

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTORS'
PAYMENTS IN JURISDICTION 10 FOR
FULL VIALS OF HERCEPTIN WERE
OFTEN INCORRECT**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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Gloria L. Jarmon
Deputy Inspector General

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Office of Inspector General

<https://oig.hhs.gov>

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EXECUTIVE SUMMARY

BACKGROUND

Herceptin (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 containing 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 containing a solution of 1.1 percent benzyl alcohol as a preservative. A vial of Herceptin reconstituted with bacteriostatic water is stable for 28 days when stored properly.

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 review 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 those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

On January 7, 2009, CMS announced that it had awarded the Medicare Administrative Contractor contract for Jurisdiction 10, which primarily includes providers in Alabama, Georgia, and Tennessee, to Cahaba Government Benefit Administrators, LLC (Cahaba). During our audit period (January 1, 2008, through December 31, 2010), 8,069 line items for Herceptin totaling approximately \$13.7 million were processed in these States. Of these 8,069 line items, 1,165 line items totaling approximately \$3.2 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.

Because Cahaba assumed responsibility for claims formerly paid by Blue Cross and Blue Shield of Georgia, Inc. (Georgia), and Riverbend Government Benefits Administrator (Tennessee) in Jurisdiction 10, we have addressed our findings and recommendations to Cahaba for review and comment.

OBJECTIVE

Our objective was to determine whether payments that Medicare contractors made to providers in Jurisdiction 10 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that Medicare contractors made to providers in Jurisdiction 10 for full vials of Herceptin were incorrect. Of the 1,165 selected line items, 936 (80 percent) were incorrect and included overpayments totaling \$1,194,647, 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 refunded overpayments on 57 line items totaling \$89,559 before our fieldwork. For another 25 line items, we could not review the line items or make a determination of overpayment because the provider was no longer in business. The remaining 147 line items were correct.

In addition, during the course of our fieldwork, 7 providers identified 278 other line items totaling \$321,571 in overpayments for the billing of full vials of Herceptin.

For the 936 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 934 line items, resulting in overpayments totaling \$1,189,995, and
- did not provide supporting documentation for 2 line items, resulting in overpayments totaling \$4,652.

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 billing systems that did not detect incorrect units of service or a lack of education regarding multiuse-vial drugs. The Medicare contractors made these incorrect payments because neither the Fiscal Intermediary Standard System nor CMS's Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments.

RECOMMENDATIONS

We recommend that Cahaba:

- recover the \$1,516,218 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.

CAHABA GOVERNMENT BENEFIT ADMINISTRATORS, LLC, COMMENTS

In written comments on our draft report, Cahaba said that it had already taken steps to recover the \$1,516,218 in identified overpayments. Cahaba said that it would put into place an edit to identify dosage units of 44, 88, 132, and 176. Cahaba also said that it would use the results of our audit in its provider education plan.

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INTRODUCTION

BACKGROUND

Herceptin¹ 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 review² 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 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 must 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

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.

description. Multiuse vials are not subject to payment for discarded amounts of the drug. Multiuse vials of Herceptin are typically used for more than 1 date of service and can be stored for up to 28 days. Therefore, a Medicare 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.

Cahaba Government Benefit Administrators, LLC

On January 7, 2009, CMS announced that it had awarded the Medicare Administrative Contractor contract for Jurisdiction 10, which primarily includes providers in Alabama, Georgia, and Tennessee, to Cahaba Government Benefit Administrators, LLC (Cahaba). Because Cahaba assumed responsibility for claims formerly paid by Blue Cross and Blue Shield of Georgia, Inc. (Georgia), and Riverbend Government Benefits Administrator (Tennessee) in Jurisdiction 10, we have addressed our findings and recommendations to Cahaba for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether payments that Medicare contractors made to providers in Jurisdiction 10 for full vials of Herceptin were correct.

Scope

During our audit period (January 1, 2008, through December 31, 2010), 8,069 line items for Herceptin totaling approximately \$13.7 million were processed in these States. Of these 8,069 line items, 1,165 line items⁵ totaling approximately \$3.2 million had unit counts in multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials of Herceptin.

We limited our review of Cahaba’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

⁵ During the course of our fieldwork, 7 providers identified an additional 278 lines with overpayments totaling \$321,571. Accordingly, we included the \$321,571 in the \$1,516,218 of identified overpayments.

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 fieldwork from December 2011 through October 2012 and contacted Cahaba in Birmingham, Alabama, and the 46 providers in Alabama, Georgia, Tennessee, and Mississippi 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 for which payments were made for HCPCS code J9355 (Herceptin);
- identified 1,165 line items in our scope that Medicare contractors paid to 46 providers;
- contacted the 46 providers that received Medicare payments for 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 Cahaba; and
- discussed the results of our review with Cahaba.

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 Medicare contractors made to providers in Jurisdiction 10 for full vials of Herceptin were incorrect. Of the 1,165 selected line items, 936 (80 percent) were incorrect and included overpayments totaling \$1,194,647, 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 refunded overpayments on 57 line items totaling \$89,559 before our fieldwork. For another 25 line items, we could not review the line items or make a determination of overpayment because the provider was no longer in business. The remaining 147 line items were correct.

In addition, during the course of our fieldwork, 7 providers identified 278 other line items totaling \$321,571 in overpayments for the billing of full vials of Herceptin.

For the 936 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 934 line items, resulting in overpayments totaling \$1,189,995, and
- did not provide supporting documentation for 2 line items, resulting in overpayments totaling \$4,652.

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 billing systems that did not detect incorrect units of service or a lack of education regarding multiuse-vial drugs. Cahaba 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 amount 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 also 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.”

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED

Incorrect Number of Units of Service

Providers reported incorrect units of service on 934 (80 percent) of the 1,165 line items reviewed, resulting in overpayments totaling \$1,189,995. 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 100 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 correct number of units to bill for 100 milligrams is 10.⁶ This error occurred on 23 separate occasions for 1 patient; as a result, Cahaba paid the provider \$53,640 when it should have paid \$9,538, an overpayment of \$44,102.

Unsupported Services

Two providers billed Medicare for two line items for which the providers did not provide supporting documentation. Cahaba adjusted to zero these line items, totaling \$4,652 in overpayments.

OTHER OVERPAYMENTS

During the course of our fieldwork, 7 providers identified 278 other line items totaling \$321,571 in overpayments for the billing of full vials of Herceptin.

CAUSES OF INCORRECT MEDICARE PAYMENTS

Providers attributed the incorrect payments to billing systems that did not detect incorrect units of service or a lack of education regarding multiuse-vial drugs. 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.

RECOMMENDATIONS

We recommend that Cahaba:

- recover the \$1,516,218 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.

⁶ 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.

CAHABA GOVERNMENT BENEFIT ADMINISTRATORS, LLC, COMMENTS

In written comments on our draft report, Cahaba said that it had already taken steps to recover the \$1,516,218 in identified overpayments. Cahaba said that it would put into place an edit to identify dosage units of 44, 88, 132, and 176. Cahaba also said that it would use the results of our audit in its provider education plan. Cahaba's comments are included in their entirety as the Appendix.

APPENDIX

**APPENDIX: CAHABA GOVERNMENT BENEFIT ADMINISTRATORS, LLC,
COMMENTS**



December 17, 2012

Department of Health and Human Services
Office of Inspector General
Office of Audit Services Region IV
Attention: Lori S. Pilcher, Regional Inspector General for Audit Services
61 Forsyth Street, SW, Suite 3T41
Atlanta, Georgia 30303

RE: Report Number: A-04-12-03070 The Medicare Contractors' Payments in Jurisdiction 10 for Full Vials of Herceptin Were Often Incorrect

Dear Mrs. Pilcher:

We appreciate the opportunity to respond to the above mention draft report. Steps have already been taken to recover the \$1,516,218 identified overpayments. An edit will be put in place to identify units of 44, 88, 132 or 176. The results of this audit will be included in our education plan for J10 providers. This will include an article in our Newslines, listserv notification and discussed in upcoming Provider Outreach Part A events.

If you should have any questions regarding this report, please contact Molly Echols, Compliance Officer at (205) 220-1587 or via email at Mechols@cahabagba.com.

Sincerely,



Molly Echols
Compliance Officer
Cahaba Government Benefit Administrators®, LLC

ME/add