

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS TO PROVIDERS
IN 26 STATES FROM THE
WPS LEGACY WORKLOAD 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

February 2013
A-05-11-00114

Office of Inspector General

<https://oig.hhs.gov>

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EXECUTIVE SUMMARY

BACKGROUND

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

For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. This audit is part of a nationwide review of the drug Herceptin. The pilot of these reviews found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services administers the program.

Prior to Medicare contracting reform, Wisconsin Physicians Service Insurance Corporation (WPS) processed claims for hospitals and other institutional providers from all 15 jurisdictions. This workload, referred to as the "WPS Legacy Workload," will eventually transition to the appropriate Medicare contractors. However, during this transition period, WPS continues to process most of the claims from this WPS Legacy Workload. We reviewed claim lines processed by WPS for providers that had not transitioned from the WPS Legacy Workload.

During our audit period (January 2008 through December 2010), 8,637 line items for Herceptin totaling approximately \$16.9 million were processed in the WPS Legacy Workload. Of these 8,637 line items, 2,975 line items totaling approximately \$7.8 million had unit counts in multiples of 44, which represent billings equivalent to 1 or more full multiuse vials of Herceptin. We reviewed 2,947 line items totaling approximately \$7.7 million; we did not review 28 line items associated with 1 provider whose records center was destroyed during a tornado. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims that met these criteria.

OBJECTIVE

Our objective was to determine whether Medicare payments that WPS made to providers in 26 States from the WPS Legacy Workload for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that WPS made to providers from the WPS Legacy Workload for full vials of Herceptin were incorrect. Specifically, of the 2,947 selected line items, 2,609 (89 percent) were incorrect and included overpayments totaling \$3,056,167, or about 40 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 175 line items totaling \$223,225 before our fieldwork. The 163 remaining line items were correct.

On each of the 2,609 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 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 \$3,056,167 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 agreed with our findings and recommendations and stated that it was in the process of recovering the overpayment amount. Additionally, WPS stated that it was monitoring the effectiveness of the Fiscal Intermediary Standard System edit for improper units of Herceptin to see if a local system edit will be needed in the future as well. Finally, WPS stated that it was in the process of evaluating its education content to determine whether to include specific billing examples for Herceptin.

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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 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 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.

Wisconsin Physicians Service Insurance Corporation

Prior to Medicare contracting reform, Wisconsin Physicians Service Insurance Corporation (WPS) processed claims for hospitals and other institutional providers from all 15 jurisdictions. This workload, referred to as the “WPS Legacy Workload,” will eventually transition to the appropriate Medicare contractors.⁵ However, during this transition period, WPS continues to process most of the claims from this WPS Legacy Workload. We reviewed claim lines processed by WPS for providers that had not transitioned from the WPS Legacy Workload. During our audit period (January 2008 through December 2010), WPS processed 8,637 line items for Herceptin from the WPS Legacy Workload.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that WPS made to providers in 26 States from the WPS Legacy Workload for full vials of Herceptin were correct.

Scope

During our audit period, WPS processed 8,637 outpatient Part B service line items of Herceptin totaling approximately \$16.9 million from the WPS Legacy Workload. Of these 8,637 line items, 2,975 had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 2,975, we reviewed 2,947 line items totaling approximately \$7.7 million. We did not review 28 line items associated with 1 provider whose records center was destroyed during a tornado.

⁵ Some of the WPS Legacy Workload has been transitioned to the appropriate Medicare contractors. Providers in Jurisdictions 1, 4, and 12 were transitioned effective April 19, 2010, October 18, 2010, and February 21, 2011, respectively.

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 October 2011 through August 2012 and included contacting WPS in Madison, Wisconsin, and the 83 providers in the WPS Legacy Workload 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 2,947 line items in our scope that the WPS paid to 83 providers;
- contacted the 83 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 on September 5, 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 WPS made to providers from the WPS Legacy Workload for full vials of Herceptin were incorrect. Specifically, of the 2,947 selected line items, 2,609 (89 percent) were incorrect and included overpayments totaling \$3,056,167, or about 40 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 175 line items totaling \$223,225 before our fieldwork. The 163 remaining line items were correct.

On each of the 2,609 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: "... 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

Providers reported incorrect units of service on 2,609 (89 percent) of the 2,947 line items reviewed, resulting in overpayments totaling \$3,056,167 (40 percent) of the \$7.7 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, 1 provider administered 85 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 85 milligrams is 9.⁶ This

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.

error occurred on 69 separate occasions for 1 patient; as a result, WPS paid the provider \$150,355 when it should have paid \$30,862, an overpayment of \$119,493.

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*⁷ and disclose any overpayments.

RECOMMENDATIONS

We recommend that WPS:

- recover the \$3,056,167 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 agreed with our findings and recommendations and stated that it was in the process of recovering the overpayment amount. Additionally, WPS stated that it was monitoring the effectiveness of the Fiscal Intermediary Standard System edit for improper units of Herceptin to see if a local system edit will be needed in the future as well. Finally, WPS stated that it was in the process of evaluating its education content to determine whether to include specific billing examples for Herceptin.

WPS'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: WISCONSIN PHYSICIANS SERVICE INSURANCE
CORPORATION COMMENTS**



Medicare

November 29, 2012

Ms. Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

RE: Office of Inspector General (OIG) Draft Report – A-05-11-00114

Dear Ms. Fulcher,

This letter is in response to the OIG draft report titled *The Medicare Contractor's Payments to Providers in 26 States From the WPS Legacy Workload for Full Vials of Herceptin Were Often Incorrect*.

OIG reviewed 2,947 line items totaling approximately \$7.7 million. Specifically, of the 2,947 selected line items, 2,609 (89 percent) were incorrect and included overpayments totaling \$3,056,167 or about 40 percent of total dollars reviewed.

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 \$3,056,167 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 \$3,056,167 in identified overpayments,*
 - WPS has determined the claim level overpayment amount relating to the 2,609 identified lines to be approximately \$3,233,663. WPS has recovered \$886,942 to date with a remaining balance of \$2,346,721.
- 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),*
 - FISS has made changes to the 39132 edit that will assist in editing for improper units of Herceptin. WPS is monitoring the effectiveness of the edit at this time, to see if a local system edit will be needed in the future as well.
- 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.

- 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