Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS TO PROVIDERS IN JURISDICTION 11 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

August 2012
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Office of Inspector General

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EXECUTIVE SUMMARY

BACKGROUND

Herceptin (trastuzumab) is a Medicare-covered biological drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial containing 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. A vial of Herceptin reconstituted with bacteriostatic water is stable for 28 days when stored properly. An entire multiuse vial of Herceptin represents 44 units for billing Medicare. However, for multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded amounts of the 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.

Title XVIII of the Social Security Act established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to process and pay Medicare claims submitted for outpatient services. The Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims. The CWF can detect certain improper payments during prepayment validation.

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. The Medicare program encourages physicians to schedule patients in such a way that they can administer drugs most efficiently.

During our audit period (January 2008 through December 2010), Palmetto GBA, LLC (Palmetto), was the Medicare contractor for North Carolina and South Carolina, and National Government Services was the Medicare contractor for Virginia and West Virginia. Effective May 16, 2011, Palmetto became the Medicare contractor for Jurisdiction 11 (North Carolina, South Carolina, Virginia, and West Virginia) and assumed responsibility for claims formerly paid by National Government Services for Virginia and West Virginia. Accordingly, we have addressed our findings and recommendations to Palmetto for review and comment.

The Medicare contractors processed 14,112 line items totaling approximately $24.8 million for Herceptin. Of these 14,112 line items, 2,507 line items totaling approximately $6.7 million had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent to 1 or more full multiuse vials of Herceptin. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

OBJECTIVE

Our objective was to determine whether payments that the Medicare contractors made to providers in Jurisdiction 11 for full vials of the drug Herceptin were correct.

SUMMARY OF FINDINGS

Most payments that the Medicare contractors made to providers in Jurisdiction 11 for one or more full vials of Herceptin were incorrect. Of the 2,507 selected line items, 2,029 were incorrect and included overpayments totaling $2,397,839 that the providers had not identified or refunded by the beginning of our audit. Providers refunded overpayments on 138 line items totaling $131,461 before our fieldwork. The remaining 340 line items were correct.

For the 2,029 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,985 line items, resulting in overpayments totaling $2,264,571 and

- did not provide supporting documentation for 44 line items, resulting in overpayments totaling $133,268.

The providers attributed the incorrect payments to chargemaster errors, clerical errors, and billing systems that could not prevent or detect the incorrect billing of units of service. (A provider's chargemaster contains data on every chargeable item or procedure that the provider offers, including a factor that converts a drug's dosage to the number of units to bill and whether to charge for waste.)

In several cases, providers could not store unused doses for later use because their pharmacies incorrectly reconstituted the Herceptin using sterile water instead of bacteriostatic water. When this occurred, the providers billed Medicare for the entire vial, including waste. 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.

RECOMMENDATIONS

We recommend that Palmetto:

- recover the $2,397,839 in identified overpayments,

- implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials, and

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

PALMETTO GBA, LLC, COMMENTS

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

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PALMETTO GBA, LLC, COMMENTS

INTRODUCTION

BACKGROUND

Herceptin[1] is a Medicare-covered biological drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial containing 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. Multiuse vials are typically used for more than one date of service and can be stored 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 amounts of the 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.[2]

Medicare Contractors

Title XVIII of the Social Security Act established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. The Centers for Medicare & Medicaid Services (CMS) administers the program.

CMS contracts with Medicare contractors to, among other things, process and pay 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 the 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 Outpatient Drugs and Biologicals

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains line items that detail each provided service. Providers must

[1] Herceptin is Genentech's registered trademark for the biological drug trastuzumab. Biologicals are substances made from a living organism or its products that are used to prevent, diagnose, treat, or relieve symptoms of a disease.

[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.

use the appropriate Healthcare Common Procedure Coding System (HCPCS)[4] code for drugs administered and report units of service in multiples of the units shown in the HCPCS narrative description. CMS encourages physicians to schedule patients in such a way that they can administer drugs most efficiently.[5] Because providers must discard the remainder of a single-use vial after administering a portion of it to a Medicare patient, the Medicare program pays for the amount discarded as well as the drug administered. However, unlike single-use vials, multiuse vials are not subject to payment for discarded amounts of the drug. Therefore, a Medicare payment for an entire multiuse vial is likely to be an overpayment.

Palmetto GBA, LLC, and National Government Services

During our audit period (January 2008 through December 2010), Palmetto GBA, LLC (Palmetto), was the Medicare contractor for North Carolina and South Carolina, and National Government Services was the Medicare contractor for Virginia and West Virginia. Effective May 16, 2011, Palmetto became the Medicare contractor for Jurisdiction 11 (North Carolina, South Carolina, Virginia, and West Virginia) and assumed responsibility for claims formerly paid by National Government Services for Virginia and West Virginia. 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 payments that the Medicare contractors made to providers in Jurisdiction 11 for full vials of the drug Herceptin were correct.

Scope

During our audit period, the Medicare contractors in Jurisdiction 11 processed 14,112 outpatient Part B line items for Herceptin totaling $24,845,525. Of the 14,112 line items, 2,507 totaling $6,701,936 had unit counts in multiples of 44 (44, 88, 132 …) that represent billings equivalent to full multiuse vials of Herceptin. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

We limited our review of the Medicare contractor'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 January 2012 by contacting Palmetto in Columbia, South Carolina, and 82 providers in Jurisdiction 11 that received the selected Medicare payments during our audit period.

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

[5] *CMS Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 17, section 40.

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 for which payments were made for HCPCS code J9355 (Herceptin);
- identified the 2,507 line items in our scope that the Medicare contractors paid to 82 providers;
- contacted the 82 providers that received Medicare payments for the selected line items to determine whether the information for 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:
    - a physician's order for the medication,
    - the administration of the medication for the amount ordered, and
    - the type of solution (bacteriostatic water for injection or sterile water for injection) used to reconstitute the Herceptin;
- coordinated the calculation of overpayments with the Medicare contractor; and
- discussed the results of our review with the Medicare contractor.

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 payments that the Medicare contractors made to providers in Jurisdiction 11 for one or more full vials of Herceptin were incorrect. Of the 2,507 selected line items, 2,029 were incorrect and included overpayments totaling $2,397,839 that the providers had not identified or refunded by the beginning of our audit. Providers refunded overpayments on 138 line items totaling $131,461 before our fieldwork. The remaining 340 line items were correct.

For the 2,029 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,985 line items, resulting in overpayments totaling $2,264,571 and

- did not provide supporting documentation for 44 line items, resulting in overpayments totaling $133,268.

The providers attributed the incorrect payments to chargemaster[6] errors, clerical errors, and billing systems that could not prevent or detect the incorrect billing of units of service. In several cases, providers could not store unused doses for later use because their pharmacies incorrectly reconstituted the Herceptin using sterile water instead of bacteriostatic water. When this occurred, the providers billed Medicare for the entire vial, including waste. 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 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." Chapter 17, section 70, of the Manual states: "[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 [milligrams], and 200 mg are provided, units are shown as 4 …."

Chapter 17, section 40, of the Manual states: "[m]ulti-use vials are not subject to payment for discarded amounts of drug or biological." 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."

MEDICARE BILLING FOR HERCEPTIN

The HCPCS code for Herceptin is J9355, with a narrative description of "injection, trastuzumab 10 mg [milligrams]." 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 containing a solution of 1.1 percent of benzyl alcohol, as a preservative. An entire multiuse vial of 440 milligrams of reconstituted Herceptin would be reported as 44 units for billing Medicare. A vial of Herceptin reconstituted with bacteriostatic water is stable for 28 days when stored properly. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded.

[6] A provider's chargemaster contains data on every chargeable item or procedure that the provider offers, including a factor that converts a drug's dosage to the number of units to bill and whether to charge for waste.

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED

Incorrect Number of Units of Service

Fifty-one providers reported incorrect units of service on 1,985 line items, resulting in overpayments totaling $2,264,571. Providers billed Medicare for 1 to 6 full vials of Herceptin (44 units to 264 units of service), rather than for the amount of the drug actually administered. For example:

- One provider administered 700 milligrams of Herceptin to a patient and billed for 88 units of service (880 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the correct number of units to bill for 700 milligrams was 70. On 215 separate occasions, this type of error occurred, and as a result, the Medicare contractor paid the provider $586,772 when it should have paid $310,106, an overpayment of $276,666.

- Another provider administered 168 milligrams (17 units)[7] of Herceptin to a patient but incorrectly billed for 44 units of service (440 milligrams). The provider's pharmacy incorrectly reconstituted Herceptin using sterile water instead of bacteriostatic water, and the provider billed Medicare for the full vial, including waste. On 66 separate occasions, that provider billed for 1 or 2 full vials of Herceptin (44 or 88 units of service) for each patient dose rather than the amount administered. As a result, the Medicare contractor paid the provider $182,344 when it should have paid $103,397, an overpayment of $78,947.

As a result of these unit-of-service errors, the Medicare contractors paid 51 providers a total of $5,479,764 when it should have paid $3,215,193, an overpayment of $2,264,571.

Unsupported Services

Seventeen providers billed Medicare for 44 line items for which the providers did not provide any documentation to support that a patient was seen or received treatment. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined $133,268 in overpayments that they received.

CAUSES OF INCORRECT MEDICARE PAYMENTS

Provider Billing Errors

Providers attributed the incorrect billing to chargemaster errors, clerical errors, or billing systems that could not prevent or detect the incorrect billing of units of service. In several cases, the provider's pharmacy incorrectly reconstituted Herceptin using sterile water instead of bacteriostatic water. Because sterile water does not contain a preserving agent, the unused drug could not be stored for later use. When this occurred, providers treated the multiuse vial of Herceptin as a single-use vial and billed Medicare for the entire amount, including waste.

[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 for the code to report the administered dose.

Medicare Contractor System Edits

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. In effect, CMS relied on providers to notify the Medicare contractors of incorrect payments and on beneficiaries to review their *Medicare Summary Notice* and disclose any overpayments.[8]

RECOMMENDATIONS

We recommend that Palmetto:

- recover the $2,397,839 in identified overpayments,
- implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials, and
- use the results of this audit in its provider education activities.

PALMETTO GBA, LLC, COMMENTS

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

[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.

APPENDIX

APPENDIX: PALMETTO GBA, LLC, COMMENTS

Palmetto GBA
PARTNERS IN EXCELLENCE℠

Walter J. Johnson
President and Chief Operating Officer

July 13, 2012

Mr. Stephen Virbitsky
Office of Inspector General
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

RE: Draft Report No. A-03-11-00013

Dear Mr. Virbitsky:

This letter is in response to your letter dated June 15, 2012, to Bruce Hughes, regarding the recent Office of Inspector General (OIG) report entitled "*Medicare Contractors' Payments to Providers in Jurisdiction 11 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.

Palmetto GBA, LLC assumed full responsibility as the Medicare Administrative Contractor (MAC) for Jurisdiction 11 effective June 2011. During the audit period of January 2008 through December 2010, Palmetto GBA was the Medicare contractor for North Carolina and South Carolina, and National Government Services (NGS) was the Medicare contractor for Virginia and West Virginia.

During the audit period approximately 2,029 line items were selected in which:

(1) providers reported incorrect units of service on 1,985 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $2,264,571 and;

(2) providers did not submit supporting documentation for 44 line items resulting in overpayments totaling $133,268.

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 $2,397,839 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 $2,397,839 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 agrees with this recommendation. However, the Medicare Administrative Contractor's (MAC's) ability to implement local system edits is programmatically problematic and onerous due to the vast number of multiuse-vial drugs administered in the Medicare environment.

  In the alternative, Palmetto GBA recommends that the Centers of Medicare & Medicaid Services (CMS) consider this issue as a Medically Unlikely Edit (MUE) or a Maximum Allowed Units (MAUs), which would be an edit for all MACs in the shared system claims processing environment.

  Palmetto GBA will assess its ability and authority to implement a correct coding edit to specifically deny any claim for Herceptin indicating full vial use (44 units) for one date of service and/or a correct coding edit to suspend any claim for Herceptin over 44 units for medical necessity review.

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

  Palmetto GBA Response:

  Palmetto GBA will review 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.

In closing, Palmetto GBA understands the importance of correct coding, billing and payment activities. As part of its Program Integrity functions, Palmetto GBA will evaluate the necessity of a Local Coverage Determination (LCD) and/or a Billing and Coding Article for Herceptin and/or Multi-use Vial Drugs. While Palmetto GBA's data analysis activities have not identified any aberrancies related to this issue to date which would rise to the level of progressive corrective action, we will conduct a focused, stratified data analysis on Herceptin going forward. Therefore, as we determine the feasibility of implementing a pre-pay edit for Herceptin, Palmetto GBA will conduct an annual data analysis report on this issue with the goal of conducting post-pay review activities assuming that it is not part of the audit plans of the Recovery Audit Contractors (RACs) or the Zone Program Integrity Contractors (ZPICs). If feasible, it is our intent to implement a Herceptin-specific prepay probe by no later than September 2012.

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 at 803-763-1176.

Sincerely

Walter D. Johnson

cc: Amy Drake, COR, CMS
Sandra Brown, CMS
Bruce Hughes, BCBSSC
Ed Sanchez, Palmetto GBA
Carol Sutton, Palmetto GBA