

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE MEDICARE CONTRACTOR'S
PAYMENTS IN JURISDICTION 2
FOR FULL VIALS OF HERCEPTIN
WERE OFTEN INCORRECT**

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**Lori A. Ahlstrand
Regional Inspector General**

**November 2012
A-09-12-02003**

Office of Inspector General

<https://oig.hhs.gov>

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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. An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

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 review found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.

During our audit period (January 1, 2008, through December 31, 2010), Noridian Administrative Services, LLC (Noridian), was the Medicare contractor for Jurisdiction 2, which comprised four States. For Jurisdiction 2, Noridian processed 7,948 line items for Herceptin totaling approximately \$13.1 million. Of these 7,948 line items, 714 totaling approximately \$1.8 million had unit counts in 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 made to providers in Jurisdiction 2 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that Noridian made to providers in Jurisdiction 2 for full vials of Herceptin were incorrect. Specifically, of the 714 selected line items, 487 (68 percent) were incorrect and included overpayments totaling \$567,008, or 31 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. One provider refunded overpayments on 93 line items totaling \$86,867 before our fieldwork. The 134 remaining line items were correct.

On each of the 487 incorrect line items, the providers reported the units of service for the entire content of 1 or more vials, 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 the 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 \$567,008 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 provided information on actions that it had taken to address the recommendations. Noridian's 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 review² 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 benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded. The HCPCS code for Herceptin is J9355, with a narrative description of “injection, trastuzumab, 10 mg.” An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

Noridian Administrative Services, LLC

During our audit period (January 1, 2008, through December 31, 2010), Noridian Administrative Services, LLC (Noridian), was the Medicare contractor for Jurisdiction 2, which comprised four States: Alaska, Idaho, Oregon, and Washington.⁵ For Jurisdiction 2, Noridian processed 7,948 line items for Herceptin.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments that Noridian made to providers in Jurisdiction 2 for full vials of Herceptin were correct.

Scope

During our audit period, Noridian processed 7,948 outpatient Part B service line items of Herceptin totaling approximately \$13.1 million. Of these 7,948 line items, 714 items totaling approximately \$1.8 million had unit counts in 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.

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

⁵ Because there was no MAC for Jurisdiction 2 during our audit period, Noridian processed the Jurisdiction 2 workload under its legacy Medicare contract. On August 22, 2011, CMS awarded Noridian the MAC contract for Jurisdiction F, which includes the four States. The contract became effective on February 1, 2012.

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 to July 2012 and included contacting Noridian in Fargo, North Dakota, and the 27 providers in Jurisdiction 2 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 714 line items in our scope that Noridian paid to 27 providers;
- contacted the 27 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 on July 23, 2012.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Most Medicare payments that Noridian made to providers in Jurisdiction 2 for full vials of Herceptin were incorrect. Specifically, of the 714 selected line items, 487 (68 percent) were incorrect and included overpayments totaling \$567,008, or 31 percent of total dollars reviewed. These providers had not identified or refunded these overpayments by the beginning of our audit. One provider refunded overpayments on 93 line items totaling \$86,867 before our fieldwork. The 134 remaining line items were correct.

On each of the 487 incorrect line items, the providers reported the units of service for the entire content of 1 or more vials, 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 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 487 (68 percent) of the 714 line items reviewed, resulting in overpayments totaling \$567,008 (31 percent) of the approximately \$1.8 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 150 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 15.⁶ This error occurred on 30 separate occasions for 1 patient; as a result, Noridian paid the provider \$64,714 when it should have paid \$22,062, an overpayment of \$42,652.

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. 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*⁷ and disclose any overpayments.

RECOMMENDATIONS

We recommend that Noridian:

- recover the \$567,008 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 provided information on actions that it had taken to address the recommendations. Noridian's comments are included in their entirety as the Appendix.

⁷ The Medicare contractor sends a *Medicare Summary Notice*—an explanation of benefits—to the beneficiary after the provider files a claim for services. The notice explains the services billed, the approved amount, the Medicare payment, and the amount due from the beneficiary.

APPENDIX

APPENDIX: NORIDIAN ADMINISTRATIVE SERVICES, LLC, COMMENTS



Medicare

October 22, 2012

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Inspector General
Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

RE: Report Number A-09-12-02003

Dear Ms. Ahlstrand:

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 27, 2012, entitled, *The Medicare Contractor's Payments in Jurisdiction 2 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 \$567,008 in identified overpayments**

NAS Response: NAS concurs with the recommendation that all overpayments identified are to be collected. As stated in the draft report, one provider refunded 93 line items totaling \$86,867 before fieldwork began. There were 487 line item overpayments remaining to be collected.



On each of the 487 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 8, 2011, NAS received the detailed claims listing/findings from the OIG. NAS collected the \$567,008 for 487 line items as of June 27, 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,

/s/ Paul O'Donnell

Paul O'Donnell
Vice President
Noridian Administrative Services, LLC