

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE
CONTRACTORS NATIONWIDE
OVERPAID MILLIONS TO
PROVIDERS FOR FULL VIALS OF
HERCEPTIN**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



**Daniel R. Levinson
Inspector General**

**November 2013
A-05-13-00024**

Office of Inspector General

<https://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 <https://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

Most payments that Medicare contractors made to providers for full vials of Herceptin were incorrect, resulting in overpayments of approximately \$24.2 million.

WHY WE DID THIS REVIEW

Herceptin, also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body and is supplied in a multiuse vial containing 440 milligrams. For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug.

In recent years, the Office of Inspector General (OIG) has conducted several audits that, among other things, found that overpayments were made on claims for full vials of Herceptin. On the basis of these reviews, we performed a pilot review that focused specifically on payments for full vials of Herceptin by a Medicare contractor. This pilot review found that \$3.3 million, or 78 percent, of the payments that the contractor made to providers were incorrect. Because of the significant error rate of this pilot review, we expanded our review of the billing for Herceptin to include reviews at all Medicare contractors nationwide.

Our objectives were to (1) summarize the results of our individual reviews related to incorrect billings for full vials of Herceptin and (2) determine the effectiveness of the Herceptin-specific edit that was implemented after our audit period.

BACKGROUND

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains line items that detail each provided service. Providers must 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. Multiuse vials are not subject to payment for discarded amounts of the drug. 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.

HOW WE CONDUCTED THIS REVIEW

For the 3-year period January 1, 2008, through December 31, 2010, Medicare contractors processed 170,606 outpatient Part B service line items of Herceptin totaling approximately \$295.3 million. Of these 170,606 line items, 26,143 had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 26,143 line items, we reviewed 26,042 items totaling approximately \$69 million paid by 12 Medicare contractors in 15 jurisdictions in 18 separate audit reports. We did not review 101 line items associated with 6 providers. Three of the six providers are no longer in business, one provider's records center was destroyed during a tornado, and two providers' line items were reviewed in other OIG audits.

We also analyzed all lines in error for the various Herceptin reviews to determine whether the Herceptin-specific edit that was implemented after our audit period would have identified these errors had it been in place during our audit period.

WHAT WE FOUND

Most payments that Medicare contractors made to providers for full vials of Herceptin were incorrect. Specifically, of the 26,042 line items reviewed, 19,954 (77 percent) were incorrect and included overpayments of about \$24.2 million, or more than one-third of total dollars reviewed. These providers had not identified or refunded these payments by the beginning of our reviews. Prior to our audit work, and not as a result of our audit, providers had refunded overpayments on 1,484 line items totaling approximately \$1.9 million. The 4,604 remaining line items were correct.

On nearly all of the 19,954 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.

Medicare contractors 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. During our audit period, there was no specific edit to identify Herceptin claims incorrectly billed as full vials.

In March 2011, CMS issued guidance to Medicare contractors that required them to implement certain Medically Unlikely Edits (MUEs), including an edit related to Herceptin. However, of the 19,954 lines in error identified through the various reviews, we determined that 19,805 (99 percent) were instances in which the providers billed units that did not represent unlikely dosages administered to patients. Although we have not addressed in this report the specific reasons that the MUE was ineffective, we have discussed this issue with CMS officials. Herceptin is one of many multiuse drugs. Therefore, the problem of provider billing for full vials may exist with other such drugs.

WHAT WE RECOMMEND

We recommend that CMS:

- ensure that Medicare contractors collect the identified overpayment amounts as recommended in our individual reports,
- review payments made to providers after our audit period ended December 31, 2010, for full vials of Herceptin and recover any identified overpayments,

- require that Medicare contractors implement a Herceptin-specific system edit to identify for review claim lines billed for HCPCS code J9355 with unit counts in multiples of 44 that represent billings equivalent to entire multiuse vial(s), and
- review other multiuse-vial drugs to determine whether system edits are needed to prevent incorrect billings.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first two recommendations but disagreed with our remaining two recommendations. Regarding our first recommendation, CMS confirmed that its contractors have already recovered \$17.8 million of the approximately \$24 million in overpayments identified in our reviews and will continue to ensure that the remaining overpayments are collected to the maximum extent possible. Regarding our second recommendation, CMS stated that it would direct its contractors to review payments made to providers after our audit period ended December 31, 2010, and to recover, as appropriate, any identified overpayments.

CMS disagreed with our recommendation to implement a Herceptin-specific edit. CMS stated that an edit “with no manual review by a clinician would not accurately identify incorrect billing in all cases, while any such medical review would not likely be feasible due to resource constraints.” CMS also disagreed with our recommendation to review other multiuse-vial drugs to determine whether system edits are needed. CMS stated that Herceptin “is an unusual situation in that reconstitution with the supplied diluent creates a multidose vial” and “[d]iscarded amounts of the drug cannot be paid under Medicare Part B’s discarded drugs policy as this policy pertains to single use vials.” CMS added that most drugs are reconstituted with sterile water resulting in a single-use vial.

We appreciate CMS’s efforts to recover all identified Herceptin-related overpayments and to direct its contractors to review all Herceptin-related payments of full vials to providers subsequent to our audit period. However, after review and consideration of CMS’s comments, we maintain that our remaining two recommendations are valid.

Regarding our recommendation to implement a Herceptin-specific edit, we acknowledge that the claims identified by such an edit would require manual review. However, considering that 77 percent of the claims we reviewed had overpayments totaling \$24.2 million, we encourage CMS to explore the potential return on investment of performing these reviews. In addition, we continue to recommend that CMS review other multiuse-vial drugs to determine whether system edits are needed to prevent incorrect billings. A multiuse vial, when reconstituted with a preservative, is generally stable for up to 28 days unless the manufacturer specifies otherwise. CMS guidance states that Medicare does not pay for discarded amounts of multiuse-vial drugs. Therefore, billing the entire amount of a multiuse-vial drug reconstituted with a preservative has a greater possibility of being incorrectly billed and resulting in overpayments, as evident from our 18 reviews.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objectives	1
Background	1
The Medicare Program: How It Is Administered and How Medicare Contractors Pay Providers for Outpatient Services	1
Providers Must Submit Accurate Claims for Drugs Under the Medicare Program.....	2
Herceptin Attacks Specific Cancer Cells	2
How We Conducted This Review.....	3
FINDINGS	3
Overpayments Occurred on Most Line Items	4
Incorrect Number of Units of Service.....	5
Unsupported Services	5
Other Incorrect Line Items.....	5
The Existing Herceptin-Specific Edit Would Not Have Identified Most Errors	5
Conclusion	5
RECOMMENDATIONS	6
CMS COMMENTS	6
OUR RESPONSE	7
APPENDIXES	
A: Audit Scope and Methodology	8
B: Related Office of Inspector General Reports	10
C: List of Overpayment Amounts by Jurisdiction	11
D: Agency Comments.....	12

INTRODUCTION

WHY WE DID THIS REVIEW

Herceptin,¹ also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body and is supplied in a multiuse vial containing 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug.

In recent years, the Office of Inspector General (OIG) has conducted several audits that, among other things, found that overpayments were made on claims for full vials of the drug Herceptin. On the basis of these reviews, we performed a pilot review² that focused specifically on payments for full vials of Herceptin by a Medicare contractor. This pilot review found that \$3.3 million, or 78 percent, of the payments that the contractor made to providers were incorrect. Because of the significant error rate of this pilot review, we expanded our review of the billing for Herceptin to include reviews at all Medicare contractors nationwide.

OBJECTIVES

Our objectives were to (1) summarize the results of our individual reviews related to incorrect billings for full vials of Herceptin and (2) determine the effectiveness of the Herceptin-specific edit that was implemented after our audit period.

BACKGROUND

The Medicare Program: How It Is Administered and How Medicare Contractors Pay Providers for Outpatient Services

The Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease.³ The Centers for Medicare & Medicaid Services (CMS) administers the program. CMS contracts with Medicare contractors to, among other things, process and pay Medicare claims submitted for outpatient services.⁴ The contractors' responsibilities include determining reimbursement amounts, conducting reviews and audits, and

¹ Herceptin is Genentech's registered trademark for the drug trastuzumab.

² *The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect*, A-05-10-00091, issued July 10, 2012.

³ Sections 1811 and 1836 of the Social Security Act.

⁴ Federal law required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors (MACs) between October 2005 and October 2011 (§ 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173). 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, that processes and pays outpatient Part B claims.

safeguarding against fraud and abuse. Federal guidance requires that Medicare contractors 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.

Providers Must Submit Accurate Claims for Drugs Under the Medicare Program

Medicare guidance requires providers to submit accurate claims for outpatient services.⁵ Each claim contains line items that detail each provided service.⁶ Providers must use the appropriate Healthcare Common Procedure Coding System (HCPCS) code⁷ for the drug administered and report units of service in multiples of the units shown in the HCPCS narrative description.⁸ Multiuse vials are not subject to payment for discarded amounts of the drug.⁹ Multiuse vials are typically used for more than one date of service and can be stored for several days. Therefore, a payment for an entire multiuse vial is likely to be incorrect.

Herceptin Attacks Specific Cancer Cells

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.

⁵ CMS guidance states that bills must be submitted accurately to be processed correctly (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 1, § 80.3.2.2).

⁶ Section 1833(e) of the Social Security Act states that no payment shall be made to any provider of services unless the necessary information about the amounts being paid has been furnished.

⁷ CMS guidance states that providers must use HCPCS codes for most outpatient services (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 23, § 20.3).

⁸ CMS guidance states that 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..." (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 17, § 70).

⁹ CMS guidance states that multiuse vials are not subject to payment for discarded amounts of the drug (CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 17, § 40).

HOW WE CONDUCTED THIS REVIEW

For the 3-year period January 1, 2008, through December 31, 2010, Medicare contractors processed 170,606¹⁰ outpatient Part B service line items of Herceptin totaling approximately \$295.3 million. Of these 170,606 line items, 26,143¹¹ had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 26,143 line items, we reviewed 26,042 items totaling approximately \$69 million. We did not review 101 line items associated with 6 providers. Three of the six providers are no longer in business, one provider's records center was destroyed during a tornado, and two providers' line items were reviewed in other OIG audits.

We also analyzed all lines in error for the various Herceptin reviews to determine whether the Herceptin-specific edit that was implemented after our audit period would have identified these errors had it been in place during our audit period.

We conducted this review 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.

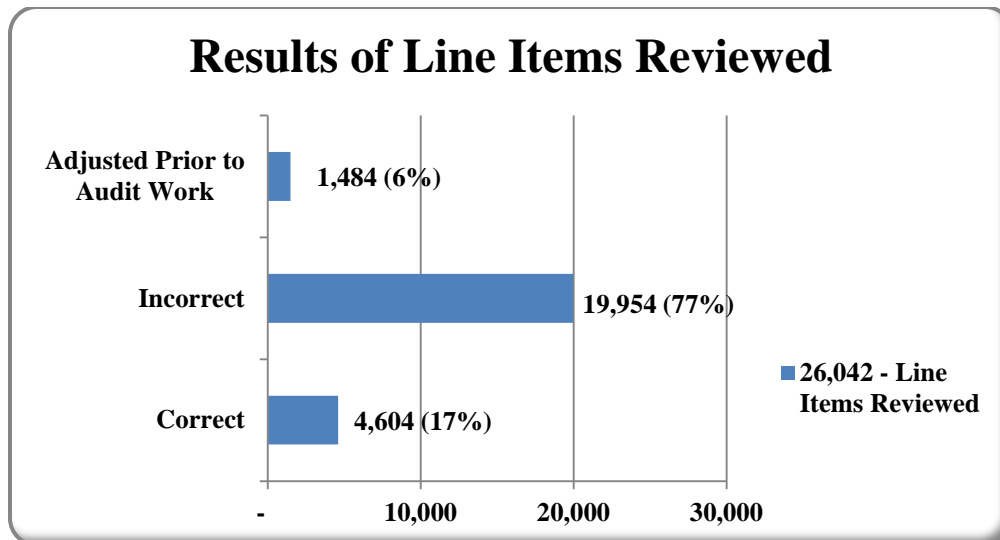
Appendix A contains the details of our audit scope and methodology. Appendix B lists the final reports on the individual reviews of all Medicare contractors' payments to providers for full vials of Herceptin. Appendix C summarizes the results of those reviews.

FINDINGS

Most payments that Medicare contractors made to providers for full vials of Herceptin were incorrect. (See the figure on the next page.)

¹⁰ Of these 170,606 line items, 7,548 items totaling \$11.6 million were processed during calendar year 2007 and were included in the pilot report, *The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect*, A-05-10-00091, issued July 10, 2012.

¹¹ Of the 26,143 line items, 27 were included because they exceeded \$10,000. Although these high-dollar items did not represent billings equivalent to a full vial, they were included because they were likely to be incorrect.



Of the 26,042 line items reviewed, 19,954 (77 percent) were incorrect and included overpayments of about \$24.2 million, or more than one-third of total dollars reviewed. (See Appendix C for a listing by jurisdiction of the number of lines reviewed, lines in error, and overpayment amounts.) For the 19,954 incorrect lines, providers had not identified or refunded these payments by the beginning of our reviews. Prior to our audit work, and not as a result of our audit, providers had refunded overpayments on 1,484 line items totaling approximately \$1.9 million. The 4,604 remaining line items were correct.

On nearly all of the incorrect line items, providers reported the units of service for the entire content of one or two 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 units of service. The Medicare contractors 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.

During our audit period, there was no specific edit to identify Herceptin claims incorrectly billed as full vials. After our audit period, CMS issued guidance to Medicare contractors that required them to implement certain Medically Unlikely Edits (MUEs), including an edit related to Herceptin. Of the 19,954 claim lines we identified as containing errors, we determined that the current MUE would not have identified for review 19,805 (99 percent) of these claim lines.

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS

Providers reported incorrect units of service on 19,954 (77 percent) of the 26,042 line items reviewed, resulting in overpayments totaling approximately \$24.2 million (35 percent) of the approximately \$69 million reviewed.

Incorrect Number of Units of Service

Providers reported incorrect units of service on 19,737 line items, resulting in overpayments totaling \$23,316,522. Providers billed Medicare for entire vials containing 440 milligrams of Herceptin, rather than billing only for the amounts actually administered.

For example, one provider administered 130 milligrams of Herceptin to a patient and billed for 44 units of service (440 milligrams). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 130 milligrams is 13.¹² This error occurred on 98 separate occasions for 1 patient; as a result, the Medicare contractor paid the provider \$218,486 when it should have paid \$64,552, an overpayment of \$153,934.¹³

Unsupported Services

Providers billed Medicare for 209 line items for which the providers did not provide supporting documentation. The providers agreed to cancel the line items and refund \$583,692 in overpayments received.

Other Incorrect Line Items

Providers billed Medicare for eight line items that contained incorrectly billed services or charges, or a combination of unit and HCPCS coding errors, resulting in overpayments of \$16,171.

THE EXISTING HERCEPTIN-SPECIFIC EDIT WOULD NOT HAVE IDENTIFIED MOST ERRORS

In March 2011, CMS issued guidance to Medicare contractors that required them to implement certain MUEs, including an edit related to Herceptin. However, of the 19,954 lines in error identified through the various reviews, we determined that the MUE implemented after our audit period would not have identified 19,805 (99 percent) of these lines. Although we have not addressed in this report the specific reasons that the MUE was ineffective, we have discussed this issue with CMS officials.

CONCLUSION

Our individual reviews of Herceptin nationwide found a significant error rate (77 percent), with overpayments of \$24.2 million for providers billing full vials of Herceptin. On the basis of our analysis of the identified errors in these reviews, we determined that the current Herceptin-specific edit would not have identified 99 percent of claim lines in error. Herceptin is one of

¹² 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 on the basis of the HCPCS long descriptor to report the dose.

¹³ Example obtained from report *Medicare Contractors' Payments in Jurisdiction 1 for Full Vials of Herceptin Were Often Incorrect*, A-09-12-02069, issued February 13, 2013.

many multiuse-vial drugs. Therefore, the problem of provider billing for full vials may exist with other such drugs.

RECOMMENDATIONS

We recommend that CMS:

- ensure that Medicare contractors collect the identified overpayment amounts as recommended in our individual reports,
- review payments made to providers after our audit period ended December 31, 2010, for full vials of Herceptin and recover any identified overpayments,
- require that Medicare contractors implement a Herceptin-specific system edit to identify for review claim lines billed for HCPCS code J9355 with unit counts in multiples of 44 that represent billings equivalent to entire multiuse vial(s), and
- review other multiuse-vial drugs to determine whether system edits are needed to prevent incorrect billings.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our first two recommendations but disagreed with our remaining two recommendations. Regarding our first recommendation, CMS confirmed that its contractors have already recovered \$17.8 million of the approximately \$24 million in overpayments identified in our reviews and will continue to ensure that the remaining overpayments are collected to the maximum extent possible. Regarding our second recommendation, CMS stated that it would direct its contractors to review payments made to providers after our audit period ended December 31, 2010, for full vials of Herceptin and to recover, as appropriate, any identified overpayments.

CMS disagreed with our recommendation to implement a Herceptin-specific edit. CMS stated that an edit “with no manual review by a clinician would not accurately identify incorrect billing in all cases, while any such medical review would not likely be feasible due to resource constraints.” CMS also disagreed with our recommendation to review other multiuse-vial drugs to determine whether system edits are needed. CMS stated that Herceptin “is an unusual situation in that reconstitution with the supplied diluent creates a multidose vial” and “[d]iscarded amounts of the drug cannot be paid under Medicare Part B’s discarded drugs policy as this policy pertains to single use vials.” CMS added that most drugs are reconstituted with sterile water resulting in a single-use vial.

CMS’s comments are included in their entirety as Appendix D.

OUR RESPONSE

We appreciate CMS's efforts to recover all identified Herceptin-related overpayments and to direct its contractors to review all Herceptin-related payments of full vials to providers subsequent to our audit period. However, after review and consideration of CMS's comments, we maintain that our remaining two recommendations are valid.

Regarding our recommendation to implement a Herceptin-specific edit, we acknowledge that the claims identified by such an edit would require manual review. However, considering that 77 percent of the claims that we reviewed had overpayments totaling \$24.2 million, we encourage CMS to explore the potential return on investment of performing these reviews. In addition, we continue to recommend that CMS review other multiuse-vial drugs to determine whether system edits are needed to prevent incorrect billings. A multiuse vial, when reconstituted with a preservative, is generally stable for up to 28 days unless the manufacturer specifies otherwise. CMS guidance states that Medicare does not pay for discarded amounts of multiuse-vial drugs. Therefore, billing the entire amount of a multiuse-vial drug reconstituted with a preservative has a greater possibility of being incorrectly billed and resulting in overpayments, as evident from our 18 reviews.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

During our audit period, Medicare contractors processed 170,606¹⁴ outpatient Part B service line items of Herceptin totaling approximately \$295.3 million. Of these 170,606 line items, 26,143¹⁵ had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 26,143 line items, we reviewed 26,042 items totaling approximately \$69 million. We did not review 101 line items associated with 6 providers. Three of the six providers are no longer in business, one provider's records center was destroyed during a tornado, and two providers' line items were reviewed in other OIG audits.

We also analyzed all lines in error for the various reviews to determine whether the Herceptin-specific edit that was implemented after our audit period would have identified these errors had it been in place during our audit period.

We limited our review of Medicare contractors' 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.

We conducted the fieldwork for individual reviews from November 2010 through December 2012 and contacted all Medicare contractors and providers that received the selected Medicare payments. We conducted fieldwork for this review from February through May 2013.

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 26,042 line items in our scope that the Medicare contractors paid to 1,006 providers nationwide;

¹⁴ Of these 170,606 line items, 7,548 totaling \$11.6 million were processed during calendar year 2007 and were included in the pilot report, *The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect*, A-05-10-00091, issued July 10, 2012.

¹⁵ Of the 26,143 line items, 27 were included because they exceeded \$10,000. Although these high-dollar items did not represent billings equivalent to a full vial, they were included because they were likely to be incorrect.

- contacted 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,
 - the fact 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 and discussed the results of our review with Medicare contractors;
- summarized the results of the various Herceptin reviews;
- analyzed all lines in error for the various Herceptin reviews and determined whether the Herceptin-specific edit that was implemented after our audit period would have identified these errors had it been in place during our audit period; and
- discussed the results of our reviews and the ineffectiveness of the current Herceptin-specific edit with CMS.

We conducted this review 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.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<u>Medicare Contractors' Payments in Jurisdiction 1 for Full Vials of Herceptin Were Often Incorrect</u>	A-09-12-02069	2/13/2013
<u>The Medicare Contractor's Payments in Jurisdiction 2 for Full Vials of Herceptin Were Often Incorrect</u>	A-09-12-02003	11/6/2012
<u>The Medicare Contractor's Payments in Jurisdiction 3 for Full Vials of Herceptin Were Often Incorrect</u>	A-07-12-04186	11/20/2012
<u>Medicare Contractors' Payments Made to Providers Currently Assigned to Jurisdiction 4 for Full Vials of Herceptin Were Often Incorrect</u>	A-06-12-00001	12/3/2012
<u>The Medicare Contractor's Payments in Jurisdiction 5 for Full Vials of Herceptin Were Often Incorrect</u>	A-07-12-04187	10/23/2012
<u>The Medicare Contractor's Payments in Jurisdiction 6 for Full Vials of Herceptin Were Often Incorrect</u>	A-05-12-00010	7/27/2012
<u>The Medicare Contractor's Payments in Jurisdictions 6 and 8 for Full Vials of Herceptin Were Often Incorrect</u>	A-05-11-00112	12/13/2012
<u>The Medicare Contractor's Payments in Jurisdictions 6, 8, and 15 to Providers for Full Vials of Herceptin Were Often Incorrect</u>	A-05-10-00091	7/10/2012
<u>Medicare Contractors' Payments Made to Providers in Jurisdiction 7 for Full Vials of Herceptin Were Often Incorrect</u>	A-06-11-00068	4/23/2013
<u>The Medicare Contractor's Payments to Providers in Jurisdiction 9 for Full Vials of Herceptin Were Often Incorrect</u>	A-04-12-06146	1/7/2013
<u>The Medicare Contractors' Payments in Jurisdiction 10 for Full Vials of Herceptin Were Often Incorrect</u>	A-04-12-03070	1/25/2013
<u>Medicare Contractors' Payments to Providers in Jurisdiction 11 for Full Vials of Herceptin Were Often Incorrect</u>	A-03-11-00013	8/10/2012
<u>Medicare Contractors' Payments to Providers in Four States in Jurisdiction 12 for Full Vials of Herceptin Were Often Incorrect</u>	A-03-11-00014	7/25/2012
<u>The Medicare Contractor's Payments to Maryland Providers in Jurisdiction 12 for Full Vials of Herceptin Were Sometimes Incorrect</u>	A-03-12-00014	8/16/2012
<u>The Medicare Contractor's Payments to Providers in Jurisdiction 13 for Full Vials of Herceptin Were Often Incorrect</u>	A-02-12-01003	5/22/2013
<u>Medicare Contractors' Payments in Jurisdiction 14 for Full Vials of Herceptin Were Often Incorrect</u>	A-01-11-00539	8/17/2012
<u>Medicare Contractors' Payments in Jurisdiction 15 to Providers for Full Vials of Herceptin Were Often Incorrect</u>	A-05-12-00017	12/21/2012
<u>The Medicare Contractor's Payments to Providers in 26 States From the WPS Legacy Workload for Full Vials of Herceptin Were Often Incorrect</u>	A-05-11-00114	2/19/2013

APPENDIX C: LIST OF OVERPAYMENT AMOUNTS BY JURISDICTION

Jurisdiction	Contractor	Lines Reviewed	Lines in Error	Error Rate	Overpayment Amount
1	Palmetto	2,005	1,498	75%	\$1,731,460
2	Noridian	714	487	68%	567,008
3	Noridian	634	399	63%	404,746
4	Trailblazer	1,701	1,349	79%	1,777,877
5	WPS	665	540	81%	635,023
6	Noridian	464	368	79%	556,908
6, 8	NGS	713	558	78%	682,748
6, 8, 15	NGS	3,966	3,093	78%	3,351,807
7	Pinnacle	1,607	1,466	91%	1,753,744
9	First Coast	1,330	1,043	78%	1,315,409
10	Cahaba	1,140	936	82%	1,516,218
11	Palmetto	2,507	2,029	81%	2,397,839
12	Novitas	1,454	1,165	80%	1,576,374
12	Novitas	1,113	319	29%	351,904
13	NGS	1,156	788	68%	1,007,413
14	NHIC	853	391	46%	403,396
15	CGS	1,073	916	85%	1,151,915
Legacy	WPS	2,947	2,609	89%	3,056,167
Total		26,042	19,954	77%	\$24,237,956

CGS = CGS Administrators, NGS = National Government Services, NHIC = NHIC, Corp.,
WPS = Wisconsin Physician Services Insurance Corporation

APPENDIX D: AGENCY COMMENTS



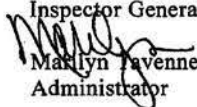
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP 19 2013

TO: Daniel R. Levinson
Inspector General

FROM: 
Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Contractors Nationwide Overpaid Millions to Providers for Full Vials of Herceptin (A-05-13-00024)"

Thank you for the opportunity to review and comment on the above subject OIG draft report. OIG's objectives for this study are to--(1) Summarize the results of its individual reviews; and (2) Determine the effectiveness of the existing Herceptin-specific edit in preventing incorrect billings for full vials of Herceptin. This report summarizes OIG's review of Medicare contractors' claims processing for Herceptin, a chemotherapy drug, performed at the individual claims processing contractor level, and describes findings related to CMS's implementation of a Medically Unlikely Edit (MUE) in 2011.

In total, the study reported findings regarding 170,606 claim lines for Herceptin, representing approximately \$295 million in total Medicare billing for a 3-year period, beginning January 1, 2008. Of these 170,606 claim lines, OIG determined that 26,143 corresponded to exact multiples of vials (that is, 44, 88, or 132 billing units), and found, after examining payments for claims corresponding to the exact multiples of vials, that approximately 77 percent (representing approximately \$24.2 million) were paid incorrectly. Specifically, OIG found that providers were billing in increments of an entire vial, rather than reporting the number of billing units corresponding to the dose that was actually administered. The report notes that providers attributed the incorrect payments to clerical errors and lack of billing system checks. OIG also reports that the MUE established for Herceptin would not have effectively identified the vast majority of the incorrect claims.

The OIG recommendations and CMS responses to the recommendations are discussed below.

OIG Recommendation

The OIG recommends that CMS ensure that Medicare contractors collect the identified overpayment amounts as recommended in OIG's individual reports.

CMS Response

The CMS concurs with this recommendation. The overpayments should be recovered by the contractors as appropriate, and of the approximately \$24 million of overpayments identified in the individual reports, CMS confirms that its contractors have already recovered \$17.8 million. CMS will continue to work with the contractors to ensure that the overpayments identified in the individual reports are collected to the maximum extent possible.

OIG Recommendation

The OIG recommends that CMS review payments made to providers after our audit period ending December 31, 2010, for full vials of Herceptin and recover any identified overpayments.

CMS Response

The CMS concurs with this recommendation. CMS will direct contractor(s) to review payments made to providers after OIG's audit period ending December 31, 2010, for full vials of Herceptin, and to recover, as appropriate, any identified overpayments.

OIG Recommendation

The OIG recommends that CMS require that Medicare contractors implement a Herceptin-specific system edit to identify, for review, claim lines billed for Healthcare Common Procedure Coding System (HCPCS) code J9355 with unit counts in multiples of 44 that represent billings equivalent to entire multiuse vial(s).

CMS Response

The CMS does not concur with this recommendation. Herceptin doses must be individualized and the doses vary over a large range. This range encompasses one or two vials of the drug, which is 440mg (44 HCPCS billing units) or 880mg (88 HCPCS billing units). A national edit for J9355 at 44 or 88 units of service with no manual review by a clinician would not accurately identify incorrect billing in all cases, while any such medical review would not likely be feasible due to resource constraints. However, CMS believes that education about proper billing and follow-up scrutiny of claims by the Recovery Audit Contractors would reduce incorrect billing of Herceptin and will be taking steps to educate providers on this issue.

OIG Recommendation

The OIG recommends that CMS review other multiuse-vial drugs to determine whether system edits are needed to prevent incorrect billings.

CMS Response

The CMS does not concur with this recommendation. CMS believes that Herceptin is an unusual situation in that reconstitution with the supplied diluent creates a multidose vial. Discarded

Page 3 – Daniel R. Levinson

amounts of the drug cannot be paid under the Medicare Part B's discarded drugs policy as this policy pertains to single use vials. Most drugs that require reconstitution are reconstituted with preservative free diluent and result in a single use vial. However, if OIG believes there are other multidose vials that are subject to incorrect billing as single dose vials, CMS encourages OIG to bring them to our attention for further review.

The CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.