

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PAYMENTS FOR
DRUGS USED TO TREAT WET
AGE-RELATED MACULAR
DEGENERATION**



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EXECUTIVE SUMMARY: MEDICARE PAYMENTS FOR DRUGS USED TO TREAT WET AGE-RELATED MACULAR DEGENERATION OEI-03-10-00360

WHY WE DID THIS STUDY

Wet age-related macular degeneration (AMD), a leading cause of vision loss in people aged 60 and older, affects millions of Americans. Lucentis is a Medicare Part B-covered drug approved by the Food and Drug Administration (FDA) for the treatment of wet AMD. Avastin is a Part B-covered drug approved by FDA for the treatment of various forms of cancer, but smaller doses of the drug are being used off-label to treat wet AMD. A dose of Avastin used to treat wet AMD costs a small fraction of the cost of a dose of Lucentis. The Centers for Medicare & Medicaid Services (CMS) established a national Medicare payment amount for Lucentis; however, there is no national Medicare payment amount for Avastin when used to treat wet AMD in a physician's-office setting. In 2010, combined Part B expenditures for Lucentis and Avastin totaled nearly \$2 billion.

HOW WE DID THIS STUDY

Using Medicare claims data, we selected 2 stratified random samples: 1 sample of 160 physicians who received Medicare payment for Lucentis and 1 sample of 160 physicians who received Medicare payment for Avastin. We sent electronic surveys asking physicians to provide the total dollar amount and quantity purchased of Lucentis and Avastin in the first quarter of 2010. We also asked physicians to describe the factors that they consider when choosing Avastin instead of Lucentis for the treatment of wet AMD. We compared physician acquisition costs to Medicare payment amounts obtained from CMS and Medicare contractors. Additionally, we analyzed Medicare contractor payment policies and the reasons physicians reported for administering Avastin instead of Lucentis.

WHAT WE FOUND

In the first quarter of 2010, physician acquisition costs for Lucentis and Avastin were 5 and 53 percent below the Medicare payment amount, respectively. Medicare contractors' payment amounts for Avastin when used to treat wet AMD differed by as much as 28 percent, although payment policies were similar. Additionally, we found that the majority of physicians who administered Avastin to treat wet AMD reported the substantial cost difference compared to Lucentis as a primary factor in their decision.

WHAT WE RECOMMEND

We recommend that CMS (1) establish a national payment code for Avastin when used for the treatment of wet AMD and (2) educate providers about the clinical and payment issues related to Lucentis and Avastin. CMS did not concur with our first recommendation at this time but did concur with our second recommendation.

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OBJECTIVES

1. To compare the Medicare payment amount for Lucentis to physicians' acquisition costs.
2. To determine the average Medicare contractor payment amount for Avastin when used to treat wet age-related macular degeneration (AMD) and compare it to physicians' acquisition costs.
3. To examine Medicare contractor payment policies for Avastin when used to treat AMD.
4. To examine the factors considered by physicians when choosing Avastin for the treatment of AMD.

BACKGROUND

AMD, a leading cause of vision loss in people aged 60 and older, affects millions of Americans, according to the National Eye Institute (NEI), part of the National Institutes of Health (NIH). Wet AMD is an advanced form of the disease that reduces the ability to see objects clearly and inhibits the performance of common daily tasks, such as reading and driving.

Lucentis is a Part B-covered drug approved by the Food and Drug Administration (FDA) for the treatment of wet AMD. Avastin is a Part B-covered drug approved by FDA for the treatment of various forms of cancer, but smaller doses of the drug (usually prepared for an additional cost by compounding pharmacies) are being used off-label to treat wet AMD.¹ A dose of Avastin used to treat wet AMD costs a small fraction of the cost of a dose of Lucentis. In 2010, combined Part B expenditures for Lucentis and Avastin totaled nearly \$2 billion.

Medicare Part B Coverage of Prescription Drugs

Although Medicare Part D covers most outpatient prescription drugs, the Centers for Medicare & Medicaid Services (CMS) continues to cover a limited number of outpatient prescription drugs and biologicals (hereinafter referred to as drugs) under its Part B benefit. Part B-covered drugs generally fall into the following categories: drugs furnished incident to a physician's service (e.g., injectable drugs such as Lucentis and Avastin); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with durable medical

¹ The term "off-label use" refers to the prescribing of FDA-approved medications by physicians for purposes outside the scope of the drugs' approved labels.

equipment (e.g., inhalation drugs).² Medicare beneficiaries can receive Part B-covered drugs in several settings, including physicians' offices and hospital outpatient departments.

Medicare Part B Payments for Prescription Drugs

CMS contracts with private companies (i.e., contractors) to process and pay Medicare Part B claims, including those for prescription drugs.³ To obtain payment for covered outpatient prescription drugs, health care providers submit claims to their Medicare contractors using codes established by CMS, called Healthcare Common Procedure Coding System (HCPCS) codes.⁴ In 2010, Medicare and its beneficiaries spent \$12 billion for Part B drugs.

Payment Methodology for Part B Drugs

CMS pays physicians for most Part B-covered drugs using a methodology based on average sales prices (ASP).⁵ The ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.⁶ Manufacturers provide CMS with the ASP and volume of sales for their drugs on a quarterly basis.⁷

As required by law, CMS sets a single national payment amount for most Part B-covered prescription drugs at 106 percent of the volume-weighted ASP.⁸ Medicare beneficiaries are generally responsible for 20 percent of this amount in the form of coinsurance.

² Section 1861(s)(2) of the Social Security Act (the Act), 42 U.S.C. § 1395x(s)(2); 42 CFR § 414.900(b) and CMS, *Medicare Benefit Policy Manual (BPM)*, Pub. 100-02, ch. 15, § 50.

³ CMS is transitioning from a system of fiscal intermediaries and carriers to Medicare Administrative Contractors. Medicare contracting reform was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 § 911 (Dec. 8, 2003).

⁴ HCPCS codes provide a standardized system for describing the specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug name and the amount of drug represented by the code but does not specify manufacturer or package size information.

⁵ Several Part B drugs, including certain vaccines and blood products, are not paid under the ASP methodology. See sections 1847A(a)(1) and 1842(o)(1) of the Act, 42 U.S.C. §§ 1395w-3a(a)(1) and 1395u(o)(1).

⁶ Per section 1847A(c) of the Act, the ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.

⁷ Sections 1847A(f) and 1927(b)(3) of the Act, 42 U.S.C § 1396r-8(b)(3).

⁸ Section 1847A(b) of the Act.

Part B-Covered Drugs Used to Treat Wet AMD

Lucentis, which was approved by FDA in 2006 to treat wet AMD, is manufactured by Genentech. This drug is sold in single-use vials and administered by physicians through a monthly 0.5-mg intravitreal injection (i.e., delivered via the eye). Genentech also manufactures Avastin, which FDA approved in 2004 to treat various forms of cancer. Ophthalmologists also use Avastin in an off-label manner to treat wet AMD. When using Avastin to treat wet AMD, physicians typically inject a much smaller amount of it (1.25 mg per month) than when the drug is used in cancer treatments.⁹

Both Lucentis and Avastin are typically administered by physicians in an office setting. However, Avastin is sold by Genentech in 100-mg or 400-mg vials that are intended for use in treating cancer. The smaller (1.25-mg) Avastin dose used to treat wet AMD must be prepared in a sterile environment through a process known as compounding.^{10, 11} Compounding is a pharmacy practice that enables physicians to prescribe—and patients to take—medicines that are specially prepared by pharmacists to meet patients' individual needs.¹²

Physicians who use Avastin to treat wet AMD obtain the drug primarily through two methods. Some physicians purchase Avastin in 100-mg or 400-mg vials and send the vials to compounding pharmacies. Therefore, in addition to the cost of acquiring Avastin, these eye doctors typically incur separate compounding costs. Other physicians purchase ready-to-use syringes prefilled with smaller doses of Avastin, directly from a compounding pharmacy. In these cases, the drug costs and compounding costs are combined into a single price.

Medicare Payment for Lucentis and Avastin

For Lucentis, physicians bill for and are paid under HCPCS code J2778. The Medicare payment amount for one dose of Lucentis administered in a physician's office, typically 0.5 mg (one vial), was \$2,023 in the first quarter

⁹ Physicians administer approximately 1.25 mg of Avastin every 4 to 6 weeks to treat wet AMD. However, physicians could administer hundreds of milligrams of Avastin per cancer treatment depending on the patient's weight and type of cancer. For example, a 150-pound person being treated for lung cancer could be administered approximately 1,000 mg of Avastin every 3 weeks.

¹⁰ James Folk, M.D. *Avastin*. Accessed at <http://www.medrounds.org> on May 19, 2011.

¹¹ Because Avastin is packaged in 100- and 400-mg vials that exceed the 1.25-mg dose commonly used for treating wet AMD, physicians often use compounding pharmacies to repack the drug into single-use syringes that contain the smaller dose for intravitreal use. In August 2011, in response to a cluster of eye infections traced to patients who had received Avastin repackaged by a pharmacy in Florida, FDA alerted health care professionals of infection risk from repackaged Avastin intravitreal injections.

¹² Compounding is not exclusive to drugs used for off-label purposes.

of 2010. In total, Medicare and its beneficiaries spent \$1.1 billion for Lucentis in 2010.

As of September 2011, CMS does not have a single HCPCS code or payment amount for Avastin when used to treat wet AMD in a physician's-office setting. Medicare contractors that process and pay claims determine the Medicare payment amount for Avastin used to treat wet AMD.¹³ The contractors also instruct physicians administering Avastin in an office setting to use the HCPCS codes for unclassified drugs (J3490), unclassified biologics (J3590), or Avastin used to treat cancer (J9035). Regardless of the HCPCS code used, the Medicare payment amount for one Avastin dose used to treat wet AMD is always substantially less than the Medicare payment amount for Lucentis. In total, Medicare and its beneficiaries spent \$27 million for Avastin used to treat wet AMD in 2010.¹⁴

In August 2009, CMS announced that it would create a new HCPCS code (Q2024), to take effect in the fourth quarter of 2009, for the use of Avastin in treating wet AMD. This change would have set a national Medicare payment amount at \$7.185 for every 1.25-mg dose (an amount determined by taking the payment amount for the 10-mg dose of Avastin and dividing it by 8).¹⁵ Some doctors expressed concern that this new payment amount would not cover the extra compounding costs that they incurred when using Avastin to treat wet AMD. In an October 2009 letter to CMS, a member of Congress noted this concern, writing that the new payment policy could cause physicians to switch from Avastin to the more expensive Lucentis. This, in turn, would have resulted in higher payment amounts and coinsurance for Medicare and its beneficiaries. In November 2009, CMS decided to rescind the new payment code (Q2024) and policy. Payment reverted to the previous codes established by individual Medicare contractors.

National Eye Institute Study

In 2008, NEI began the *Comparison of AMD Treatments Trials (CATT)* to assess the safety and effectiveness of Lucentis and Avastin to treat wet AMD. NEI is also determining whether both drugs remain effective when doses are administered more than 1 month apart.

¹³ Off-label use is covered by Medicare if the Medicare contractor determines the use to be medically accepted. See *BPM*, ch. 15, § 50.4.2. Moreover, Medicare contractors determine pricing for compounded drugs. See *BPM*, ch. 17, § 20.1.2.

¹⁴ Because there is not a unique HCPCS code for Avastin used to treat wet AMD, we projected a total based on Part B claims data.

¹⁵ When CMS created the new HCPCS code Q2024 to pay for Avastin used to treat wet AMD, it took the payment amount for J9035 (\$57.479) and divided it by 8, arriving at an amount of \$7.185.

In April 2011, NEI released the preliminary results from the first year of the CATT. NEI found that Avastin was as effective as Lucentis in treating wet AMD.¹⁶ It also found evidence that Avastin and Lucentis could be administered effectively at longer intervals than the normal once-per-month schedule. Finally, NEI found that “serious adverse events (primarily hospitalizations)” occurred at a rate of 24 percent for patients receiving Avastin and a rate of 19 percent for patients receiving Lucentis. However, NEI was unable to determine a causal link between the type of treatment and particular adverse events. Longer term study results will provide additional information about the relative safety and efficacy of Avastin and Lucentis.

Related Office of Inspector General Work

A September 2011 Office of Inspector General (OIG) audit report¹⁷ found that if Medicare reimbursement for all beneficiaries treated for wet AMD with Avastin or Lucentis had been based on the Avastin payment amount, Medicare and its beneficiaries would have saved approximately \$1.4 billion. Twenty percent of these savings would have been from decreases in beneficiary copayments. Conversely, the report found that if Medicare reimbursement for all beneficiaries treated for wet AMD with Avastin or Lucentis had been based on the Lucentis payment amount, spending for Medicare and its beneficiaries would have increased by \$1.9 billion. Similarly, 20 percent of that total would have been from increases in beneficiary copayments. OIG recommended that CMS (1) consider the results of that report when evaluating coverage and reimbursement policies related to Avastin and Lucentis and (2) seek additional authority as necessary to control Part B drug expenditures.

METHODOLOGY

Data Sources and Collection

Sample Selection. We extracted all Part B drug claims for Lucentis (HCPCS code J2778) and Avastin (HCPCS codes J3490, J3590, J9035, and Q2024) with dates of service in the first quarter of 2010 from CMS’s National Claims History File. The sampling frame for this analysis included only claims associated with the treatment of wet AMD in ophthalmologists’ offices in the 50 States and the District of Columbia based on the claims’ HCPCS codes, physician specialty code, diagnosis code, place of service code, and procedure code for related treatment. See Table 1 for a detailed description of the criteria for claims selection.

¹⁶ NEI, *NIH Study finds Avastin and Lucentis are equally effective in treating age-related macular degeneration*, April 2011. Accessed at <http://www.nei.nih.gov> on May 4, 2011.

¹⁷ OIG, *Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration* (A-01-10-00514), September 2011.

Table 1. Claims Selection Criteria

Criteria	Value for Inclusion in Sampling Frame
HCPSC Code	J2778 (Lucentis); J3490, J3590, J9035, Q2024 (Avastin)
Physician Specialty Code	18 (ophthalmologist)
Diagnosis Code	36252 (exudative (wet) senile macular degeneration, i.e., wet AMD)
Place of Service	11 (office)
Procedure Code for Related Treatment	67028 (intravitreal (eye) injection)

Source: Part B claims data dictionary, OIG analysis of Part B claims data, 2010.

After selecting the claims that met the above criteria, we grouped them by prescribing physician and summarized the claims data in each group. From these summarized data, we selected 2 stratified random samples: 1 sample of 160 physicians who received Medicare payment for Lucentis and 1 sample of 160 physicians who received Medicare payment for Avastin. To increase the precision of our estimates and to keep the sample size within reason, we stratified each sample based on total allowed charges for administering Avastin or Lucentis.¹⁸ See Table 2 for a description of our sampling frame.

Table 2. Sampling Frame

Description of Stratum		Number of Physicians in Population	Number of Physicians in Sample
Lucentis	Physicians with allowed charges ≤ \$190,000 in the first quarter of 2010	1,334	68
	Physicians with allowed charges > \$190,000 in the first quarter of 2010	369	92
Total		1,703	160
Avastin	Physicians with allowed charges ≤ \$4,600 in the first quarter of 2010	1,623	67
	Physicians with allowed charges > \$4,600 in the first quarter of 2010	490	93
Total		2,113	160

Source: OIG analysis of Lucentis and Avastin Medicare Part B claims, 2010.

Medicare Payment Amounts and Policies. We obtained from CMS's Web site the first-quarter 2010 Medicare payment amount for Lucentis.

¹⁸ We ran simulations of our universe to determine the dividing point for each stratum (i.e., \$190,000 for Lucentis and \$4,600 for Avastin).

Because there is no national payment amount for Avastin when used to treat wet AMD in a physician's-office setting, we obtained first-quarter 2010 Medicare payment amounts and coverage policies for it from all 11 Medicare contractors that paid claims for Part B-covered drugs in the first quarter of 2010. In addition, we obtained from CMS's Web site the (now-rescinded) fourth-quarter 2009 national Medicare payment amount for Avastin when used to treat wet AMD.

Physician Surveys. We sent electronic surveys to the physicians in each sample, using mailing addresses obtained from CMS. We made up to three attempts to contact the physicians in each sample to increase the response rate. Between January and April 2011, 131 of 160 (82 percent) physicians who administered Lucentis responded to our survey and 122 of 160 (76 percent) physicians who administered Avastin responded to our survey.

In the survey, we asked physicians to provide us with the total dollar amount they purchased, the quantity they purchased, and any discounts or rebates they received for Lucentis or Avastin in the first quarter of 2010. We asked physicians who administered Avastin to describe the steps taken to prepare Avastin for the treatment of wet AMD (i.e., compounding), including identifying the entity responsible for compounding and the total cost of compounding. We also asked physicians how many 1.25-mg doses of Avastin were produced from the vials purchased. Additionally, we asked physicians to describe the factors that they consider when choosing Avastin instead of Lucentis for the treatment of wet AMD.¹⁹

Data Analysis

Lucentis. Of the 131 responding physicians, 125 supplied complete data that could be used in our analysis.²⁰ To calculate physicians' first-quarter 2010 average acquisition cost for Lucentis, we summed acquisition costs (net of discounts) among all respondents and divided that number by the number of vials purchased. We compared the first-quarter 2010 Medicare payment amount to physicians' average acquisition cost and calculated the percentage difference. We also calculated the acquisition cost of Lucentis for each individual responding physician and determined the percentage of physicians that purchased the drug at prices below the Medicare payment amount.²¹

¹⁹ We asked this question because Avastin is not approved by FDA to treat wet AMD. Conversely, as Lucentis is approved by FDA to treat wet AMD, we did not ask why physicians use Lucentis instead of Avastin.

²⁰ Six responding physicians were excluded for not providing complete data.

²¹ All of the cost calculations were weighted based on the stratified sample selection.

Avastin. Of the 122 responding physicians, 113 supplied complete data that could be used in our analysis.²² We then calculated the average first-quarter 2010 Medicare payment amount for Avastin when used to treat wet AMD based on payment amounts provided by 10 of the 11 Medicare contractors.²³

To calculate physicians' average acquisition costs for Avastin in the first quarter of 2010, we summed acquisition costs (net of discounts) among all respondents and divided that number by the number of doses purchased. We compared the average first-quarter 2010 Medicare payment amount to physicians' average acquisition cost and calculated the percentage difference. In addition, we compared physicians' average acquisition cost to the rescinded national Medicare payment amount from the fourth quarter of 2009.²⁴

Additionally, we calculated both the average drug costs and average compounding costs (i.e., the two components of physicians' acquisition costs) separately by (1) dividing the drug acquisition costs by the number of doses purchased and (2) dividing compounding costs by the number of doses purchased.²⁵

We reviewed each contractor's payment amounts and policies for Avastin used to treat wet AMD to determine the extent to which payment amounts and payment policies differed. We calculated the difference in contractor payment amounts and identified the payment and diagnosis codes that contractors required physicians to use when submitting claims for Avastin used to treat wet AMD.

We reviewed the reasons physicians reported for using Avastin instead of Lucentis to treat wet AMD and determined the frequency of each factor.²⁶ Because Lucentis is approved by FDA for the treatment of wet AMD, we did not ask a similar question of physicians who administered Lucentis.

Limitations

The analysis and results in this report are based only on physicians' and contractors' self-reported data. We did not verify the accuracy or completeness of physicians' or contractors' responses.

²² Nine responding physicians were excluded for not providing complete data.

²³ One contractor bases its payment for Avastin used to treat wet AMD on cost and does not have a single payment amount. Therefore, we excluded this contractor from our calculation of an average Medicare payment amount. Several other contractors reported a single payment amount that we included in our calculation, but noted that they paid based on cost if that amount was lower than the usual payment amount.

²⁴ All cost calculations were weighted based on the stratified sample selection.

²⁵ Because of the small number of physicians who provided these data, we were unable to project these results.

²⁶ These calculations were weighted based on the stratified sample selection.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Physician acquisition costs for Lucentis were 5 percent below the Medicare payment amount in the first quarter of 2010

On average, physicians paid \$1,928 (net of discounts) per vial of Lucentis in the first quarter of 2010. This was 5 percent below the Medicare payment amount of \$2,023 during that quarter. Nearly all physicians (98 percent) purchased Lucentis at a price below the Medicare payment amount during the time period under review.

Physician acquisition costs for Avastin were 53 percent below the average Medicare contractor payment amount in the first quarter of 2010; however, these acquisition costs were nearly four times the rescinded national Medicare payment amount from the previous quarter

On average, physicians paid \$26 per dose of Avastin (including drug and compounding costs) in the first quarter of 2010. This was 53 percent below the average Medicare contractor payment amount of \$55 per dose in that quarter. Almost all physicians (96 percent) were able to purchase Avastin to treat wet AMD at a price below the average Medicare contractor payment amount.

In contrast, average physician acquisition costs substantially exceeded the national Medicare payment amount of about \$7 that CMS proposed and then rescinded for the fourth quarter of 2009. The average acquisition cost—\$26 per dose—is almost 4 times greater than the rescinded national payment amount.²⁷ Because CMS rescinded the national payment amount and policy, there is currently no national payment amount for Avastin used to treat wet AMD in a physician's-office setting. Had the national payment amount been implemented, physicians would have been reimbursed at 72 percent below their costs.

Physicians who purchased Avastin in vials (as opposed to in prefilled syringes) needed to compound the drug prior to administering it to patients. For responding physicians from the sample, the two components of the total cost—i.e., the average drug cost (\$15 per dose) and the average compounding cost (\$10 per dose)—by themselves exceeded the rescinded Medicare payment amount. We could not calculate separate drug and

²⁷ This calculation assumes that the Medicare payment amount stayed the same from the fourth quarter of 2009 to the first quarter of 2010.

compounding costs for physicians who purchased Avastin in syringes because the drug in these syringes had already undergone the compounding process prior to purchase.

Contractors' payment amounts for Avastin differed by as much as 28 percent, although payment policies were similar

Generally, CMS is required to set a national Medicare payment amount for Part B-covered drugs at 106 percent of ASP. However, as previously stated, there is no national Medicare payment amount for Avastin used to treat wet AMD in a physician's-office setting; Medicare contractors must set the payment amount in their jurisdictions. Consequently, payment amounts differed by as much as 28 percent in the first quarter of 2010 (although 5 of the 11 contractors had the same payment amount).²⁸ Ten Medicare contractors reported per-dose payment amounts for Avastin ranging from \$45 (1 contractor) to \$57 (7 contractors) per dose during the first quarter of 2010. The remaining contractor paid claims based on cost and did not establish a specific payment amount.

Similarly, Medicare contractors established their own policies for the coding and payment of Avastin claims when the drug is used to treat wet AMD. All contractors instructed providers to use one of three HCPCS billing codes (J3490, J3590, or J9035) on these claims. Additionally, all contractors except one reported that they require a related diagnosis code for wet AMD and/or procedure code on these claims. See Table 3 for a description of contractor payment amounts and policies.

Table 3. Contractor Payment Amounts and Policies

Contractor	HCPCS Codes	Payment Amount	Related Diagnosis or Procedure Code Required
1	J3590	\$50.00	Yes
2	J9035	\$57.46	Yes
3	J9035	\$57.46	Yes
4	J3590	\$45.00	No
5	J3490	\$50.00	Yes
6	J9035	\$57.46	Yes
7	J9035	\$57.46	Yes
8	J3590 or J3490	\$57.40	Yes
9	J9035	\$57.46	Yes
10	J3590 or J3490	\$57.44	Yes
11	J3590 or J3490	Based on invoice cost	Yes

Source: OIG analysis of Medicare contractor responses, 2010.

²⁸ Two additional contractors had payment amounts within \$0.06 of the five contractors with the same payment amount.

The majority of physicians who administered Avastin to treat wet AMD reported the substantial cost difference compared to Lucentis as a primary factor in their decision

Physicians reported several reasons for using Avastin rather than Lucentis to treat wet AMD with cost being the primary factor (70 percent). Forty-five percent reported efficacy/effectiveness as a reason, and 40 percent cited patient insurance coverage. Additional reasons—cited by 1 to 14 percent of physicians—included less frequent injections, patient preference, patient condition, ease of use, and safety. One physician reported giving Avastin to all patients unless they do not respond to that treatment.

Based on our analysis, the final cost of a dose of Avastin is about 1 percent the cost of a dose of Lucentis, on average (\$26 vs. \$1,928). Physician acquisition costs for Lucentis are much higher; those costs, in turn, are passed on to the Medicare program and beneficiaries in the form of higher program payments and coinsurance. Beneficiaries would pay approximately \$400 in coinsurance for each dose of Lucentis, compared to approximately \$11 in coinsurance for each dose of Avastin. One physician's rationale for choosing Avastin raised all of these concerns:

I believe that Avastin works as well if not better than Lucentis. Why would I not want to save expenses for my patients, our society, and government by using a product I believe is as effective as the incredibly more expensive alternative? My personal income would have been higher if I had used Lucentis, but I do not believe that is the right thing to do.

CONCLUSION AND RECOMMENDATIONS

Lucentis and Avastin are the primary drugs that ophthalmologists use to treat wet AMD, a leading cause of severe vision loss that affects millions of Americans. Congressional interest, media reports, and other OIG work have recently focused on the substantial price difference between Lucentis and Avastin as well as on physician reimbursement concerns. Additionally, in April 2011, NEI released the preliminary results of the CATT, which found that Avastin was equally as effective as Lucentis in treating wet AMD.

Our findings indicate that in the first quarter of 2010, physicians could purchase both Lucentis and Avastin at prices below their Medicare payment amounts. The results also demonstrate that physicians' acquisition costs for Avastin used to treat wet AMD (\$26) are substantially lower than acquisition costs for Lucentis (\$1,928). The majority of physicians who used Avastin generally reported that they chose the drug because of its substantially lower costs. Our findings also highlight the variability in contractor payment in the absence of a national Medicare payment amount.

Given the lack of a national payment policy for Avastin used to treat wet AMD in a physician's-office setting and the substantial difference in cost of the two drugs to Medicare and its beneficiaries, we recommend that CMS:

Establish a National Payment Code for Avastin When Used for the Treatment of Wet AMD

Generally, the law requires CMS to set a national payment amount for Part B-covered drugs at 106 percent of ASP, an amount that is based on actual sales data and is consistent nationwide. Currently, CMS does not have a national payment amount for Avastin used to treat wet AMD; consequently, the Medicare contractor in each jurisdiction has to set its own payment amount. Most contractors paid nearly identical amounts for Avastin used to treat wet AMD and had similar payment policies, although in some cases contractor payment amounts differed by up to 28 percent.

We recognize that physicians incur additional costs (i.e., compounding costs) when using Avastin to treat wet AMD and that these costs are not factored into the drug's ASP. The unique circumstances surrounding the acquisition and administration of Avastin to treat wet AMD in a physician's-office setting would need to be considered when setting a payment amount. To help establish a national payment amount, CMS could use physician acquisition cost data collected by OIG.

Educate Providers About the Clinical and Payment Issues Related to Lucentis and Avastin

Our findings show that physicians can purchase Avastin at a much lower price than Lucentis and that many physicians are using Avastin because it

is a lower cost alternative. CMS could direct a provider education initiative to educate ophthalmologists about the clinical issues regarding Lucentis and Avastin (e.g., the results of the CATT) as well as the implications of the wide variance in cost on the program and beneficiaries.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our first recommendation at this time, but did note the existence of a unique code and payment amount for intraocular doses of Avastin in the hospital outpatient setting. CMS concurred with our second recommendation.

In not concurring with our recommendation to establish a national payment code for Avastin when used to treat wet AMD, CMS noted that it had previously taken steps to create a national payment code and amount in 2009, but that the code was rescinded in light of beneficiary access concerns.

CMS concurred with our recommendation to educate providers about the clinical and payment issues related to Lucentis and Avastin. CMS stated that it plans to inform claims processing contractors about our findings related to Avastin payment amounts. Further, CMS noted that it will instruct contractors to make our report's findings available to providers.

We acknowledge that the previous attempt to establish a national payment code and amount for the intraocular use of Avastin in physicians' offices raised concerns over beneficiary access and that the unique circumstances surrounding the acquisition and administration of the drug would need to be considered when setting a payment amount. However, given the lack of a national payment policy, the substantial cost difference between these two drugs, and the existence of a unique payment code and amount for intraocular doses of Avastin in the hospital outpatient setting, we continue to believe that CMS should establish a national payment code and amount for Avastin when administered in a physician's office that takes all of these factors into account.

For the full text of CMS's comments, see Appendix B.

APPENDIX A

Confidence Intervals

Drug	Estimate Description	Sample Size	Point Estimate	95% Confidence Interval
Lucentis	Physician average acquisition cost in the first quarter of 2010	124*	\$1,928.46	\$1,924.44 to \$1,932.49
	Percentage difference between average acquisition cost and the first-quarter 2010 Medicare payment amount	124*	-4.67	-4.87 to -4.47
	Percentage of physicians whose average acquisition cost was below the first-quarter 2010 Medicare payment amount	124*	98.34	89.42 to 99.76
Avastin	Physician average acquisition cost in the first quarter of 2010	106**	\$26.05	\$23.71 to \$28.40
	Percentage difference between average acquisition cost and the first-quarter 2010 Medicare payment amount	106**	-52.63	-56.91 to -48.35
	Percentage of physicians whose average acquisition cost was below the first-quarter 2010 Medicare payment amount	106**	95.86	86.60 to 98.81
	Percentage difference between average physician acquisition cost and the rescinded fourth-quarter 2009 Medicare payment amount	106**	-72.42	-74.90 to -69.94
	Number of times the average acquisition cost exceeded the rescinded fourth-quarter 2009 Medicare payment amount	106**	3.63	3.30 to 3.95
	Average physician cost of Avastin as a percentage of average physician cost of Lucentis	***	1.35	1.23 to 1.47
	Percentage of physicians who cited cost as a reason for administering Avastin	113	69.99	58.73 to 79.27
	Percentage of physicians who cited efficiency or effectiveness as a reason for administering Avastin	113	45.13	34.39 to 56.34
	Percentage of physicians who cited patient insurance as a reason for administering Avastin	113	39.83	29.27 to 51.43
	Percentage of physicians who cited less frequent of injection as a reason for administering Avastin	113	12.05	6.66 to 20.83
	Percentage of physicians who cited patient preference as a reason for administering Avastin	113	13.66	7.43 to 23.76
	Percentage of physicians who cited patient condition as a reason for administering Avastin	113	7.83	3.29 to 17.51
	Percentage of physicians who cited ease of use as a reason for administering Avastin	113	0.77	0.22 to 2.67
Percentage of physicians who cited patient safety as a reason for administering Avastin	113	1.15	0.41 to 3.17	

*The sample size is not 125 because 1 respondent reported not having purchased any Lucentis during the first quarter of 2010. This physician submitted claims for Lucentis in the first quarter of 2010; however, according to this individual's response, the drugs were purchased during a previous quarter.

**The sample size is not 113 because 7 respondents reported that they did not purchase any Avastin during the first quarter of 2010. These physicians submitted claims for Avastin in the first quarter of 2010; however, according to their responses, the drugs were purchased during a previous quarter.

***This point estimate is based on 2 samples: 1 sample of 124 respondents (Lucentis) and 1 sample of 106 respondents (Avastin).

Source: Office of Inspector General analysis of physicians' average acquisition costs and survey responses.

APPENDIX B

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN 19 2012

TO: Daniel R. Levinson
Inspector General

FROM: Markyn P. Pinner /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Payments for Drugs Used to Treat Wet Age-Related Macular Degeneration (OEI-03-10-00360)"

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the OIG Draft Report titled, Medicare Payments for Drugs Used to Treat Wet Age-Related Macular Degeneration (OEI-03-10-00360). OIG's objectives in this study were the following:

1. To compare the Medicare payment amount for Lucentis to physicians' acquisition costs.
2. To determine the average Medicare contractor payment amount for Avastin when used to treat wet age-related macular degeneration (AMD) and compare it to physicians' acquisition costs.
3. To examine Medicare contractor payment policies for Avastin when used to treat AMD.
4. To examine the factors considered by physicians when choosing Avastin for the treatment of AMD.

The OIG found that in the first quarter of 2010, physician acquisition costs for Lucentis and Avastin were 5 and 53 percent below the Medicare payment amount, respectively. Medicare contractors' payment amounts for Avastin when used to treat wet AMD differed by as much as 28 percent, although payment policies were similar. The majority of physicians who administered Avastin to treat wet AMD reported the substantial cost difference compared to Lucentis as a primary factor when deciding which drug to administer.

OIG Recommendation

Establish a national payment code for Avastin when used for the treatment of wet AMD.

CMS Response

We non-concur at this time with this recommendation to establish a national price for Avastin doses used to treat macular degeneration in the office setting. As discussed in the report, CMS had taken steps to create a national price for intraocular doses of Avastin in 2009. The action was rescinded in light of beneficiary access concerns. We note that a related code (C9257) is

Agency Comments (continued)

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currently in use to pay for intraocular doses of Avastin in the outpatient setting. We appreciate the information that OIG has provided about the difference in payment amounts for Avastin between contractors and OIG's research into the exact costs of a dose of Avastin in the office setting.

OIG Recommendation

Educate providers about the clinical and payment issues related to Lucentis and Avastin.

CMS Response

We concur with the recommendation to educate providers about the clinical and payment issues related to Lucentis and Avastin. We note that in response to a cluster of eye infections associated with the use of repackaged intravitreal injections of Avastin, the Food and Drug Administration has encouraged health care professionals and patients to report to its MedWatch Safety Information and Adverse Event Reporting program any adverse events, side effects or product quality problems related to the use of such injections. We plan to bring the report's payment amount findings to the attention of the claims processing contractors. When the report is finalized, we intend to instruct the contractors to make the report's findings available to providers.

The CMS thanks the OIG for the opportunity to review and comment on this draft report and for presenting the findings and perspective on these issues. We look forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Daniel J. Mallinson; other central office staff who contributed include Kevin Farber, Scott Horning, Kevin Manley, and Tasha Trusty.

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