 2, we selected the corresponding frame items.

## **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to estimate the amount of unallowable payments for intravitreal injections of Eylea and Lucentis and for other services provided on the same day as the injections. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.



**APPENDIX E: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

Stratum	No. of Beneficiary Days in Sampling Frame	Value of Beneficiary Days in Sampling Frame	Sample Size	No. of Services and Drugs in Sample	Value of Sample	No. of Unallowable Services and Drugs	Value of Unallowable Services and Drugs
1	1,124	\$2,136,735	50	311	\$96,902	145	\$8,250
2	1,181	2,207,361	50	316	94,625	156	13,431
<b>Total</b>	<b>2,305</b>	<b>\$4,344,096</b>	<b>100</b>	<b>627</b>	<b>\$191,527</b>	<b>301</b>	<b>\$21,681</b>

**Table 4: Estimated Value of Unallowable Payments in the Sampling Frame  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$502,709
Lower limit	398,625
Upper limit	606,794

## APPENDIX F: THE CLINIC'S COMMENTS

# Arnold & Porter

February 17, 2021

### **DELIVERY VIA EMAIL & FEDERAL EXPRESS**

Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
Region IX  
90 - 7th Street, Suite 3-650  
San Francisco, CA 94103

*Re: Draft Audit Report A-09-19-03022*

Dear Ms. Ahlstrand:

Thank you for the opportunity to review the draft report (Report) from the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) titled *Ophthalmology Clinic in California: Audit of Medicare Payments for Eylea and Lucentis*. This letter is submitted on behalf of the Ophthalmology Clinic (Clinic) and responds to the OIG's request for comment on the OIG findings and recommendations discussed in the Report.

#### **I. Background**

The availability of anti-VEGF drugs, such as Lucentis and Eylea, revolutionized the treatment of diabetic retinopathy/diabetic macular edema (DME) and wet age-related macular degeneration (ARMD), among other diseases. Left untreated or under treated, DME and ARMD can cause permanent irreversible vision loss or complete blindness. Patients may have active disease in one or both eyes,<sup>1</sup> and are never "cured." These patients also often suffer from a host of co-morbidities, including other eye diseases, which can further complicate the clinical management of these already high-risk patients. Thus, the care plan for these patients involves vigilant evaluation and monitoring of both eyes and treatment intervention to maintain vision.

Intravitreal injections of anti-VEGF therapy may be one of the most common eye procedures performed today, but despite being common, anti-VEGF treatment rarely is "standard." Early anti-VEGF therapy management strategy arose from the pivotal registration trials for Lucentis. The standard of care was monthly dosing (every 28 days) with examination to monitor clinical response, disease progression, and side effects. The every-28-day regimen put significant resource burdens on patients, their caregivers, and

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<sup>1</sup> Patients who initially present with disease in one eye frequently progress to having disease in both eyes.

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retinal practices. This led retinal specialist to seek alternative dosing schedules that maintained patients' vision while reducing the numbers of injections a patient received per year. One of the most important studies was supported by the National Eye Institute of the National Institutes of Health to test an "as needed" (or PRN) drug dosing schedule, which demonstrated that, while patients could be treated with injections less frequently, they still required regular examination to evaluate disease status. Retina specialists also trialed every other month and quarterly injection protocols, but these protocols resulted in worse clinical outcomes. These studies, however, lead to the investigation of a treatment protocol referred to as "treat and extend," which aims to increase the interval between a particular patient's injections by closely monitoring the patient's response to treatment and finding the "challenge interval" where the patient begins to show signs of disease breakthrough. There is no question that each patient's care plan is unique to his/her disease pattern, response to treatment, and tolerance of injections. Indeed, safe utilization of any of these alternative protocols is founded on regular examinations.

### **II. Denial of All Extended Ophthalmoscopy and E&M Services**

Because there is no "standard course of treatment," the frequency of injections, the need for diagnostic testing, and necessity for complete eye examinations must be evaluated in the context of a particular patient. Thus, the audit findings that 100% of the Clinic's extended ophthalmoscopies and evaluation and management services furnished on the day of an injection were not allowable is concerning to the Clinic, particularly (by way of example) where the record indicates such information as a new patient complaint, disease progression or a threatening finding in the fellow eye requiring assessment.

The question of under what clinical circumstances an evaluation and management service is separately payable on the same date of service as an intravitreal injection has been for more than a decade, and continues to be, the subject of debate and a myriad of evolving interpretations and understandings. As set out in the Report, in order for an E&M service to be separately billable from an intravitreal injection, the E/M service must be a "significant, separately identifiable E[&]M services above and beyond the other service provided or beyond the usual pre-operative and post-operative care associated with [an intravitreal injection]." Yet, there is no definitive guidance as to how a healthcare provider is to interpret this subjective standard in the context of anti-VEGF treatments and the management of patients with chronic disease. An interpretation that results in the ongoing evaluation and management of patients on chronic anti-VEGF therapy being done through pre-procedure checks is not consistent with standards of care. Footnote thirteen explains that "[a]ccording to Noridian, a significant, separately identifiable E&M service is defined or substantiated by documentation that satisfies the relevant criteria for the respective E&M service to be reported," but the Report does not provide particular guidance as to how this was applied. Nevertheless, the Clinic respects the concern addressed by the OIG and, consistent with the OIG's recommendations will take steps to determine the extent of any overpayment related to these services.

### III. Denial of Three Eylea Injections

The Clinic believes that the three Eylea injections found to be unallowable were medically necessary and warrant payment. Two of three patients presented to clinic on their own accord at days 25 and 26 since their previous injections. The patient presenting on day 25 complained of worsening vision. The third patient had difficulty to manage disease often requiring treatment at intervals less than 28 days. The patient was scheduled to be out of town for several weeks. Thus, it was determined the safest clinical course based on the patient's documented history would be to treat early as opposed to risk serious deterioration. Based on the facts surrounding each case, the Clinic believes treatment was reasonable and necessary.

### IV. OIG Recommendations

Finally, the OIG requested the Clinic respond to the four recommendations it proposed in the Report.

Recommendation 1. The Clinic concurs in part. Repayments will be made reflecting overpayments for services that will not be subject of an appeal.

Recommendation 2. The Clinic concurs. It will exercise reasonable diligence to comply with its 60-day obligations.

Recommendation 3. The Clinic concurs. It will implement policies and procedures to properly educate Clinic employees of the Medicare coverage, documentation and payment rules for intravitreal injections and other services furnished to patients on chronic anti-VEGF treatment so bills submitted to Medicare are correct.

Recommendation 4. The Clinic concurs. It will implement policies and procedures to properly educate Clinic employees of the Medicare coverage, documentation and payment rules for intravitreal injections and other services furnished to patients on chronic anti-VEGF treatment to assure medical records include required documentation to support that services furnished are reasonable and necessary.

Respectfully submitted,



Allison W. Shuren