

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS IN JURISDICTION 5
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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Patrick J. Cogley
Regional Inspector General

October 2012
A-07-12-04187

Office of Inspector General

<https://oig.hhs.gov/>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Herceptin, also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days.

For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug. Therefore, a payment for an entire multiuse vial is likely to be an overpayment. 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, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

As part of Medicare contracting reform, Wisconsin Physicians Service Insurance Corporation (WPS) became the Medicare contractor for Jurisdiction 5 in four States—Iowa, Kansas, Missouri, and Nebraska—and assumed full responsibility for Jurisdiction 5 in June 2008. During our audit period (January 1, 2008, through December 31, 2010), 5,964 line items for Herceptin totaling approximately \$9.2 million were processed in these States. Of these 5,964 line items, 665 line items totaling approximately \$1.75 million had 44, 88, or 132 units of service that represented billings that were 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 WPS made to providers for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that WPS made to providers for full vials of Herceptin in the line items we reviewed were incorrect. Specifically, of the 665 selected line items, 540 (81 percent) were incorrect and included overpayments totaling \$635,023, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. The 125 remaining line items were correct.

On each of the 540 incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting

the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. WPS 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 WPS:

- recover the \$635,023 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.

WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION COMMENTS

In written comments on our draft report, WPS generally concurred with our recommendations. With respect to our first recommendation, WPS stated that it was reconciling the overpayment amount. With respect to our other two recommendations, WPS described corrective actions that it had taken or planned to take.

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

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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 of these reviews² 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, people with disabilities, and people with 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 an overpayment.

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.

Wisconsin Physicians Service Insurance Corporation

As part of Medicare contracting reform, Wisconsin Physicians Service Insurance Corporation (WPS) became the Medicare contractor for Jurisdiction 5 in four States—Iowa, Kansas, Missouri, and Nebraska—and assumed full responsibility for Jurisdiction 5 in June 2008. During our audit period (January 1, 2008, through December 31, 2010), 5,964 line items for Herceptin were processed in these States.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

During our audit period, WPS processed 5,964 outpatient Part B service line items of Herceptin totaling approximately \$9.2 million. Of these 5,964 line items, 665 line items totaling approximately \$1.75 million had 44, 88, or 132 units of service that represented billings equivalent to entire multiuse vials.

We limited our review of WPS’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 through May 2012 and included contacting WPS in Omaha, Nebraska, and the 34 providers in Iowa, Kansas, Missouri, and Nebraska 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 665 line items with unit counts of 44, 88, or 132, totaling approximately \$1.75 million, that WPS paid to 34 providers;
- contacted the 34 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 WPS; and
- discussed the results of our review with WPS officials on July 10, 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 objective. 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 WPS made to providers for full vials of Herceptin in the line items we reviewed were incorrect. Specifically, of the 665 selected line items, 540 (81 percent) were incorrect and included overpayments totaling \$635,023, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. The 125 remaining line items were correct.

On each of the 540 incorrect line items, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. WPS 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

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 23, section 20.3, states: "[P]roviders 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. [milligrams], 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

Providers reported incorrect units of service on 540 (81 percent) of the 665 line items reviewed, resulting in overpayments totaling \$635,023 (36 percent) of the \$1.75 million total dollars reviewed. Providers billed Medicare for the entire vial containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, one provider administered 150 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 150 milligrams is 15.⁵ This error occurred on 62 separate occasions for 1 patient; as a result, WPS paid the provider \$136,006 when it should have paid \$46,366, an overpayment of \$89,640.

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.

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. WPS 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*⁶ and disclose any overpayments.

RECOMMENDATIONS

We recommend that WPS:

- recover the \$635,023 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.

WISCONSIN PHYSICIANS SERVICE INSURANCE CORPORATION COMMENTS

In written comments on our draft report, WPS generally concurred with our recommendations. With respect to our first recommendation, WPS stated that it was reconciling the overpayment amount. With respect to our other two recommendations, WPS described corrective actions that it had taken or planned to take.

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

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.

APPENDIX

**APPENDIX: WISCONSIN PHYSICIANS SERVICE
INSURANCE CORPORATION COMMENTS**



Medicare

August 24, 2012

Mr. Patrick J. Cogley
Regional Inspector General for Audit Services
Office of Audit Services, Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

RE: Office of Inspector General (OIG) Draft Report – A-07-12-04187

Dear Mr. Cogley,

This letter is in response to the OIG draft report titled *The Medicare Contractor's Payments in Jurisdiction 5 for Full Vials of Herceptin Were Often Incorrect*.

OIG reviewed 665 data lines with units of service of 44, 88 or 132 from Medicare Part A outpatient claims processed by Wisconsin Physicians Service (WPS). Of these, 540 lines from claims included overpayments totaling \$635,023.

The OIG report stated *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. WPS made these incorrect payments because neither the Fiscal Intermediary Standard System nor CMS' Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments.*

OIG Recommendations to WPS:

- *recover the \$635,023 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.*

WPS Response to the OIG Recommendations:

- *WPS should recover the \$635,023 in identified overpayments,*
 - *WPS is currently reconciling the latest OIG claims listing received to prior OIG claims listings associated with this OIG review in an effort to determine the final overpayment and recovery amounts.*
- *WPS should 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),*
 - *WPS is currently evaluating the possible implementation and updating of system edits within the parameters of the FISS system.*
- *WPS should use the results of this audit in its provider education activities*
 - *Currently, Part A Outreach educates hospital providers on the correct reporting of CPT/HCPCS codes and units of service for billing drugs. We state these are critical billing elements that must be reported correctly in order for the claim to process and pay accurately. As an additional note, we advise the provider that reporting units accurately ensures correct payment, and incorrect reporting of units may result in significant underpayments or overpayments and require a claim adjustment when and if the error is found.*



Wisconsin Physicians Service Insurance Corporation serving as a CMS Medicare Contractor
P.O. Box 1787 • Madison, WI 53701 • Phone 608-221-4711

- Additionally, we are in the process of evaluating our education content to determine the need to expand our volume of billing examples and the inclusion of Herceptin specifically.

If you have any questions or need additional information, please contact me at 402-995-0443.

Sincerely,



Mark DeFoil
Director, Contract Coordination

cc: John Phelps, CMS
Lisa Goschen, CMS
Joni Jones, CMS
Pamela Bragg, CMS
Debra Keasling, OIG