Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS IN JURISDICTION 1 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

February 2013
A-09-12-02069

Office of Inspector General

https://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at https://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

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

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.

During our audit period (January 1, 2008, through December 31, 2010), Palmetto GBA, LLC (Palmetto), became the Medicare contractor for Jurisdiction 1, which comprises three States and three territories, and assumed responsibility for claims formerly paid by National Government Services, Inc., and Wisconsin Physicians Service Insurance Corporation. Accordingly, we have addressed our findings and recommendations to Palmetto for review and comment.

For Jurisdiction 1, the Medicare contractors processed 9,962 line items for Herceptin totaling approximately $17.3 million during our audit period. Of these 9,962 line items, 2,005 totaling approximately $5.4 million had unit counts in 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 Medicare contractors made to providers in Jurisdiction 1 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that the Medicare contractors made to providers in Jurisdiction 1 for full vials of Herceptin were incorrect. Specifically, of the 2,005 selected line items, 1,498 (75 percent) were incorrect and included overpayments totaling $1,731,460, or 32 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 295 line items totaling $383,270 before our fieldwork. The 212 remaining line items were correct.

For the 1,498 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,427 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,569,783;

- did not provide supporting documentation for 64 line items, resulting in overpayments totaling $147,520;

- billed for unallowable services on 6 line items, resulting in overpayments totaling $13,371; and

- reported a combination of incorrect units of service and an incorrect Healthcare Common Procedure Coding System code on 1 line item, resulting in an overpayment of $786.

The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The Medicare contractors 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 Palmetto:

- recover the $1,731,460 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.

PALMETTO GBA, LLC, COMMENTS

In written comments on our draft report, Palmetto provided information on actions that it had taken or planned to take to address our recommendations.

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 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 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.

---

[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 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 the narrative description "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.

Palmetto GBA, LLC

During our audit period (January 1, 2008, through December 31, 2010), Palmetto GBA, LLC (Palmetto), became the Medicare contractor for Jurisdiction 1, which comprises three States (California, Hawaii, and Nevada) and three territories (American Samoa, Guam, and Northern Mariana Islands), and assumed responsibility for claims formerly paid by National Government Services, Inc., and Wisconsin Physicians Service Insurance Corporation. Accordingly, we have addressed our findings and recommendations to Palmetto for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that Medicare contractors made to providers in Jurisdiction 1 for full vials of Herceptin were correct.

Scope

During our audit period, the Medicare contractors processed 9,962 outpatient Part B service line items of Herceptin totaling approximately $17.3 million. Of these 9,962 line items, 2,005 items totaling approximately $5.4 million had unit counts in 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.

We limited our review of Palmetto'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 November 2011 to September 2012 and included contacting Palmetto in Columbia, South Carolina, and the 68 providers in Jurisdiction 1 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 2,005 line items in our scope that the Medicare contractors paid to 68 providers;
- contacted the 68 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 Palmetto; and
- discussed the results of our review with Palmetto on September 13, 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 objectives.

FINDINGS AND RECOMMENDATIONS

Most Medicare payments that the Medicare contractors made to providers in Jurisdiction 1 for full vials of Herceptin were incorrect. Specifically, of the 2,005 selected line items, 1,498 (75 percent) were incorrect and included overpayments totaling $1,731,460, or 32 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 295 line items totaling $383,270 before our fieldwork. The 212 remaining line items were correct.

For the 1,498 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,427 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,569,783;

- did not provide supporting documentation for 64 line items, resulting in overpayments totaling $147,520;

- billed for unallowable services on 6 line items, resulting in overpayments totaling $13,371; and

- reported a combination of incorrect units of service and an incorrect HCPCS code on 1 line item, resulting in an overpayment of $786.

The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The Medicare contractors 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 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

Forty-eight providers reported incorrect units of service on 1,427 line items, resulting in overpayments totaling $1,569,783. Providers billed Medicare for the entire vial containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, 1 provider administered 130 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 130 milligrams is 13.[5] This error occurred on 98 separate occasions for 1 patient; as a result, the Medicare contractor paid the provider $218,486 when it should have paid $64,552, an overpayment of $153,934.

Unsupported Services

Fourteen providers billed Medicare for 64 line items for which the providers did not provide supporting documentation. The providers agreed to cancel the line items and refund the combined $147,520 in overpayments that they received.

Unallowable Services

Three providers incorrectly billed Medicare for six line items for which the administration of Herceptin was not allowable for Medicare reimbursement, resulting in overpayments totaling $13,371. For example, one provider incorrectly billed Medicare for the administration of Herceptin instead of billing the patient's primary insurance carrier.[6] This error occurred on four separate occasions for one patient; as a result, the Medicare contractor paid the provider $8,720 when it should have paid $0, an overpayment of $8,720.

Combination of Incorrect Number of Units of Service and Incorrect Healthcare Common Procedure Coding System Code

One provider reported a combination of incorrect units of service and an incorrect HCPCS code on one line item. Specifically, the provider incorrectly billed Medicare for 44 units of Herceptin when it should have billed 30 units of Remicade (an injectable drug used to treat rheumatoid and psoriatic arthritis, ulcerative colitis, Crohn's disease, and ankylosing spondylitis). As a result of this error, the Medicare contractor paid the provider $2,097 when it should have paid $1,311, an overpayment of $786.

[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] Section 1862(b) of the Act prohibits Medicare from making payment if payment has been made or can reasonably be expected to be made by a primary insurance carrier.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The Medicare contractors 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*[7] and disclose any overpayments.

RECOMMENDATIONS

We recommend that Palmetto:

- recover the $1,731,460 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.

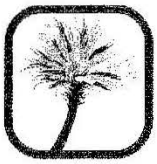
PALMETTO GBA, LLC, COMMENTS

In written comments on our draft report, Palmetto provided information on actions that it had taken or planned to take to address our recommendations. Palmetto's comments are included in their entirety as the Appendix.

[7] 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.

APPENDIX

APPENDIX: PALMETTO GBA, LLC, COMMENTS



Palmetto GBA
PARTNERS IN EXCELLENCE

Walter J. Johnson
President and Chief Operating Officer

January 3, 2013

Lori A. Ahlstrand
Office of Inspector General
Office of Audit Services, Region IX
90-7th Street, Suite 3-650
San Francisco, CA 94103

Reference: Draft Report No. A-09-12-02069

Dear Ms. Ahlstrand:

This letter is in response to the recent Office of Inspector General (OIG) report entitled *"Medicare Contractors' Payments to Providers in Jurisdiction 1 for Full Vials of Herceptin Were Often Incorrect"*. We appreciate the feedback your review provided and are committed to continuously improving our service to the Medicare beneficiaries and providers we serve.

During the audit period (January 1,2008 through December 31,2010) Palmetto GBA, LLC (Palmetto) became the Medicare Administrative Contractor (MAC) for Jurisdiction 1, which comprises three States and three Territories, and assumed responsibility for claims formerly paid by National Government Services, Inc., and Wisconsin Physicians Service Insurance Corporation.

During the audit period approximately 2,005 line items were selected in which:

(1) reported incorrect units of service on 1,427 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,569,783;

(2) did not provide supporting documentation for 64 line items, resulting in overpayments totaling $147,520;

(3) billed for unallowable services on 6 line items, resulting in overpayments totaling $13,371; and

(4) reported a combination of incorrect units of service and an incorrect HCPCS code on 1 line item, resulting in an overpayment of $786.

In several cases, providers could not store unused doses for later use because of their pharmacies incorrectly reconstituted the Herceptin using sterile water instead of bacteriostatic water. Consequently, these providers billed Medicare for the entire vial, including waste. Because neither the Fiscal Intermediary Standard System (FISS) nor the Common Working File (CWF) had sufficient edits in place to prevent or detect the overpayments the following was recommended by your office:

- **Recover the $1,731,460 identified overpayments.**

  Palmetto GBA Response:

  All claims identified in the audit were adjusted either by the provider or by Palmetto GBA. The identified overpayment of $1,731,460 was recovered in its entirety.

- **Implement system edits that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials.**

  Palmetto GBA Response:

  Palmetto GBA now performs prepay complex review on claims billed for the drug Trastuzumab. We will assess the viability and the impact of implementing a system edit which would suspend a claim line item for Herceptin that specifically is billed for 44 units. Providers billing for multi-dose vials with 44 units of service will receive an Additional Documentation Request (ADR) to justify the submission.

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

  Palmetto GBA Response:

  Palmetto GBA reviewed educational material available on the Palmetto GBA Web site and republish and disseminate through the Palmetto GBA listserv educational material regarding proper billing of multi-dose vials of drugs and biologicals. Additionally, Palmetto GBA will use the specific problems outlined in the OIG report to create an additional educational article to stress the importance of accurate billing of drugs and biologicals. While correct coding has been and continues to be discussed in each educational session conducted by Palmetto GBA, we will communicate the results of this audit in our provider education conferences.

  The following articles were published:

  Complex Medical Review of the Drug Trastuzumad (HCPCS code J9355) for Bill type 13X.
  http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%2011%20Part%20A~Articles~General~8WSKLW8378?open&navmenu=%7C%7C

  FAQ Part A:
  http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%2011%20Part%20A~Resources~FAQs~Claims~8X6TES7268?open&navmenu=%7C%7C

In closing, Palmetto GBA understands the importance of correct coding, billing and payment activities.

Thank you for providing Palmetto GBA with the opportunity to offer feedback regarding your review. If you have any questions, please do not hesitate to contact me.

Sincerely

Walter J. Johnson

Walter J. Johnson
President and Chief Operating Officer

cc: Amy Drake, COR, CMS
Sandra Brown, CMS
Mike Barlow, Palmetto GBA
Carol Sutton, Palmetto GBA