

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS IN JURISDICTION 3
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

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A-07-12-04186

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, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Effective July 2006, Noridian Administrative Services, LLC (Noridian), became the Medicare contractor in Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. During our audit period (January 1, 2008, through December 31, 2010), 4,142 line items for Herceptin totaling approximately \$7.0 million were processed in these States. Of these 4,142 line items, 634 line items totaling approximately \$1.5 million had 44 or 88 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 Noridian made to providers in Jurisdiction 3 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most payments that the Medicare contractor made to providers in Jurisdiction 3 for one or two full vials of Herceptin were incorrect. Of the 634 selected line items, 399 (63 percent) were incorrect and included overpayments totaling \$404,746, which the providers had not refunded by the beginning of the audit. A provider refunded overpayments on one line item totaling \$1,124 before our fieldwork. The remaining 234 line items were correct.

For the 399 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 397 line items, resulting in overpayments totaling \$397,830 and

- did not provide supporting documentation for two line items, resulting in overpayments totaling \$6,916.

On each of the 399 incorrect line items, the providers reported the units of service for the entire content of 1 or 2 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. Noridian 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 Noridian:

- recover the \$404,746 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.

NORIDIAN ADMINISTRATIVE SERVICES, LLC, COMMENTS

In written comments on our draft report, Noridian concurred with our recommendations and described corrective actions that it had taken or planned to take.

Our draft report included a recommendation that Noridian determine the amount of overpayment amounts for two incorrect line items that, at the time of issuance of our draft report, had not been determined. In comments on this recommendation, Noridian stated that the overpayment amounts for the two line items had been determined and an additional \$383 had been recovered.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

For this final report, we revised the findings and first recommendation to reflect the additional line items adjusted and amounts recovered. We also removed the recommendation related to the two incorrect line items that had been in our draft report because the overpayments have been determined.

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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 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.

Noridian Administrative Services, LLC

Effective July 2006, Noridian Administrative Services, LLC (Noridian), became the Medicare contractor in Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. During our audit period (January 1, 2008, through December 31, 2010), 4,142 line items for Herceptin were processed in these States.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that Noridian made to providers in Jurisdiction 3 for full vials of Herceptin were correct.

Scope

During our audit period, Noridian processed 4,142 outpatient Part B service line items of Herceptin totaling approximately \$7.0 million. Of these 4,142 line items, 634 line items totaling approximately \$1.5 million had 44 or 88 units of service that represented billings that were equivalent to entire multiuse vials.

We limited our review of Noridian’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 Noridian in Fargo, North Dakota, and the 29 providers in Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming 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 634 line items that Noridian paid to 29 providers;
- contacted the 29 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 Noridian; and
- discussed the results of our review with Noridian officials on September 6, 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 payments that the Medicare contractor made to providers in Jurisdiction 3 for one or two full vials of Herceptin were incorrect. Of the 634 selected line items, 399 (63 percent) were incorrect and included overpayments totaling \$404,746, which the providers had not refunded by the beginning of the audit. A provider refunded overpayments on one line item totaling \$1,124 before our fieldwork. The remaining 234 line items were correct.

For the 399 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 397 line items, resulting in overpayments totaling \$397,830 and
- did not provide supporting documentation for two line items, resulting in overpayments totaling \$6,916.

On each of the 399 incorrect line items, the providers reported the units of service for the entire content of 1 or 2 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. Noridian 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.

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: "[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

Incorrect Number of Units of Service

Providers reported incorrect units of service on 397 of the 634 line items reviewed, resulting in overpayments totaling \$397,830 of the \$1.5 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 between 150 milligrams and 304 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 and the number of units to be reported for 304 milligrams is 31.⁵ This error occurred on 50 separate occasions for 1 patient; as a result, Noridian paid the provider \$126,113 when it should have paid \$46,821, an overpayment of \$79,292.

Unsupported Services

Two providers billed Medicare for two line items for which the providers did not provide supporting documentation. The providers agreed to cancel the claims associated with these line items and refund the combined \$6,916 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. Noridian 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 Noridian:

- recover the \$404,746 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.

NORIDIAN ADMINISTRATIVE SERVICES, LLC, COMMENTS

In written comments on our draft report, Noridian concurred with our recommendations and described corrective actions that it had taken or planned to take.

Our draft report included a recommendation that Noridian determine the amount of overpayment amounts for two incorrect line items that, at the time of issuance of our draft report, had not been determined. In comments on this recommendation, Noridian stated that the overpayment amounts for the two line items had been determined and an additional \$383 had been recovered.

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.

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.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

For this final report, we revised the findings and first recommendation to reflect the additional line items adjusted and amounts recovered. We also removed the recommendation related to the two incorrect line items that had been in our draft report because the overpayments have been determined.

OTHER MATTER

During our review of payments made to providers for full vials of Herceptin, we found that the prescribing physicians for one provider, Campbell County Medical Center (Campbell County), located in Gillette, Wyoming, incorrectly prescribed and administered the drug Herceptin. Campbell County routinely prescribed and administered for an entire vial of the drug and did not follow the dosing guidelines published by the manufacturer, which state that the drug should be administered based on the patient's weight. Of the 144 line items that we reviewed for Campbell County, 133 line items were incorrectly prescribed and administered.⁷

Campbell County did not agree the line items were incorrectly prescribed and administered. Specifically, Campbell County stated that Herceptin was available as a 440-milligram single-dose vial and was not aware that it was a multi-use vial. Campbell County also stated that a 440-milligram dose, administered 3 times per month, resulted in the full benefit of the drug without increased toxicity in the patient.

In light of Campbell County's assertions, we consulted with the U.S. Department of Health and Human Services (HHS), Office of Inspector General's Chief Medical Officer, who performed a medical review of a sample of these claims and provided the following assessment. First, while there may be some scientific support for deviating, either up or down, from the doses recommended in the HHS, Food and Drug Administration-approved prescribing information, the administration of an entire vial of Herceptin is not attributed to an accepted rational dosing methodology that physicians follow. Second, there is no support for a default 440-milligram dose for all patients regardless of weight. Based on compendia, the potential of adverse effects of over- or underdosing is not clearly indicated, and adequate clinical studies have not been completed to support the potential of adverse effects based on dosage alone.

The current dosing methodology used by Campbell County resulted in six patients receiving, over the course of their treatment, a total of 1,030 milligrams (103 units) more than what they would have received if the provider had followed the Herceptin manufacturer's dosing guidelines.⁸ Consequently, we are concerned with the quality of care that these patients

⁷ Specifically, 56 line items involved underdosages and 77 line items involved overdosages, based on the patients' weights as recorded in their medical files.

⁸ Of the 56 line items involving underdosing, the patients received a total of 2,960 mg (296 units) less Herceptin than the amounts recommended in the manufacturer's dosing guidelines. Of the 77 line items involving overdosing, the patients received a total of 3,990 mg (399 units) more Herceptin than the amounts recommended in the manufacturer's dosing guidelines.

received. In terms of the language in the *Medicare Benefit Policy Manual*, chapter 15, section 50.4.3 (3), it appears that the physicians' methods for ordering dosages of Herceptin "... exceed the frequency or duration of injections indicated by accepted standards of medical practice"

We are providing this information as Noridian may want to use this information to study this matter further and use in its provider training program.

APPENDIX

APPENDIX: NORIDIAN ADMINISTRATIVE SERVICES, LLC, COMMENTS



Medicare

October 22, 2012

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

RE: Report Number A-07-12-04186

Dear Mr. Cogley:

Thank you for the opportunity to respond to the draft report of the U.S. Department of Health & Human Services, Office of Inspector General (OIG) dated September 24, 2012, entitled, *The Medicare Contractor's Payments in Jurisdiction 3 for Full Vials of Herceptin Were Often Incorrect*. We concur with the recommendations made by the OIG. NAS has provided our responses to the recommendations within the contents of this letter. The course of action that NAS has planned will be an ongoing effort due to the extent of activities planned and the time associated with the research, development, testing, and implementation of certain initiatives.

NAS researched the claim information and details provided by the OIG and have identified several courses of action NAS will perform to assist in reducing future overpayments. The CPT/HCPC code, J9355 identified in this audit, is now included on the non-published Medical Unlikely Edits (MUE) listing and has a unit of service limit as of April 1, 2011. MUEs are edits in the standard Part A system, FISS, and should assist in minimizing unit of service overpayments in the future.

It is important to note that future overpayments may still be possible because Medicare contractors are not funded to perform 100% complex review of claims. Without a comparison of medical records and coding on 100% of claims billed, there will always be the potential for overpayments (and underpayments) resulting from billing incorrect procedure codes, units of service, and other claims payment indicators. NAS will do our due diligence to avoid overpayments within the scope of our contracts, authorization, and experience. An important tool or step in this process that NAS has considered is to make referrals to the Program Safeguard Contractor (PSC), Recovery Audit Contractors (RAC), and CMS as a method of business collaboration.

OIG RECOMMENDATIONS:

- **Recover the \$404,363 in identified overpayments**

NAS Response: NAS concurs with the recommendation that all overpayments identified are to be collected. As stated in the draft report, providers refunded one line item totaling \$1,124 before fieldwork began. There were 399 line item overpayments remaining to be collected.



On each of the 399 incorrect line items, the providers reported the units of service for the entire contents of one or more vials, each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered.

On Thursday, November 10, 2011, NAS received the detailed claims listing/findings from the OIG. As of August 30, 2012, NAS had collected \$404,363 for 397 line items and \$383 for two line items was uncollected.

- **Determine the amount of overpayments for the two incorrect line item payments and recover that amount**

NAS Response: NAS concurs with the recommendation that the two remaining line items are to be collected. NAS determined that the amount of the overpayments on the two outstanding claim lines was \$383. NAS collected this remaining overpayment amount on September 14, 2012.

- **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)**

NAS Response: NAS concurs with this recommendation. A national Medically Unlikely Edit (MUE) for Herceptin was implemented by CMS on April 1, 2011. NAS continues to work with CMS, FISS, and the MUE Advisory Committee to refine MUE unit of service limits that may, in some cases, be set too high.

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

NAS Response: NAS completed the following provider education activities:

- A provider education article was distributed via the listserv and posted to the NAS Medicare Website on June 28, 2012, to educate providers on the proper way to bill units of Herceptin. This article was also published in NAS' Medicare A News bulletin on August 22, 2012 which is also available on NAS' Medicare A Website.
- The provider education article was revised to clarify that a multiuse vial can be used for more than one patient when reconstituted and stored properly. The article was published on the NAS Medicare Website on October 18, 2012.

Please advise if additional information or further clarification is needed on any of our response. Please contact Paul O'Donnell, Medicare Operations Vice President, at (701) 277-2401, or through e-mail at Paul.ODonnell@noridian.com.

Sincerely,



Paul O'Donnell
Vice President
Noridian Administrative Services, LLC