Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE MEDICARE CONTRACTOR'S PAYMENTS TO PROVIDERS IN JURISDICTION 9 FOR FULL VIALS OF HERCEPTIN WERE OFTEN INCORRECT

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Gloria L. Jarmon
Deputy Inspector General

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Office of Inspector General

https://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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.

EXECUTIVE SUMMARY

BACKGROUND

Herceptin, also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. 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 benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days.

For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. This audit is part of a nationwide review of the drug Herceptin. The pilot review found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

Pursuant to Title XVIII of the Social Security Act, 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.

On September 12, 2008, CMS awarded the Medicare Administrative Contractor contract for Jurisdiction 9, which primarily includes providers in Florida, Puerto Rico, and the U.S. Virgin Islands, to First Coast Service Options, Inc. (First Coast). During our audit period (January 1, 2008, through December 31, 2010), 8,181 line items were processed for Herceptin totaling approximately $14.5 million. Of these 8,181 line items, 1,330 totaling approximately $3.7 million had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. In this audit, we did not review entire claims; rather, we reviewed the specific line items within the claims that met these criteria.

OBJECTIVE

Our objective was to determine whether Medicare payments that First Coast made to providers in Jurisdiction 9 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that First Coast made to providers in Jurisdiction 9 for full vials of Herceptin were incorrect. Of the 1,330 selected line items, 1,043 (78 percent) were incorrect and included overpayments totaling $1,315,409, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers had refunded overpayments on 109 line items totaling $212,406 before our fieldwork, and the remaining 178 line items were correct.

For the 1,043 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,036 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,295,768, and

- did not provide supporting documentation for 7 line items, resulting in overpayments totaling $19,641.

On each of the incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to automated billing systems that could not prevent or detect the incorrect billing of units of service. First Coast made these incorrect payments because neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments.

RECOMMENDATIONS

We recommend that First Coast:

- recover the $1,315,409 in identified overpayments,

- implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s), and

- use the results of this audit in its provider education activities.

FIRST COAST SERVICE OPTIONS, INC., COMMENTS

In written comments on our draft report, First Coast said that it had reviewed our findings and recommendations and described corrective actions that it had taken or planned to take.

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INTRODUCTION

BACKGROUND

Herceptin[1] is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. However, for multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded amounts. This audit is part of a nationwide review of the drug Herceptin. The pilot review[2] found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

Pursuant to Title XVIII of the Social Security Act, 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.

Medicare Contractors

CMS contracts with Medicare contractors to, among other things, process and pay Medicare claims submitted for outpatient services.[3] The Medicare contractors' responsibilities include determining reimbursement amounts, conducting reviews and audits, and safeguarding against fraud and abuse. Federal guidance provides that Medicare contractors must maintain adequate internal controls over automatic data processing systems to prevent increased program costs and erroneous or delayed payments. To process providers' claims for outpatient services, the Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF). The CWF can detect certain improper payments during prepayment validation.

Claims for Drugs

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains line items that detail each provided service. Providers 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.[4] Multiuse vials are not subject to payment for discarded amounts of the drug.

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[1] Herceptin is Genentech's registered trademark for the drug trastuzumab.

[2] Report number A-05-10-00091, issued July 10, 2012.

[3] Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors (MAC) between October 2005 and October 2011. Most, but not all, of the MACs are fully operational; for jurisdictions where the MACs are not fully operational, the fiscal intermediaries and carriers continue to process claims. In this report, the term "Medicare contractor" means the fiscal intermediary, carrier, or MAC, whichever is applicable.

[4] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

Multiuse vials are typically used for more than one date of service and can be stored for up to 28 days. Therefore, a payment for an entire multiuse vial is likely to be incorrect.

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 10 mg." An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

First Coast Service Options, Inc.

On September 12, 2008, CMS awarded the MAC contract for Jurisdiction 9, which primarily includes providers in Florida, Puerto Rico, and the U.S. Virgin Islands, to First Coast Service Options, Inc. (First Coast).[5] During our audit period (January 1, 2008, through December 31, 2010), 8,181 line items were processed for Herceptin in Jurisdiction 9.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that First Coast made to providers in Jurisdiction 9 for full vials of Herceptin were correct.

Scope

During our audit period, First Coast processed 8,181 outpatient Part B service line items of Herceptin totaling approximately $14.5 million. Of these 8,181 line items, 1,330[6] totaling approximately $3.7 million had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials.

[5] Prior to the award, providers in Florida, Puerto Rico, and the U.S. Virgin Islands submitted Medicare outpatient claims through separate fiscal intermediaries. On September 12, 2008, First Coast was awarded the MAC contract for Jurisdiction 9 and is therefore responsible for collecting any overpayments and resolving the issues related to this audit.

[6] We included 6 of the 1,330 line items because they exceeded $10,000. Although this did not represent a billing equivalent to a full vial, we included these high-dollar items because they were likely to be incorrect.

We limited our review of First Coast's internal controls to those that were applicable to the selected payments 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 the National Claims History file, but we did not assess the completeness of the file.

We conducted our fieldwork from October 2011 through July 2012 and contacted First Coast in Jacksonville, Florida, and the 33 providers in Florida and the U.S. Virgin Islands that received the selected Medicare payments.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify outpatient line items in which payments were made for HCPCS code J9355 (Herceptin);
- identified the 1,330 line items in our scope that First Coast paid to 33 providers;
- contacted the 33 providers that received Medicare payments associated with the selected line items to determine whether the information conveyed in the selected line items was correct, and, if not, why the information was incorrect;
- reviewed documentation that the providers furnished to support:
    - the medical condition of the beneficiary in determining the necessity of the medication,
    - a physician's orders for medication,
    - that the medication was administered, and
    - the type of solution used to reconstitute the Herceptin (BWFI containing 1.1 percent benzyl alcohol or sterile water);
- coordinated our calculation of overpayments with First Coast; and
- discussed the results of our review with First Coast on August 16, 2012.

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 objective.

FINDINGS AND RECOMMENDATIONS

Most Medicare payments that First Coast made to providers in Jurisdiction 9 for full vials of Herceptin were incorrect. Of the 1,330 selected line items, 1,043 (78 percent) were incorrect and included overpayments totaling $1,315,409, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers had refunded overpayments on 109 line items totaling $212,406 before our fieldwork, and the remaining 178 line items were correct.

For the 1,043 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,036 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,295,768, and

- did not provide supporting documentation for 7 line items, resulting in overpayments totaling $19,641.

On each of the incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to automated billing systems that could not prevent or detect the incorrect billing of units of service. First Coast made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place during our audit period to prevent or detect the overpayments.

FEDERAL REQUIREMENTS

Section 1833(e) of the Social Security Act states: "No payment shall be made to any provider of services … unless there has been furnished such information as may be necessary in order to determine the amounts due such provider … for the period with respect to which the amounts are being paid …."

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 (the *Manual*), chapter 23, section 20.3, states: "… providers must use HCPCS codes … for most outpatient services." According to chapter 17, section 70, of the *Manual*, when a provider is billing for a drug "[w]here HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4 …."

Chapter 17, section 40, of the *Manual* also states: "Multi-use vials are not subject to payment for discarded amounts of drug …." Finally, chapter 1, section 80.3.2.2, of the *Manual* states: "In order to be processed correctly and promptly, a bill must be completed accurately."

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED

Incorrect Number of Units of Service

Providers reported incorrect units of service on 1,036 line items, resulting in overpayments totaling $1,295,768. Providers billed Medicare for 1 or more vials of Herceptin (44 units to 300 units of service), rather than for the amount of the drug actually administered.

For example, 1 provider administered 126 milligrams of Herceptin to a patient and billed for 44 units of service (440 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 126 milligrams is 13.[7] This error occurred on 32 separate occasions for 1 patient; as a result, First Coast paid the provider $66,698 when it should have paid $19,706, an overpayment of $46,992.

Unsupported Services

Six providers billed Medicare for seven line items for which the providers did not provide supporting documentation. The providers agreed that they should not have submitted the line items for payment. First Coast adjusted to zero these line items, totaling $19,641 in overpayments.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The providers attributed the incorrect payments to clerical errors and to automated billing systems that could not prevent or detect the incorrect billing of units of service. First Coast made these incorrect payments because neither the Fiscal Intermediary Standard System nor the CWF had sufficient edits in place to prevent or detect the overpayments. In effect, CMS relied on beneficiaries to review their *Medicare Summary Notice*[8] and disclose any overpayments.

RECOMMENDATIONS

We recommend that First Coast:

- recover the $1,315,409 in identified overpayments,
- implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s), and
- use the results of this audit in its provider education activities.

[7] If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor to report the dose.

[8] The Medicare contractor sends a *Medicare Summary Notice*—an explanation of benefits—to the beneficiary after the provider files a claim for services. The notice explains the services billed, the approved amount, the Medicare payment, and the amount due from the beneficiary.

FIRST COAST SERVICE OPTIONS, INC., COMMENTS

In written comments on our draft report, First Coast said that it had reviewed our findings and recommendations and described corrective actions that it had taken or planned to take. First Coast's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: FIRST COAST SERVICE OPTIONS, INC., COMMENTS

FIRST COAST
SERVICE OPTIONS, INC.
WHEN EXPERIENCE COUNTS & QUALITY MATTERS

Sandy Coston
CEO & President
First Coast Service Options, Inc.
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November 16, 2012

Mr. Andrew A. Funtal, Audit Manager
Office of Inspector General
Office of Audit Services, Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, GA 30303

Reference: A-04-12-06146

Dear Mr. Funtal:

We received the U.S. Department of Health & Human Services, Office of Inspector General (OIG) draft report entitled, "*The Medicare Contractor's Payments to Providers in Jurisdiction 9 for Full Vials of Herceptin Were Often Incorrect*" and reviewed the findings and recommendations. We appreciate the opportunity to review and provide comments prior to release of the final report.

In the draft report, you outlined three recommendations that we have addressed as follows:

Recommendation:

Recover the $1,315,409 in identified overpayments.

Response:

First Coast Service Options, Inc. (First Coast) has initiated its standard overpayment recovery procedures to recover the claims identified by the OIG.

Recommendation:

Implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s).

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Response:

A prepayment audit will be implemented on HCPCS code J9355 (Herceptin). Audit implementation will be in effect for both Part A and Part B systems and will suspend claims for review when 44, 88 or 132 units are billed.

Recommendation:

Use the results of this audit in its provider education activities.

Response:

First Coast will incorporate examples of billing errors found in this report in future education efforts. Educational efforts will include an emphasis on units of service issues that led to claims being reimbursed at excessive payment amounts.

Again, we appreciate the opportunity to review and provide comments prior to release of the final report. If you have any questions regarding our responses, please contact Mr. Gregory W. England at (904) 791-8364.

Sincerely,

/Sandy Coston/

cc: Gregory W. England