Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS IN JURISDICTION 14 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.

Michael J. Armstrong
Regional Inspector General

August 2012
A-01-11-00539

Office of Inspector General

http://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 of these reviews 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 administers the program.

Effective November 19, 2008, NHIC, Corp. (NHIC), became the Medicare contractor in Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont and assumed responsibility for claims formerly paid by National Government Services, Inc. (Maine, Massachusetts, New Hampshire, and Vermont), and Pinnacle Business Solutions, Inc. (Rhode Island). Accordingly, we have addressed our findings and recommendations to NHIC for review and comment.

During our audit period (January 1, 2008, through December 31, 2010), 13,251 line items for Herceptin totaling approximately $20.7 million were processed in these States. Of these 13,251 line items, 853 totaling approximately $1.9 million had 44, 88, 132, or 1,408 units of service 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 NHIC made to providers for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Almost half of the Medicare payments that NHIC made to providers for full vials of Herceptin were incorrect. Specifically, of the 853 selected line items, 391 (46 percent) were incorrect and included overpayments totaling $403,396, or more than one-fifth of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 130 line items totaling $141,322 before our fieldwork. The 332 remaining line items were correct.

For the 391 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 386 line items with unit counts that represented full multiuse-vials, resulting in overpayments totaling $394,934, and

- did not provide supporting documentation for 5 line items, resulting in an overpayment of $8,462.

The providers attributed the incorrect payments to clerical errors and billing systems that could not prevent or detect the incorrect billing of units of service. NHIC 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 NHIC:

- recover the $403,396 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.

NHIC, CORP., COMMENTS

In written comments on our draft report, NHIC concurred with our recommendations and described corrective actions it had taken or planned to take.

NHIC's comments are included in their entirety as the Appendix.

TABLE OF CONTENTS

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

NHIC, Corp.

Effective November 19, 2008, NHIC, Corp. (NHIC), became the Medicare contractor in Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont and assumed responsibility for claims formerly paid by National Government Services, Inc. (Maine, Massachusetts, New Hampshire, and Vermont), and Pinnacle Business Solutions, Inc. (Rhode Island). Accordingly, we have addressed our findings and recommendations to NHIC for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that NHIC made to providers for full vials of Herceptin were correct.

Scope

During our audit period (January 1, 2008, through December 31, 2010), NHIC processed 13,251 outpatient Part B service line items for Herceptin totaling approximately $20.7 million. Of these 13,251 line items, 853 totaling approximately $1.9 million had 44, 88, 132, or 1,408 units of service 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.

We limited our review of NHIC'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.

Our fieldwork was conducted from September 2011 through February 2012 and included contacting NHIC in Chico, California, and the 53 providers in Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont 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 853 line items with unit counts of 44, 88, 132, or 1,408, totaling approximately $1.9 million, that NHIC paid to 53 providers;
- contacted the 53 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 verify whether each selected line item was billed correctly; specifically, we reviewed documentation 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 the calculation of overpayments with NHIC; and
- discussed the results of our review with NHIC on May 7, 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

Almost half of the Medicare payments that NHIC made to providers for full vials of Herceptin

were incorrect. Specifically, of the 853 selected line items, 391 (46 percent) were incorrect and included overpayments totaling $403,396, or more than one-fifth of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 130 line items totaling $141,322 before our fieldwork. The 332 remaining line items were correct.

For the 391 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 386 line items with unit counts that represented full multiuse-vials, resulting in overpayments totaling $394,934, and

- did not provide supporting documentation for 5 line items, resulting in overpayments totaling $8,462.

The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing. NHIC made these incorrect payments because neither the FISS 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 …." Further, 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 ALMOST HALF OF THE LINE ITEMS REVIEWED

Incorrect Number of Units of Service

Providers reported incorrect units of service on 391 (46 percent) of the 853 line items reviewed. These errors resulted in overpayments totaling $403,396 (21 percent) of the total $1.9 million reviewed.

For 386 incorrect line items, 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, resulting in overpayments totaling $394,934. For example, a provider administered 110 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 110 milligrams is 11.[5] This error occurred on 22 separate occasions for 1 patient; as a result, NHIC paid the provider $46,813 when it should have paid $11,703, an overpayment of $35,110.

Unsupported Services

Four providers billed Medicare for 5 line items for which the providers did not provide supporting documentation. For example, one provider did not have a physician order for the medication administered to the patient. The providers agreed to cancel the claims associated with these line items and refund the combined $8,462 in overpayments that they received.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The providers attributed the incorrect payments to clerical errors and billing systems that could not prevent or detect the incorrect billing of units of service. NHIC made these incorrect payments because neither the FISS 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*[6] and disclose any overpayments.

RECOMMENDATIONS

We recommend that NHIC:

- recover the $403,396 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.

[5] 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.

[6] 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.

NHIC, CORP., COMMENTS

In written comments on our draft report, NHIC concurred with our recommendations and described corrective actions it had taken or planned to take.

NHIC's comments are included in their entirety as the Appendix.

APPENDIX

July 30, 2012

Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region 1
John F Kennedy Federal Building
15 New Sudbury Street, Room 2425
Boston, MA 02203

Attention: Michael J. Armstrong
Regional Inspector General for Audit Services

Subject: (Draft Report) *Medicare Contractors' Payments to Providers in Jurisdiction 14 for Full Vials of Herceptin Were Often Incorrect* (A-01-11-00539)

Dear Mr. Armstrong:

Please find on the following page our response to the recommendations in the draft audit report cited above. If you have any questions about NHIC's response, please contact me.

Sincerely,

/s/
Jennifer Otten
Audit & Controls Manager
402 Otterson Dr.
Chico, CA 95928

cc: Anne Bockhoff-Dalton
Robert Harrington

Summary of OIG's recommendations and NHIC's response to each:

1. **Recommendation**
   Recover the $403,396 in identified overpayments.

   NHIC Response.
   NHIC **concurs** with the recommendation and the cited overpayment amounts. We have been notified by your office that, by the end of the audit, all 391 line items which totaled $403,396 in identified overpayments were corrected in CWF, and that the claims were either resubmitted or canceled. Therefore, no additional recovery on these items is required.

2. **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), and

   NHIC Response
   NHIC **concurs** with this recommendation. The feasibility of implementing a system edit is currently being researched. However, several questions require further understanding, to include the specifics of the drug Herceptin being administered, the potential impact on the Medical Review Strategy plans, and the manual processes that may be required to effectively identify and recover overpaid services.

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

   NHIC Response
   NHIC **concurs** with this recommendation. NHIC Provider Outreach and Education (POE) will create an article based on this audit, and will post it on our website. We will highlight this in a listserv distributed to all providers, informing them of the policy and indicating where the article can be located on the website. We also plan to create a matching educational teleconference, tentatively planned for September 2012, to be announced on our website and via our list-serv, and will make the accompanying PowerPoint presentation available as a link to the session.