

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS IN
JURISDICTIONS 6 AND 8 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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Regional Inspector General**

**December 2012
A-05-11-00112**

Office of Inspector General

<https://oig.hhs.gov>

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The designation of financial or management practices as questionable,
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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 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.

Effective January 1, 2007, National Government Services became the Medicare contractor in Illinois and Wisconsin (Jurisdiction 6) and Indiana and Michigan (Jurisdiction 8). During our audit period (January 1, 2008, through December 31, 2010), 18,027 line items for Herceptin totaling approximately \$31.9 million were processed in these States. Of these 18,027 line items, 713 totaling approximately \$2 million had unit counts with 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 National Government Services made to providers in Jurisdictions 6 and 8 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that National Government Services made to providers in Jurisdictions 6 and 8 for full vials of Herceptin were incorrect. Specifically, of the 713 selected line items, 558 (78 percent) were incorrect and included overpayments totaling \$682,748 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 1 line item totaling \$203 before our fieldwork. The 154 remaining line items were correct.

On each of the 558 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. National Government Services 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 National Government Services:

- recover the \$682,748 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.

NATIONAL GOVERNMENT SERVICES COMMENTS

In written comments on our draft report, National Government Services agreed with our findings and recommendations. National Government Services stated that it had received the claims list identifying \$682,748 in overpayments and had cancelled or adjusted the claim lines accordingly with recoveries to be confirmed by its Overpayment Recovery unit. Additionally, National Government Services stated that it had implemented a system edit to suspend, for provider verification, all Herceptin (J9355) claims billed with 44 units or 88 units with dates of service on or after January 1, 2011. Finally, National Government Services stated that it had published provider education for the proper billing of Herceptin both on its website as well as its monthly Medicare letter to providers.

National Government Services' 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 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 10mg.” An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

National Government Services

Effective January 1, 2007, National Government Services became the Medicare contractor in Illinois and Wisconsin (Jurisdiction 6) and Indiana and Michigan (Jurisdiction 8). During our audit period (January 1, 2008, through December 31, 2010), 18,027 line items were processed for Herceptin in these States.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that National Government Services made to providers in Jurisdictions 6 and 8 for full vials of Herceptin were correct.

Scope

During our audit period, National Government Services processed 18,027 outpatient Part B service line items of Herceptin totaling approximately \$31.9 million. Of these 18,027 line items, 2,718 had unit counts with multiples of 44 (44, 88, 132, etc) that represent billings equivalent to entire multiuse vials. Of these 2,718, we reviewed 713⁵ line items totaling approximately \$2 million. The remaining 2,005 line items were reviewed and reported on in report A-05-10-00091.

We limited our review of National Government Services’ 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.

⁵ One of the 713 line items was included because it exceeded \$10,000. While this did not represent a billing equivalent to a full vial, this high-dollar item was included because it was likely to be incorrect.

Our fieldwork was conducted from October 2010 through July 2012 and included contacting National Government Services in Indianapolis, Indiana, and the 77 providers in Illinois, Indiana, Michigan, and Wisconsin 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 713 line items in our scope that National Government Services paid to 77 providers;
- contacted the 77 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 National Government Services; and
- discussed the results of our review with National Government Services on August 8, 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 National Government Services made to providers in Jurisdictions 6 and 8 for full vials of Herceptin were incorrect. Specifically, of the 713 selected line items, 558 (78 percent) were incorrect and included overpayments totaling \$682,748, 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 1 line item totaling \$203 before our fieldwork. The 154 remaining line items were correct.

On each of the 558 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. National Government Services 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 558 (78 percent) of the 713 line items reviewed, resulting in overpayments totaling \$682,748 (34 percent) of the \$2 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 253 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 253 milligrams is 26.⁶ This error occurred on 15 separate occasions for 1 patient; as a result, National Government Services paid the provider \$34,401 when it should have paid \$20,288, an overpayment of \$14,113. In a separate instance, this same patient had one date of service with 528 units of service (5,280 milligrams) billed for 253 milligrams of Herceptin administered. As a result of this error, National Government Services paid the provider \$34,316 when it should have paid \$1,393, an overpayment of \$32,923.

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.

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. National Government Services 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 National Government Services:

- recover the \$682,748 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.

NATIONAL GOVERNMENT SERVICES COMMENTS

In written comments on our draft report, National Government Services agreed with our findings and recommendations. National Government Services stated that it had received the claims list identifying \$682,748 in overpayments and had cancelled or adjusted the claim lines accordingly with recoveries to be confirmed by its Overpayment Recovery unit. Additionally, National Government Services stated that it had implemented a system edit to suspend, for provider verification, all Herceptin (J9355) claims billed with 44 units or 88 units with dates of service on or after January 1, 2011. Finally, National Government Services stated that it had published provider education for the proper billing of Herceptin both on its website as well as its monthly Medicare letter to providers.

National Government Services' 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: NATIONAL GOVERNMENT SERVICES COMMENTS



National Government Services, Inc.
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A CMS Contracted Agent

Medicare

October 29, 2012

REVISED

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

Report Number: A-05-11-00112

Dear Ms. Fulcher,

The following represents our response to the comments made in your report dated September 14,

2012:

Recommendation 1 - Recover the \$682,748 in identified overpayments

The claims listing has been reviewed and worked accordingly. As required, claims have been cancelled or adjusted. The recoveries have been confirmed by the NGS Overpayment Recovery unit to ensure completion. No further action is required.

NOTE: There are workloads included in the OIG review that have since transitioned from NGS. This includes the transition of J8 (00130 & 00452).

Recommendation 2 – 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)

The edits for the Herceptin (J9355) have been implemented and was effective on October 1, 2012 for claims submitted with dates of service on or after January 1, 2011. Claims will suspend with 7HERC in these regions if they have 44 units or 88 units. The claims will be 'Returned to the Provider' by the Claims unit asking for verification of units billed. If correct, the providers should enter "J9355 UNITS VERIFIED AS CORRECT" in the remarks section of the claim. If the claims have been 'Returned to the Provider', and are resubmitted with the above remark, the edit will be bypassed and claim will pay. If the units are incorrect and the provider fixes them, it should not hit the edit upon resubmission. Reason Code 7HERC will be used.

Recommendation 3 - Use the results of this audit in its provider education activities

Provider Outreach and Education has completed the education required for Herceptin. This was published on the web on August 1, 2012. In addition, this was included in the September 2012 MMR. No additional questions have been received since the publication.



Sincerely yours,

/s/ Sharon Weddel

Sharon Weddel,
Director NGS Operations