

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

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

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**A-09-19-03025**

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## Report in Brief

Date: September 2021  
Report No. A-09-19-03025



### 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 Florida (the Clinic) frequently billed for other services as being distinct from or significant and separately identifiable from intravitreal (inside the eye) injections of the drugs Avastin, Eylea, and Lucentis.

Our objective was to determine whether the Clinic complied with Medicare requirements when billing for intravitreal injections of Avastin, 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 \$2.1 million for intravitreal injections of Avastin, 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 543 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 Avastin, 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 Florida: Audit of Medicare Payments for Eye Injections of Avastin, Eylea, and Lucentis

### What OIG Found

The Clinic complied with Medicare requirements when billing for intravitreal injections of Avastin, Eylea, and Lucentis. (Injections of Lucentis were not included in our sample.) 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). All 100 sampled beneficiary days included at least 1 service that did not comply with Medicare requirements. For 317 of the 543 services and drugs associated with the 100 sampled beneficiary days, the Clinic complied with Medicare requirements. However, for the remaining 226 services, the Clinic did not comply with the requirements: 156 services were not separately payable, and 70 services were not reasonable and necessary.

The Clinic did not have policies and procedures to ensure that it: (1) did not bill for services that were not separately payable from intravitreal injections of Avastin, Eylea, and Lucentis and (2) billed only for services that were reasonable and necessary. On the basis of our sample results, we estimated that at least \$215,606 of the \$2.1 million paid to the Clinic for intravitreal injections of Avastin, Eylea, and Lucentis and for other services provided on the same day as the injections was unallowable for Medicare reimbursement.

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

We recommend that the Clinic refund to the Medicare contractor \$215,606 in estimated overpayments for other services provided on the same day as intravitreal injections of Avastin, Eylea, and Lucentis. We also recommend that the Clinic implement policies and procedures to ensure that it: (1) does not bill for services that are not separately payable from intravitreal injection of Avastin, Eylea, and Lucentis and (2) bills only for services that are reasonable and necessary. The report contains one other recommendation.

The Clinic concurred in part with our first recommendation and stated that a repayment will be made but that it will appeal certain determinations. 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 are valid. As stated in the report, OIG audit recommendations do not represent final determinations by Medicare.

## TABLE OF CONTENTS

INTRODUCTION .....	1
Why We Did This Audit.....	1
Objective .....	1
Background .....	2
The Medicare Program .....	2
Ophthalmology Services and Intravitreal Injections .....	2
Medicare Coverage of Intravitreal Injections of Avastin, Eylea, and Lucentis.....	3
An Ophthalmology Clinic in Florida .....	5
Medicare Requirements for Providers To Identify and Return Overpayments.....	6
How We Conducted This Audit.....	6
FINDINGS .....	7
The Clinic Billed for Services That Were Not Separately Payable .....	8
Injections of an Anesthesia Drug Were Not Distinct or Independent From the Intravitreal Injections.....	8
Evaluation and Management Services Were Not Significant and Separately Identifiable From the Intravitreal Injections .....	10
The Clinic Billed for Services That Were Not Reasonable and Necessary .....	13
The Clinic Received Unallowable Medicare Payments .....	14
RECOMMENDATIONS.....	15
THE CLINIC’S COMMENTS AND OFFICE OF INSPECTOR GENERAL’S RESPONSE .....	15
The Clinic’s Comments .....	16
Office of Inspector General’s Response.....	16
APPENDICES	
A: Audit Scope and Methodology.....	17
B: Related Office of Inspector General Reports.....	20
C: Statistical Sampling Methodology .....	21

D: Sample Results and Estimates.....	23
E: The Clinic's Comments .....	24

## INTRODUCTION

### WHY WE DID THIS AUDIT

Medicare Part B reimburses physicians for injections of the drugs Avastin, 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 \$3.3 billion for Avastin, 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 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 and (2) services that were billed as being distinct from other services provided on the same day. (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 Florida (the Clinic) was one of those providers identified for audit.<sup>3</sup> Our analysis showed that during our audit period, the Clinic frequently billed for other services as being distinct from or significant and separately identifiable from intravitreal injections of Avastin, Eylea, and Lucentis.<sup>4</sup>

### OBJECTIVE

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

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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> We plan to issue a separate report for each provider. The report on the first provider we selected for audit was entitled *An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea and Lucentis* ([A-09-19-03022](#)), issued March 29, 2021.

<sup>4</sup> The generic names for Avastin, Eylea, and Lucentis are bevacizumab, aflibercept, and ranibizumab, respectively.

## 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, First Coast Service Options, Inc. (First Coast), was the MAC that processed and paid the Clinic's Medicare claims.

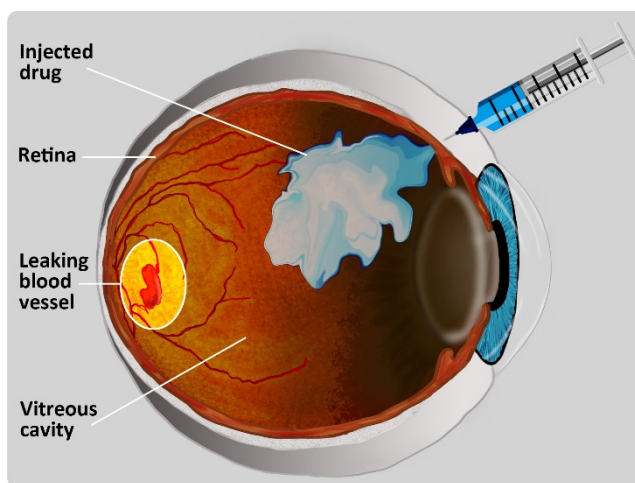
### Ophthalmology Services and Intravitreal Injections

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. Avastin, a drug used to treat certain cancers, may be prescribed "off-label" to treat the same eye diseases that are treated by Eylea and Lucentis.<sup>5</sup>

Wet AMD occurs when abnormal blood vessels begin to grow underneath the retina and leak blood or fluid that blurs central vision. Avastin, 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.

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



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<sup>5</sup> "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.




## Medicare Coverage of Intravitreal Injections of Avastin, 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 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 a separate payment for an injection of an anesthesia drug when billed with an intravitreal injection.<sup>9</sup>

Medicare Part B pays for Avastin, 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

**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)(2)(B). See also, *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 50.

identifiable from the surgery.<sup>11, 12</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>13</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>14</sup>
- **Modifier 59** indicates that a service was distinct or independent from other non-E&M services provided on the same day.<sup>15</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>16</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>17</sup>

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<sup>11</sup> An example of a diagnostic imaging service is scanning computerized ophthalmic diagnostic imaging of the retina.

<sup>12</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>13</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. 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>14</sup> American Medical Association (AMA), *Current Procedural Terminology (CPT) 2018 Professional*. According to First Coast, to be eligible for payment, the medically necessary E&M service and the procedure must be appropriately and sufficiently documented in the patient’s medical record to support the claim for these services.

<sup>15</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>16</sup> NCCI Policy Manual, chapter I, § E(1).

<sup>17</sup> The Act § 1833(e). See also, CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 12, §§ 30.6.6(B), 40.2(A)(8), and 40.4(A).

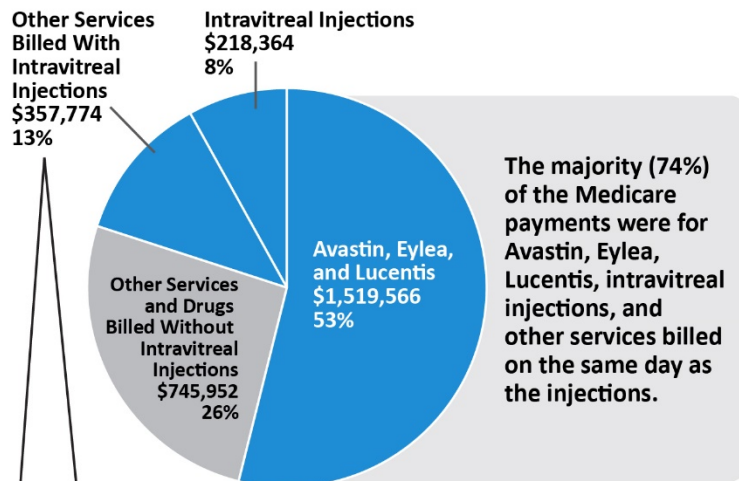
## An Ophthalmology Clinic in Florida

The Clinic is located in Bonita Springs, Florida. It was established in 2006 by a physician, who is the sole owner and medical director of the clinic. The medical director is the only physician in the clinic and specializes in the treatment of eye diseases and surgery of the retina and macula (the functional center of the retina).

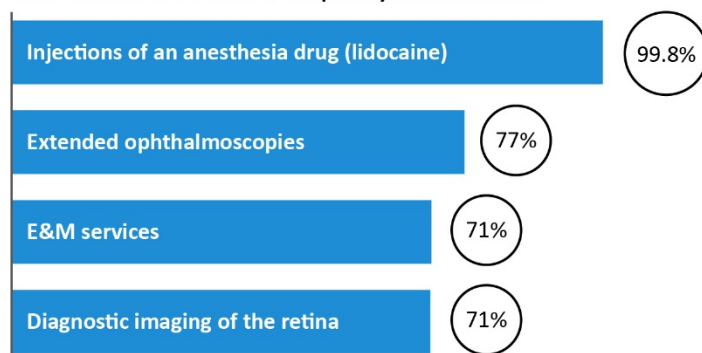
For our audit period, Medicare paid the Clinic \$2.8 million. Our analysis of Medicare claims data indicated that the majority (74 percent) of these payments were for intravitreal injections of Avastin, Eylea, and Lucentis and for other services that were billed on the same day as the intravitreal injections.<sup>18</sup> The remaining 26 percent of the Medicare payments were for other services and drugs billed without an intravitreal injection of Avastin, Eylea, or Lucentis (top half of Figure 3).

Our data analysis showed that 93 percent of Medicare payments for other services billed on the same days as intravitreal injections of Avastin, Eylea, and Lucentis were for four services that the Clinic frequently billed on the same days as the intravitreal injections (bottom half of Figure 3).<sup>19</sup>

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



Ninety-three percent of the Medicare payments for these other services were for four frequently billed services:



○ The percentage of days on which the Clinic billed the service with an intravitreal injection.

<sup>18</sup> Our audit covered payments for these services. Other services billed on the same day as the intravitreal injections included injections of an anesthesia drug (lidocaine), extended ophthalmoscopies, E&M services, and various diagnostic imaging services. (An extended ophthalmoscopy is a detailed examination of the part of the eye that includes the retina.)

<sup>19</sup> The Clinic billed injections of an anesthesia drug (lidocaine) and E&M services with bypass modifiers and billed extended ophthalmoscopies with modifiers indicating that these procedures were performed on the eye that did not receive an intravitreal injection. Bypass modifiers are not required when billing for diagnostic imaging of the retina.

## 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 Avastin, 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 2,578 beneficiary days, with payments totaling \$2.1 million.<sup>22</sup> We selected a stratified random sample of 100 beneficiary days, totaling \$98,476 and consisting of the following 543 services and drugs:<sup>23</sup>

- 100 intravitreal injections,
- 99 injections of an anesthesia drug (lidocaine),
- 94 diagnostic imaging services,
- 77 extended ophthalmoscopies,
- 73 E&M services,
- 50 doses of Avastin, and
- 50 doses of Eylea.

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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 Avastin, Eylea, or Lucentis were administered.

<sup>23</sup> Each beneficiary day in the sample consisted of at least two services, including the intravitreal injection, and one drug. Most of the beneficiary days included the intravitreal injection, the drug (Avastin or Eylea), and these other services: an injection of an anesthesia drug (lidocaine), a diagnostic imaging service, an extended ophthalmoscopy, and an E&M service. Two injections of Lucentis were included in our sampling frame; however, the Lucentis injections were not selected for the sample.

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 Avastin and Eylea 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 C describes our statistical sampling methodology, and Appendix D contains our sample results and estimates.

## FINDINGS

The Clinic complied with Medicare requirements when billing for intravitreal injections of Avastin, Eylea, and Lucentis.<sup>24</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 that did not comply with Medicare requirements.<sup>25</sup> For 317 of the 543 services and drugs associated with the 100 sampled beneficiary days, the Clinic complied with Medicare requirements. However, for the remaining 226 services, the Clinic did not comply with the requirements: 156 services were not separately payable, and 70 services 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 their related payments.

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<sup>24</sup> All of the intravitreal injections in our sample and the related doses of the drugs Avastin and Eylea complied with Medicare requirements. The intravitreal injections and the related doses of Avastin and Eylea accounted for 85 percent of the total payments in our sample. Injections of Lucentis were not selected for our sample.

<sup>25</sup> For each beneficiary day, we disallowed only the amounts paid for the services that did not comply 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
Intravitreal injections	100	100	0	\$8,478	\$8,478	\$0
Injections of an anesthesia drug	99	0	99	1,705	0	1,705
Diagnostic imaging services	94	94	0	3,651	3,651	0
Extended ophthalmoscopies	77	7	70	1,571	139	1,432
E&M services	73	16	57	7,458	1,607	5,851
Doses of Avastin	50	50	0	1,955	1,955	0
Doses of Eylea	50	50	0	73,658	73,658	0
<b>Totals</b>	<b>543</b>	<b>317</b>	<b>226</b>	<b>\$98,476</b>	<b>\$89,488</b>	<b>\$8,988</b>

\* There were no unallowable drugs in the sample.

The Clinic's medical director was unaware that injections of an anesthesia drug were included in the Medicare payment for intravitreal injections and were not separately payable. In addition, the Clinic did not have policies and procedures to ensure that it: (1) did not bill for services that were not separately payable from intravitreal injections of Avastin, Eylea, and Lucentis and (2) billed only for services that were reasonable and necessary. As a result, the Clinic received \$8,988 in unallowable Medicare payments for the 226 services that did not meet Medicare requirements. On the basis of our sample results, we estimated that at least \$215,606 of the \$2.1 million paid to the Clinic for intravitreal injections of Avastin, Eylea, and Lucentis and for other services provided on the same day as the injections 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 156 services that were not separately payable. Specifically, 99 injections of an anesthesia drug (lidocaine) were not distinct or independent from the intravitreal injections, and 57 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 a 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 99 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 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 intravitreal 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 Lidocaine That Was Not Distinct or Independent From the Intravitreal Injection

On July 11, 2018, the Clinic billed Medicare for a lidocaine injection in addition to an intravitreal injection of Avastin into a beneficiary’s left eye. Medicare paid the Clinic \$17 for the lidocaine injection, \$85 for the intravitreal injection, \$39 for Avastin, and \$157 for other services (an E&M service, an extended ophthalmoscopy, and a diagnostic imaging service). 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 \$17 for the lidocaine injection was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$103 for the E&M service and \$20 for the extended ophthalmoscopy.)

The Clinic's medical director stated that during our audit period, he was not aware that the injection of an anesthesia drug was included in the global surgery payment for an intravitreal injection. He was also not aware that modifier 59 was being used incorrectly. He stated that he provided the lidocaine injections because they reduced the infection rate and reduced pain for patients.

The Clinic did not have policies and procedures to ensure that injections of anesthesia drugs were not billed with intravitreal injections; however, the Clinic's biller stated that she stopped billing for injections of an anesthesia drug when she became aware that these injections were included in the payment for intravitreal injections. The medical director stated that the Clinic stopped billing Medicare for anesthesia drug injections in August or September 2019.<sup>26</sup>

### **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 performed 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.

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<sup>26</sup> The Medicare claims data showed that the Clinic stopped billing for the injections of an anesthesia drug on August 23, 2019, which was almost 8 months after the end of our audit period.

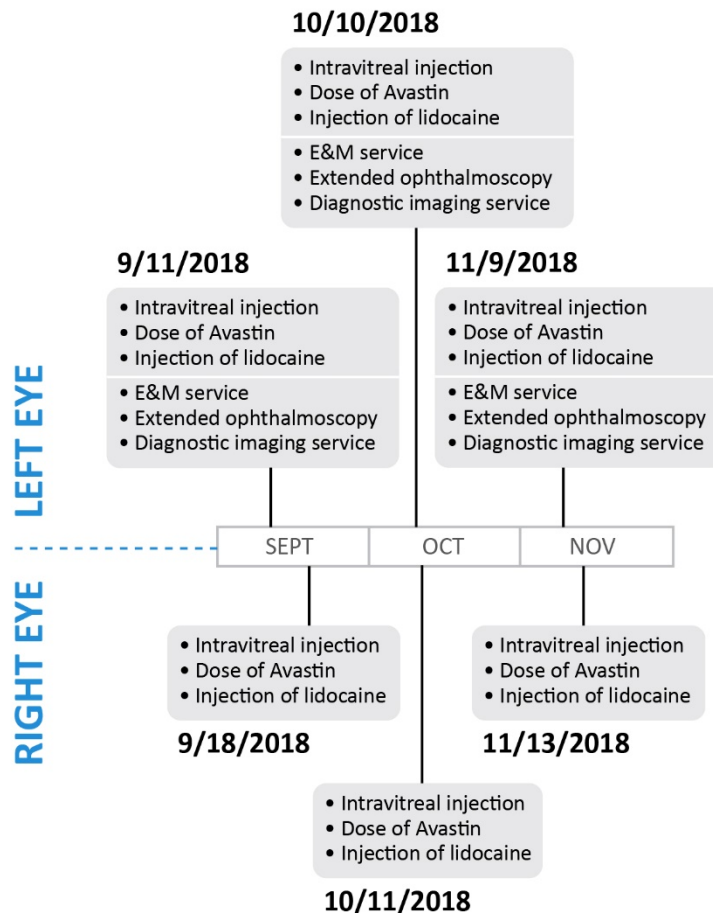


### *Ophthalmological Medical Examinations and Evaluations Were Not Significant and Separately Identifiable From Intravitreal Injections Provided on the Same Day*

For 57 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 E&M services were significant and separately identifiable from the injection procedures. 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.<sup>27</sup> Because minor surgical procedures, such as intravitreal injections, include preprocedural, intra-procedural, and postprocedural work inherent in the procedure, the provider must not report an E&M service for this work.

The Clinic's medical director stated that he provided E&M services on the eye that did not receive the intravitreal injection (i.e., the other eye). Our data analysis showed that the Clinic had a billing pattern in which it alternated the number of other services billed with the intravitreal injections provided to beneficiaries who received intravitreal injections in both eyes. For example, on 1 day, the Clinic billed an intravitreal injection of Avastin for the left eye along with four other services (i.e., an injection of lidocaine, an E&M service, an extended ophthalmoscopy, and a diagnostic imaging service). A few days later, the Clinic billed an intravitreal injection of Avastin for the right eye along with an injection of lidocaine. Figure 4 illustrates this billing pattern for one beneficiary.

**Figure 4: The Clinic's Billing Pattern for One Beneficiary**



<sup>27</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.

For 21 of the 57 E&M services that were not significant and separately identifiable from the intravitreal injections, the independent medical review contractor determined that the E&M services were for the purpose of deciding to treat the beneficiary's other eye with an intravitreal injection on a future date. However, 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.

#### Example of an E&M Service That Was Not Significant and Separately Identifiable From the Intravitreal Injection

On March 22, 2018, the Clinic billed Medicare for an E&M service (i.e., an ophthalmological medical examination and evaluation) in addition to an intravitreal injection of Eylea into a beneficiary's right eye. Medicare paid the Clinic \$103 for the E&M service, \$85 for the intravitreal injection, \$1,524 for Eylea, and \$72 for other services (an injection of lidocaine, an extended ophthalmoscopy, and a diagnostic imaging service).

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 medical review 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."

In addition, the medical review contractor determined that the E&M service was for the purpose of deciding to treat the beneficiary's other eye with an intravitreal injection on a future date. The medical record and claims data showed that the intravitreal injection for the beneficiary's other eye was performed on March 23, 2018 (1 day after the sampled date of service). 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.

As a result, the \$103 for the E&M service was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$17 for the injection of lidocaine and \$20 for the extended ophthalmoscopy.)

The Clinic's medical director stated that he was aware that E&M services may be separately payable from the intravitreal injection if the patient's condition required a significant and separately identifiable E&M service. According to the medical director, the E&M services that he billed were appropriate because they were provided for the other eye. He stated that most of his patients have diseases in both eyes and that an examination in both eyes is warranted for patients with macular degeneration. He said that he checks the other eye to ensure that a disease does not develop.

The Clinic did not have policies and procedures to ensure that the Clinic billed only for E&M services that were indicated in the medical records as significant and separately identifiable E&M services above and beyond the other services provided. Furthermore, the Clinic did not have policies and procedures to ensure that it did not bill E&M services for the work associated with the decision to perform a minor surgical procedure.

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

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)). “In all instances extended ophthalmoscopies must be medically necessary. It must add information not available from the standard evaluation services and/or information that will demonstrably affect the treatment plan. It is not necessary, for example, to confirm information already available by other means” (First Coast’s Local Coverage Determination (LCD) L34017).<sup>28</sup>

For 70 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 extended ophthalmoscopies did not add information that was not available from the standard evaluation services nor did they add information that would demonstrably affect the treatment plans. In addition, the medical review contractor indicated that the diagnostic information obtained from the extended ophthalmoscopies was already available by other means (i.e., from other diagnostic imaging services) and that the extended ophthalmoscopies were not medically necessary to confirm this information.

See the following page for an example of an extended ophthalmoscopy that was not reasonable and necessary.

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<sup>28</sup> LCDs are determinations made by a MAC whether to cover a particular item or service in a MAC’s jurisdiction (region).

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

On September 12, 2018, the Clinic billed Medicare for an extended ophthalmoscopy in a beneficiary's left eye in addition to an intravitreal injection of Eylea into the right eye. Medicare paid the Clinic \$20 for the extended ophthalmoscopy, \$85 for the intravitreal injection, \$1,517 for Eylea, and \$154 for other services (an E&M service, a diagnostic imaging service, and a lidocaine injection).

According to the independent medical review contractor, the extended ophthalmoscopy was not reasonable and necessary. The medical review contractor stated:

. . . [T]he medical record does not support that a subsequent extended ophthalmoscopy examination reported on the opposite eye [as the injection] was medically reasonable and necessary for this encounter . . . . [T]he extended ophthalmoscopy examination did not add information that was not available from the standard evaluation services nor did it add information that would demonstrably affect the treatment plan. The diagnostic information obtained was already available by other means and the extended ophthalmoscopy was not medically necessary to confirm this information.

As a result, the \$20 for the extended ophthalmoscopy was unallowable. (The sampled beneficiary day contained multiple errors and, based on applicable requirements, we also disallowed \$120 for the E&M service and the lidocaine injection.)

The Clinic's medical director stated that extended ophthalmoscopies are normally performed by retina specialists, not general ophthalmologists. He stated that he performs extended ophthalmoscopies to look at the outer area of the eye to gather additional information about the eye's condition. He also stated that the other diagnostic imaging tests were performed to look at the macula.

The Clinic did not have policies and procedures to ensure that the Clinic billed for extended ophthalmoscopies that were reasonable and necessary. According to the Clinic's medical director, he had not read the details of First Coast's LCD, which covers extended ophthalmoscopies.

### THE CLINIC RECEIVED UNALLOWABLE MEDICARE PAYMENTS

The Clinic received \$8,988 in Medicare payments for the 226 services that did not meet Medicare requirements. On the basis of our sample results, we estimated that at least \$215,606 of the \$2.1 million paid to the Clinic for intravitreal injections of Avastin, Eylea, and Lucentis and for other services provided on the same day as the injections was unallowable for Medicare reimbursement.

These overpayments occurred because the Clinic did not have policies and procedures to ensure that it: (1) did not bill for services that were not separately payable from intravitreal injections of Avastin, Eylea, and Lucentis and (2) billed only for services that were reasonable and necessary.

## **RECOMMENDATIONS**

We recommend that the Clinic:

- refund to First Coast \$215,606 in estimated overpayments for other services provided on the same day as intravitreal injections of Avastin, Eylea, and Lucentis;<sup>29</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>30</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 Avastin, Eylea, and Lucentis; and
- implement policies and procedures to ensure that it bills only for services that are reasonable and necessary.

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

In written comments on our draft report, the Clinic concurred in part with our first recommendation. 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 E.

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

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<sup>29</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>30</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**

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

- The Clinic concurred in part with our first recommendation and stated that a repayment will be made but that it will appeal certain determinations.
- The Clinic concurred with our second recommendation and stated that it will exercise reasonable diligence to comply with its obligations under the 60-day rule.
- The Clinic concurred with our third and fourth recommendations and stated that it will implement policies and procedures to properly educate the Clinic's employees on the Medicare coverage, documentation, and payment rules for intravitreal injections and other services furnished to its patients: (1) so that bills submitted to Medicare are correct and (2) to assure that medical records include required documentation to support that services furnished are reasonable and necessary.

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

As stated in the footnote to our first recommendation, OIG audit recommendations do not represent final determinations by Medicare. Action officials at CMS, acting through a MAC or other contractor, will determine whether an overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered Medicare Part B payments for intravitreal injections of Avastin, 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 2,578 beneficiary days, with payments totaling \$2,095,704.<sup>31</sup> We selected a stratified random sample of 100 beneficiary days, totaling \$98,476 and consisting of the following 543 services and drugs:<sup>32</sup>

- 100 intravitreal injections,
- 99 injections of an anesthesia drug (lidocaine),
- 94 diagnostic imaging services,
- 77 extended ophthalmoscopies,
- 73 E&M services,
- 50 doses of Avastin, and
- 50 doses of Eylea.

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 Avastin and Eylea 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 intravitreal injections. We assessed whether the Clinic designed the entity's information system and control activities to achieve objectives and respond to risks. We also assessed whether the Clinic implemented control activities through its 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

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<sup>31</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 Avastin, Eylea, or Lucentis were administered.

<sup>32</sup> Each beneficiary day in the sample consisted of at least two services, including the intravitreal injection, and one drug. Most of the beneficiary days included the intravitreal injection, the drug (Avastin or Eylea), and these other services: an injection of an anesthesia drug (lidocaine), a diagnostic imaging service, an extended ophthalmoscopy, and an E&M service. Two injections of Lucentis were included in our sampling frame; however, the Lucentis injections were not selected for the sample.

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 August 2019 to June 2021, which included fieldwork performed at the Clinic, which is located in Bonita Springs, Florida.

## **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and coding guidance, as well as AMA's *CPT 2018 Professional*, First Coast's LCDs, and FDA-approved dosing guidelines;
- interviewed First Coast 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>33</sup>
- created a sampling frame of 2,578 beneficiary days for intravitreal injections of Avastin, 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 C);
- 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 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 related to 41 sampled beneficiary days and submitted the additional information to the

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<sup>33</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.



independent medical review contractor to re-review and determine whether the services 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 D); 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

Report Title	Report Number	Date Issued
<i>An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea and Lucentis</i>	<a href="#">A-09-19-03022</a>	3/29/2021
<i>The Medicare Contractor for Jurisdiction 1 Overpaid a Provider That Incorrectly Billed for Aflibercept</i>	<a href="#">A-06-14-00055</a>	6/30/2015
<i>Wisconsin Physicians Service Insurance Corporation Overpaid a Provider That Incorrectly Billed for Aflibercept</i>	<a href="#">A-06-14-00051</a>	6/22/2015
<i>CGS Administrators, LLC, Overpaid Providers That Incorrectly Billed for Aflibercept</i>	<a href="#">A-06-14-00053</a>	5/14/2015
<i>Medicare Paid \$22 Million in 2012 for Potentially Inappropriate Ophthalmology Claims</i>	<a href="#">OEI-04-12-00281</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="#">A-01-11-00515</a>	5/21/2012
<i>Medicare Payments for Drugs Used to Treat Wet Age Related Macular Degeneration</i>	<a href="#">OEI-03-10-00360</a>	4/20/2012
<i>Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration</i>	<a href="#">A-01-10-00514</a>	9/6/2011
<i>Use of Modifier 59 to Bypass Medicare's National Correct Coding Initiative Edits</i>	<a href="#">OEI-03-02-00771</a>	11/25/2005

## APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

### SAMPLING FRAME

We obtained Medicare Part B claims data for intravitreal injections of Avastin, Eylea, and Lucentis and for other services and drugs that the Clinic provided during our audit period. We grouped the line items by beneficiary Health Insurance Claim Number and date of service to identify the beneficiary days. (Each line item represented a billed service or drug on a claim.) The sampling frame consisted of 2,578 beneficiary days, which had 13,785 line items totaling \$2,095,704. The sampling frame included beneficiary days that: (1) contained the procedure codes for an intravitreal injection of Avastin, Eylea, or Lucentis and (2) had not been reviewed by other Medicare contractors.

### 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	Beneficiary days with payments from \$100 to \$500	1,595	50	\$421,200
2	Beneficiary days with payments greater than \$500	983	50	1,674,504
Total		2,578	100	\$2,095,704

### SOURCE OF RANDOM NUMBERS

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

### 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 other services provided on the same day as intravitreal injections of Avastin, Eylea, and Lucentis. 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 D: 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	1,595	\$421,200	50	283	\$14,011	121	\$5,037
2	983	1,674,504	50	260	84,465	105	3,951
<b>Total</b>	<b>2,578</b>	<b>\$2,095,704</b>	<b>100</b>	<b>543</b>	<b>\$98,476</b>	<b>226</b>	<b>\$8,988</b>
* There were no unallowable drugs in the sample.							

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

Point estimate	\$238,365
Lower limit	215,606
Upper limit	261,125

## APPENDIX E: THE CLINIC'S COMMENTS



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June 29, 2021

### DELIVERY VIA EMAIL

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-09-19-03025*

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 Florida: Audit of Medicare Payments for Avastin, 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.

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

Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
June 29, 2021  
Page 2

Early anti-VEGF therapy management strategy derives from the pivotal trials of Lucentis. The standard of care with Lucentis 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 retinal practices. This led retinal specialist to seek alternative dosing schedules that balanced maintaining patients' vision with reducing the numbers of injections a patient received per year. Through years of trials, the retinal medical community developed a treatment protocol referred to as "treat and extend," whereby the retinal specialist increases the interval between a particular patient's injections by closely monitoring the patient's response to treatment and finding the patient-specific time interval where the patient begins to show signs of disease breakthrough. Treat and extend requires regular evaluation of a patient in order to make the judgment as to the length of time between injections, in turn, it most often leads to a decrease in the number of injections a patient receives, which provides a significant improvement to patients' quality of life and substantial cost savings to the Medicare program. Without regular full examination, however, physicians and patients may lean to treat more frequently to reduce the risk that a patient may experience a break through event and vision loss.

Patients with chronic eye disease must have thorough regular eye examinations. Coverage and payment of examinations associated with intravitreal injections should be the subject of a larger policy discussion to assure that a standard of care based on the retinal community's expertise is maintained.

## **II. OIG Recommendations**

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

Recommendation 1. The Clinic concurs in part. A repayment will be made, but certain services will be the 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.

## Arnold & Porter

Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
June 29, 2021  
Page 3

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