



DEPARTMENT OF HEALTH AND HUMAN SERVICES

## OFFICE OF INSPECTOR GENERAL



OFFICE OF AUDIT SERVICES, REGION V  
233 NORTH MICHIGAN, SUITE 1360  
CHICAGO, IL 60601

July 27, 2012

Report Number: A-05-12-00010

Craig Campbell  
Interim President and CEO  
Noridian Administrative Services  
900 42<sup>nd</sup> Street South  
Fargo, ND 58103

Dear Mr. Campbell:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *The Medicare Contractor's Payments in Jurisdiction 6 for Full Vials of Herceptin Were Often Incorrect*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Stephen Slamar, Audit Manager, at (312) 353-7905 or through email at [Stephen.Slamar@oig.hhs.gov](mailto:Stephen.Slamar@oig.hhs.gov). Please refer to report number A-05-12-00010 in all correspondence.

Sincerely,

/Sheri L. Fulcher/  
Regional Inspector General  
for Audit Services

Enclosure

**Direct Reply to HHS Action Official:**

Ms. Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management and Fee for Service Operations  
601 East 12<sup>th</sup> Street, Room 355  
Kansas City, MO 64106

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S  
PAYMENTS IN JURISDICTION 6 FOR  
FULL VIALS OF HERCEPTIN WERE  
OFTEN INCORRECT**



Daniel R. Levinson  
Inspector General

July 2012  
A-05-12-00010

# *Office of Inspector General*

<http://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <http://oig.hhs.gov>

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

## **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 administers the program.

Noridian Administrative Services became the fiscal intermediary for the State of Minnesota in August 1999. On September 30, 2011, CMS awarded the Medicare Administrative Contractor contract for Jurisdiction 6, which includes Minnesota, to National Government Services; however, protests were filed against the award. In the meantime, Noridian Administrative Services, acting as the legacy fiscal intermediary, continues to process claims for providers in Minnesota. During our audit period (January 1, 2008, through December 31, 2010), 3,634 line items for Herceptin totaling approximately \$6.5 million were processed in Minnesota. Of these 3,634 line items, 464 totaling approximately \$1.3 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 Noridian Administrative Services made to providers for full vials of Herceptin were correct.

### **SUMMARY OF FINDINGS**

Most Medicare payments that Noridian Administrative Services made to providers for full vials of Herceptin were incorrect. Specifically, of the 464 selected line items, 368 (79 percent) were incorrect and included overpayments totaling \$556,908, or more than two-fifths of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 20 line items totaling \$83,575 before our fieldwork. The 76 remaining line items were correct.

On each of the 368 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. Noridian Administrative 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 Noridian Administrative Services:

- recover the \$556,908 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 COMMENTS**

In written comments on our draft report, Noridian Administrative Services concurred with our recommendations and confirmed the overpayments had been recovered. Noridian Administrative Services has identified several courses of action to assist in reducing future overpayments and will continue to work with CMS to update system edits minimizing units of service overpayments to address our the second recommendation. Regarding our third recommendation, Noridian Administrative Services distributed an article educating providers on the proper way to bill units of Herceptin.

Noridian Administrative Services comments are included in their entirety as the Appendix.

## TABLE OF CONTENTS

	<u>Page</u>
<b>INTRODUCTION .....</b>	<b>1</b>
<b>BACKGROUND .....</b>	<b>1</b>
Medicare Contractors.....	1
Claims for Drugs.....	1
Herceptin.....	2
Noridian Administrative Services.....	2
<b>OBJECTIVE, SCOPE, AND METHODOLOGY .....</b>	<b>2</b>
Objective.....	2
Scope.....	2
Methodology.....	3
<b>FINDINGS AND RECOMMENDATIONS .....</b>	<b>4</b>
<b>FEDERAL REQUIREMENTS.....</b>	<b>4</b>
<b>OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED .....</b>	<b>4</b>
<b>CAUSES OF INCORRECT MEDICARE PAYMENTS.....</b>	<b>5</b>
<b>RECOMMENDATIONS.....</b>	<b>5</b>
<b>NORIDIAN ADMINISTRATIVE SERVICES COMMENTS.....</b>	<b>5</b>
<b>APPENDIX</b>	
<b>NORIDIAN ADMINISTRATIVE SERVICES COMMENTS</b>	

# INTRODUCTION

## BACKGROUND

Herceptin<sup>1</sup> 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 reviews<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> Multiuse vials are not subject to payment for discarded amounts of the drug.

---

<sup>1</sup> Herceptin is Genentech's registered trademark for the drug trastuzumab.

<sup>2</sup> Report number A-05-10-00091, issued July 10, 2012.

<sup>3</sup> 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.

<sup>4</sup> 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 BWFI, unpreserved sterile water 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.

## **Noridian Administrative Services**

Noridian Administrative Services became the fiscal intermediary for the State of Minnesota in August 1999. On September 30, 2011, CMS awarded the Medicare Administrative Contractor contract for Jurisdiction 6, which includes Minnesota, to National Government Services; however, protests were filed against the award. In the meantime, Noridian Administrative Services, acting as the legacy fiscal intermediary, continues to process claims for providers in Minnesota. During our audit period (January 1, 2008, through December 31, 2010), 3,634 line items were processed for Herceptin in Minnesota.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

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

### **Scope**

During our audit period, Noridian Administrative Services processed 3,634 outpatient Part B service line items of Herceptin totaling approximately \$6.5 million. Of these 3,634 line items, 464<sup>5</sup> totaling approximately \$1.3 million had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials.

We limited our review of Noridian Administrative 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

---

<sup>5</sup> One of the 464 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 in our review because it was likely to be an incorrect.

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 March 2012 and included contacting Noridian Administrative Services in Fargo, North Dakota, and the 25 providers in Minnesota 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 464 line items in our scope that Noridian Administrative Services paid to 25 providers;
- contacted the 25 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 Administrative Services; and
- discussed the results of our review with Noridian Administrative Services on April 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 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 Noridian Administrative Services made to providers for full vials of Herceptin were incorrect. Specifically, of the 464 selected line items, 368 (79 percent) were incorrect and included overpayments totaling \$556,908, or more than two-fifths of total dollars reviewed. These providers had not identified nor refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 20 line items totaling \$83,575 before our fieldwork. The remaining 76 line items were correct.

On each of the 368 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. Noridian Administrative 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 368 (79 percent) of the 464 line items reviewed, resulting in overpayments totaling \$556,908 (42 percent) of the \$1.3 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, one provider administered 600 milligrams of Herceptin to a patient and billed for 88 units of service (880 milligrams). Based on the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 600 milligrams is 60.<sup>6</sup> This error occurred on 14 separate occasions for 1 patient; as a result, Noridian Administrative Services paid the provider \$67,276 when it should have paid \$44,652 an overpayment of \$22,624.

---

<sup>6</sup> 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. Noridian Administrative 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*<sup>7</sup> and disclose any overpayments.

## **RECOMMENDATIONS**

We recommend that Noridian Administrative Services:

- recover the \$556,908 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 COMMENTS**

In written comments on our draft report, Noridian Administrative Services concurred with our recommendations and confirmed the overpayments had been recovered. Noridian Administrative Services has identified several courses of action to assist in reducing future overpayments and will continue to work with CMS to update system edits minimizing units of service overpayments to address our the second recommendation. Regarding our third recommendation, Noridian Administrative Services distributed an article educating providers on the proper way to bill units of Herceptin.

Noridian Administrative Services comments are included in their entirety as the Appendix.

---

<sup>7</sup> 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: NORIDIAN ADMINISTRATIVE SERVICES COMMENTS



Medicare

July 17, 2012

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

RE: Report Number A-05-12-00010 – NAS' Amended Response to the Draft Report

Dear Ms. Fulcher:

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 June 1, 2012, entitled, *The Medicare Contractor's Payments in Jurisdiction 6 for Full Vials of Herceptin Were Often Incorrect*. We concur with the recommendations made by the OIG. NAS has provided our amended 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 \$556,908 in identified overpayments**

NAS Response: NAS concurs with the recommendation that all overpayments identified are to be collected.



- **Determine the amount of overpayment for the 368 incorrect line item payments and recover that amount.**

NAS Response: As stated in the draft report, providers refunded on 20 line items totaling \$83,575 before fieldwork began. There were 368 line items remaining to be collected on.

On each of the 368 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 Tuesday, January 17, 2012, NAS received the detailed claims listing/findings from the OIG and has since recovered all overpayments related to this issue.

- **Implement system edits that identify line item payments that exceed billed charges by a prescribed amount**

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 plans the following provider education activities:

- A provider education article has been distributed via the listserv and posted to the NAS website in June 2012, to educate providers on the proper way to bill units of Herceptin.

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,

*/s/ Paul O'Donnell*

Paul O'Donnell  
Vice President  
Noridian Administrative Services, LLC