Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PAYMENTS TO CONNECTICUT PHYSICIANS FOR FULL VIALS OF HERCEPTIN WERE GENERALLY CORRECT

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June 2013
A-01-12-00515

Office of Inspector General

https://oig.hhs.gov

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

INTRODUCTION

WHY WE DID THIS REVIEW

When a physician administers a dose of a drug from a multiuse vial to a beneficiary, Medicare Part B will pay only for the amount of the drug actually administered, and any discarded amount is not reimbursable. A multiuse vial contains more than one dose of medication, as labeled by the manufacturer. Herceptin is packaged in multiuse vials of 440 milligrams and is a relatively expensive[1] drug used to treat breast cancer that has spread to other parts of the body. Based on prior audit work at outpatient providers,[2] we found that doses billed in multiples of the entire vial size (e.g., 440 milligrams, 880 milligrams, etc.) may include amounts of discarded drug billed in error. Medicare Part B and the beneficiaries are responsible only for the payment for the amount of the drug actually administered.

OBJECTIVE

Our objective was to determine whether Medicare payments that National Government Services, Inc. (NGS), made to physicians in Connecticut for full vials of Herceptin furnished during CYs 2009 through 2011 were correct.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. CMS contracts with Medicare administrative contractors (MAC) to process and pay Medicare claims submitted for physician services. NGS is the Medicare contractor for Jurisdiction 13, which includes Connecticut.

Claims for Drugs

Medicare guidance requires physicians to submit accurate claims for Part B services. Each submitted Medicare claim contains line items that detail each provided service. Physicians should use the appropriate Healthcare Common Procedure Coding System (HCPCS) code for the drug administered and report units of service in multiples of the units shown in the HCPCS narrative description. Multiuse vials are not subject to payment for discarded amounts of the drug. Multiuse vials are typically used for more than one date of service and can be stored for up

[1] Connecticut physicians were paid a total of approximately $8.4 million for Herceptin furnished during calendar years (CY) 2009 through 2011. During this period, physicians were paid approximately $2, 258 for a full vial (440 milligrams) of Herceptin.

[2] For example, see *Medicare Contractors' Payments in Jurisdiction 14 For Full Vials of Herceptin Were Often Incorrect* (A-01-11-00539), August 17, 2012. Available online at https://oig.hhs.gov/oas/reports/region1/11100539.pdf. Accessed March 8, 2013.

to 28 days. Therefore, a payment for an entire multiuse vial may include amounts of discarded drug billed in error.

Herceptin

Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent of benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded. The HCPCS code for Herceptin is J9355, with a narrative description of "injection, trastuzumab 10mg." An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

HOW WE CONDUCTED THIS REVIEW

We used CMS's National Claims History file to identify Part B line items which represented payments to Connecticut physicians for entire vials of Herceptin furnished during CYs 2009 through 2011. We found 110 line items with unit counts of 44 or 88, totaling approximately $259,578, which NGS paid to 21 physicians. We reviewed medical records to determine whether each line item was billed correctly.

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 contains the details of our scope and methodology.

RESULTS OF AUDIT

The Medicare payments that NGS made to physicians in Connecticut for full vials of Herceptin furnished during CYs 2009 through 2011 were generally correct. Of the 110 line items reviewed, 107 were billed correctly. For the remaining 3 line items, physicians reported incorrect units of service resulting in overpayments of $1,927. These overpayments have been refunded. Consequently, this report contains no recommendations.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 110 line items for 44 or 88 units of Herceptin furnished during CYs 2009 through 2011, which represent billings equivalent to entire multiuse vials. These line items represent $259,578 in Medicare payments to 21 Connecticut physicians. In this audit, we did not review entire claims; rather, we reviewed only the Herceptin line items within the claims.

We limited our review of NGS's internal controls to those that were applicable to the 110 line items of service because our objective did not require an understanding of all internal controls over the submission and processing of claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not address the completeness of the file.

Our fieldwork was conducted from March 2012 through July 2012 and included contacting NGS and all 21 physicians that received Medicare payments for the 110 line items.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify Part B line items which represented payments to Connecticut physicians for entire vials of Herceptin furnished during CYs 2009 through 2011;
- identified 110 line items with unit counts of 44 or 88;
- reviewed Common Working File records to determine whether any line items were adjusted prior to fieldwork;
- obtained medical records from the 21 physicians;
- reviewed the medical records the physicians furnished to determine whether each selected line item was billed correctly; and
- discussed the results of our review with NGS.

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.