The Office of the Inspector General and You

BY GEORGE A. WILLIAMS, MD

Intravitreal anti-VEGF therapy has revolutionized the management of retinal vascular diseases, resulting in immeasurable clinical benefit to hundreds of thousands of patients affected by these potentially blinding conditions. The continuing development of anti-VEGF therapy is the result of a partnership among ophthalmologists, industry, and clinical trial participants. However, the cost of anti-VEGF therapy is great. In 2010, the combined Part B expenditures for ranibizumab (Lucentis, Genentech) and bevacizumab (Avastin, Genentech) were $2 billion. Additionally, delivery of anti-VEGF therapy has substantially increased office-based imaging, evaluation and management services, and procedures. In 2012, more than 4 million retinal optical coherence tomography (OCT) scans (CPT code 92134) were performed in the Medicare fee-for-service population. Intravitreal injections (CPT code 67028) increased from approximately 1 million in 2009 to 2 million in 2012 in the same population.

This unprecedented growth has attracted the attention of the Centers for Medicare & Medicaid Services (CMS). As a result, the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) issued a report in 2012 called *Medicare Payments for Drugs Used to Treat Wet Age-Related Macular Degeneration*.[1] The OIG was created to protect the integrity of HHS programs and the well-being of beneficiaries by detecting and preventing fraud, waste, and abuse; by identifying opportunities to improve program economy, efficiency, and effectiveness; and by holding accountable those who do not meet program requirements or who violate federal laws. The OIG comprises more than 1800 professionals, including lawyers, accountants, and investigators to conduct audits, evaluations, and investigations. The OIG collaborates with the Department of Justice when necessary.[2]

For fiscal year (FY) 2011, the OIG reported expected recoveries of about $5.2 billion, consisting of $627.8 million in audit receivables and $4.6 billion in investigative receivables. The OIG also identified about $19.8 billion in savings estimated for FY 2011 as a result of legislative, regulatory, or administrative actions that were supported by their recommendations. Such savings generally reflect third-party estimates (such as those by the Congressional Budget Office [CBO]) of funds made available for better use through reductions in federal spending.[3] The OIG reported FY 2011 exclusions of 2662 individuals and entities from participation in federal health care programs; 723 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 382 civil actions, which included false claims and unjust enrichment lawsuits filed in federal district court, civil monetary penalty settlements, and administrative recoveries related to provider self-disclosure matters. The financial success of the OIG process has been identified by Congress as both a source of health care revenue and evidence that fraud, waste, and abuse are significant factors in escalating health care costs.

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The objectives of the OIG study on age-related macular degeneration (AMD) were:

- to compare the Medicare payment amount for ranibizumab to physicians' acquisition costs;

- to determine the average Medicare contractor payment amount for bevacizumab when used to treat wet AMD and compare it to physicians' acquisition costs;
- to examine Medicare contractor payment policies for bevacizumab; and
- to examine the factors considered by physicians when choosing bevacizumab.

The study used Medicare claims data to identify 2 stratified random samples: (1) a sample of 160 physicians who received Medicare payment for ranibizumab, and (2) a sample of 160 physicians who received Medicare payment for bevacizumab. The study sent electronic surveys asking physicians to provide the total dollar amount and quantity purchased of both drugs in the first quarter of 2010. The study also asked physicians to describe the factors they consider when choosing which drug to use for the treatment of wet AMD. The study compared physician acquisition costs to Medicare payment amounts obtained from CMS and Medicare contractors. Additionally, it analyzed Medicare contractor payment policies and the reasons physicians reported for administering bevacizumab instead of ranibizumab.

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

OIG RECOMMENDATIONS

Based on the findings of its AMD study, the OIG recommended that CMS (1) establish a national payment code for bevacizumab when used for the treatment of wet AMD; and (2) educate providers about the clinical and payment issues related to ranibizumab and bevacizumab.

As required by law, CMS replied to both recommendations. They "non-concurred" with the first recommendation and concurred with the second. In their reason for declining the first recommendation, they cited the 2009 fiasco in which CMS proposed creating a national Medicare payment rate of $7.185 per 1.25-mg dose, which was calculated by taking the payment amount for the 10-mg dose of bevacizumab and dividing by 8. The OIG study confirmed the inadequacy of the 2009 proposal by finding that ophthalmologists paid, on average, $26 including drug and compounding costs per 1.25-mg dose of bevacizumab. The OIG noted that the average Medicare contractor payment of $55 per dose was 53% higher than the acquisition cost. The implication is that this payment may be too high. For ranibizumab, ophthalmologists paid $1928 (net of discounts) per vial in the first quarter of 2010, which was 5% below the Medicare payment amount of $2,023. This finding demonstrates that the average sales price plus 6% methodology for Part B drug payments is working, at least for CMS. The OIG study provides ophthalmologists with an interesting perspective on payment policy at CMS.

CONTINUED REVIEWS

Although the OIG study of AMD is complete, the OIG work plan for 2013 includes further scrutiny of ophthalmology payments. The OIG will review Medicare claims data to identify questionable billing for ophthalmologic services during 2011 and will also review the geographic locations of providers exhibiting questionable billing for ophthalmologic services in 2011. The criteria used to determine questionable billing are not described in the work plan. This year, the OIG will also report the results of an ongoing review of the appropriateness of ambulatory surgery center payments, and it will begin a study on the safety and quality of surgery in ambulatory surgery centers and hospital outpatient departments. The results of these studies will likely affect all of ophthalmology.

In 2010, Medicare allowed more than $6.8 billion for services provided by ophthalmologists, which is more than 10% of the total Part B pie. With such numbers at stake, we can expect continued OIG interest in the provision of ophthalmic care. ■

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1. Levinson DR. Medicare payments for drugs used to treat wet age-related macular degeneration. Department of Health and Human Services. Office of Inspector General. April 2012. OEI-03-10-00360.
2. Office of Inspector General. Available at: oig.hhs.gov. Accessed February 20, 2013.
3. 2013 Work Plan. Office of the Inspector General. Available at: oig.hhs.gov. Accessed February 20, 2013.