

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS TO PROVIDERS IN
JURISDICTION 13 FOR
FULL VIALS OF HERCEPTIN
WERE OFTEN INCORRECT**

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Deputy Inspector General

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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 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 (CMS) administers the program.

Effective November 2008, National Government Services (NGS) assumed full responsibility as the Medicare contractor for Jurisdiction 13, which covers Connecticut and New York. During our audit period (January 1, 2008, through December 31, 2010), 15,210 line items were processed for Herceptin in Jurisdiction 13, totaling approximately \$24.1 million. Of these 15,210 line items, 1,181 had unit counts in multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. We reviewed 1,156 of these line items, totaling approximately \$3.3 million. 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 NGS made to providers in Jurisdiction 13 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that NGS made to providers in Jurisdiction 13 for full vials of Herceptin were incorrect. Of the 1,156 selected line items, 788 (68 percent) were incorrect and included overpayments totaling \$1,007,413, or nearly 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 89 line items totaling \$71,829 before our fieldwork. The remaining 279 line items were correct.

For the 788 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 784 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling \$987,609, and
- did not provide supporting documentation for 4 line items, resulting in overpayments totaling \$19,804.

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. NGS 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 NGS:

- recover the \$1,007,413 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, NGS described corrective actions it has taken or planned to take to address our recommendations.

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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 November 2008, National Government Services (NGS) assumed full responsibility as the Medicare contractor for Jurisdiction 13, which covers Connecticut and New York. During our audit period (January 1, 2008, through December 31, 2010), 15,210 line items were processed for Herceptin in Jurisdiction 13 totaling approximately \$24.1 million.⁵

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that NGS made to providers in Jurisdiction 13 for full vials of Herceptin were correct.

Scope

During our audit period, NGS processed 15,210 outpatient Part B service line items of Herceptin totaling approximately \$24.1 million. Of these 15,210 line items, 1,181⁶ had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 1,181 items, we reviewed 1,156 line items totaling approximately \$3.3 million. We did not review 25 line items associated with 3 providers.⁷

⁵ Prior to NGS being awarded the MAC contract for Jurisdiction 13, providers in Connecticut and New York submitted Medicare outpatient claims through separate fiscal intermediaries. As the awardee of the MAC contract for Jurisdiction 13, NGS is responsible for collecting any overpayments and resolving the issues related to this audit.

⁶ We included 3 of the 1,181 line items because they exceeded \$10,000. Although these high-dollar items did not represent billings equivalent to a full vial, we included them because they were likely to be incorrect.

⁷ Specifically, 1 provider with 3 line items was no longer in business, and 2 others with 4 and 18 line items, respectively, were reviewed in other Office of Inspector General audits.

We limited our review of NGS'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 December 2011 through January 2013 and included contacting NGS in East Syracuse, New York, and South Portland, Maine, and the 56 providers in Jurisdiction 13 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 that included payments for HCPCS code J9355 (Herceptin);
- identified 1,156 line items in our scope that NGS paid to 56 providers;
- contacted the 56 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 NGS; and
- discussed the results of our review with NGS on January 10, 2013.

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 NGS made to providers in Jurisdiction 13 for full vials of Herceptin were incorrect. Of the 1,156 selected line items, 788 (68 percent) were incorrect and included overpayments totaling \$1,007,413, or nearly 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 89 line items totaling \$71,829 before our fieldwork. The remaining 279 line items were correct.

For the 788 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 784 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling \$987,609, and
- did not provide supporting documentation for 4 line items, resulting in overpayments totaling \$19,804.

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. NGS 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.” 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: “[m]ulti-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

Incorrect Number of Units of Service

Providers reported incorrect units of service on 784 (68 percent) of the 1,156 line items reviewed, resulting in overpayments totaling \$987,609 (30 percent) of the \$3.3 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 170 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 170 milligrams is 17.⁸ This error occurred on 46 separate occasions for 1 patient; as a result, NGS paid the provider \$105,103 when it should have paid \$40,608, an overpayment of \$64,495.

Unsupported Services

The providers associated with four line items did not provide adequate documentation to support that the associated beneficiary was seen by the provider or received treatment. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined \$19,804 in overpayments that they received.

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. NGS 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*⁹ and disclose any overpayments.

RECOMMENDATIONS

We recommend that NGS:

- recover the \$1,007,413 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.

⁸ 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.

⁹ 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.

NATIONAL GOVERNMENT SERVICES COMMENTS

In written comments on our draft report, NGS described corrective actions it has taken or planned to take to address our recommendations. Specifically, NGS stated that it has adjusted the claims related to the overpayments we identified and is currently reviewing the claims to ensure they are fully recovered. NGS also stated that it has implemented an edit to identify all Herceptin claims billed with units of 44 or 88. Finally, NGS described its provider education activities related to Herceptin.

NGS's comments appear in their entirety as the Appendix.

APPENDIX

APPENDIX: NATIONAL GOVERNMENT SERVICES COMMENTS



MEDICARE

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April 25, 2013

Mr. James P. Edert
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region II
26 Federal Plaza, Room 3900
New York, NY 10278

Report Number: A-02-12-01003

Dear Mr. Edert,

The following presents our response to the comments made in your report dated March 12, 2013:

Recommendation 1 - Recover the \$1,007,413 in identified overpayments

Working with the OIG, NGS has completed the required claims adjustments as requested. With the adjustments having been confirmed, the overpayment recovery unit is currently reviewing the claims listing to ensure the identified overpayments are fully recovered.

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. This process has been automated through ECPS.





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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. At the Hematology Oncology Managers of New York (HOMNY) Annual Meeting held on March 15, 2013, attendees were again advised to go to the website. No additional questions have been received since the publication.

Sincerely yours,

/s/ Barbie Williams

Barbie Williams,
Director NGS Operations Excellence

