Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS IN JURISDICTION 15 TO PROVIDERS FOR FULL VIALS OF HERCEPTIN WERE OFTEN INCORRECT

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

Gloria L. Jarmon
Deputy Inspector General

December 2012
A-05-12-00017

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

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.

CGS Administrators assumed full responsibility as the Medicare contractor for Jurisdiction 15 (Ohio and Kentucky) effective October 17, 2011. During our audit period (January 2008 through December 2010), National Government Services was the fiscal intermediary for Ohio and Kentucky and processed 11,249 line items totaling approximately $20.6 million for Herceptin. Of these 11,249 line items, 1,096 had unit counts in multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. We reviewed 1,073 line items totaling approximately $3.1 million. We did not review 23 line items associated with 1 provider that is no longer in business. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims that met these criteria.

Because CGS Administrators assumed responsibility for claims formerly paid by National Government Services for Jurisdiction 15, we have addressed our findings and recommendations to CGS Administrators for review and comment.

OBJECTIVE

Our objective was to determine whether payments that Medicare contractors made to providers in Jurisdiction 15 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most Medicare payments that Medicare contractors made to providers in Jurisdiction 15 for full vials of Herceptin were incorrect. Specifically, of the 1,073 selected line items, 916 (85 percent) were incorrect and included overpayments totaling $1,151,915, or more than one-third of total dollars reviewed. These providers had not identified or refunded these overpayments by the

beginning of our audit. Providers refunded overpayments on 54 line items totaling $125,216 before our fieldwork. The 103 remaining line items were correct.

On each of the 916 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. The 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.

RECOMMENDATIONS

We recommend that CGS Administrators:

- recover the $1,151,915 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.

CGS ADMINISTRATORS' COMMENTS

In written comments on our draft report, CGS Administrators agreed with our findings and recommendations and stated that it would ensure that all overpayment claims identified in the audit are adjusted and finalized for payment recovery. CGS Administrators said it would reconcile all adjusted claims and recoupments to verify that all overpayments are settled in full. Additionally, CGS Administrators implemented a specific prepay edit to correct future overpayments effective October 17, 2012, and posted a related notification article on its Web site. Finally, CGS Administrators outlined steps that it is taking to address aberrant billing for Herceptin in its educational sessions with providers.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

Herceptin[1] 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[2] 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. 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.

---

[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.

Herceptin

Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent of benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded. The HCPCS code for Herceptin is J9355, with a narrative description of "injection, trastuzumab, 10 mg." An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

CGS Administrators and National Government Services

CGS Administrators assumed full responsibility as the Medicare contractor for Jurisdiction 15 (Ohio and Kentucky) effective October 17, 2011. During our audit period (January 2008 through December 2010), National Government Services was the fiscal intermediary for Ohio and Kentucky and processed 11,249 line items for Herceptin in these States.

Because CGS Administrators assumed responsibility for claims formerly paid by National Government Services for Jurisdiction 15, we have addressed our findings and recommendations to CGS Administrators for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether payments that Medicare contractors made to providers in Jurisdiction 15 for full vials of Herceptin were correct.

Scope

During our audit period, Medicare contractors processed 11,249 outpatient Part B service line items of Herceptin totaling approximately $20.6 million. Of these 11,249 line items, 1,852 had unit counts with multiples of 44 (44, 88, 132, etc.) that represent billings equivalent to entire multiuse vials. Of these 1,852 items, we reviewed 1,073 line items[5] totaling approximately $3.1 million. We did not review 23 line items associated with 1 provider that is no longer in business. For the remaining 756 line items, National Government Services made final adjustment on these claims prior to CGS Administrators assuming responsibility for Ohio providers. Accordingly, we reviewed and reported these line items in report A-05-10-00091.

[5] Two of the 1,073 line items were included because they exceeded $10,000. While this did not represent a billing equivalent to a full vial, this high-dollar item was included because it was likely to be incorrect.

We limited our review of CGS Administrators' internal controls to those that were applicable to the selected payments because our objective did not require an understanding of all internal controls over the submission and processing of claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

Our fieldwork was conducted from November 2011 through March 2012 and included contacting CGS Administrators in Louisville, Kentucky, and the 42 providers in Jurisdiction 15 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 1,073 line items in our scope that the Medicare contractors paid to 42 providers;
- contacted the 42 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 CGS Administrators; and
- discussed the results of our review with CGS Administrators on July 24, 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 the Medicare contractors made to providers in Jurisdiction 15 for full vials of Herceptin were incorrect. Specifically, of the 1,073 selected line items, 916 (85 percent) were incorrect and included overpayments totaling $1,151,915, or more than one-third of total dollars reviewed. These providers had not identified nor refunded these overpayments by the beginning of our audit. Providers refunded overpayments on 54 line items totaling $125,216 before our fieldwork. The remaining 103 line items were correct.

On each of the 916 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. 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.

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: "[m]ulti-use vials are not subject to payment for discarded amounts of drug …." Finally, chapter 1, section 80.3.2.2, of the Manual states: "In order to be processed correctly and promptly, a bill must be completed accurately."

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS REVIEWED

Providers reported incorrect units of service on 916 (85 percent) of the 1,073 line items reviewed, resulting in overpayments totaling $1,151,915 (37 percent) of the $3.1 million total dollars reviewed. Providers billed Medicare for the entire vial containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, 1 provider administered 588 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 588 milligrams is 59.[6] This

[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.

error occurred on 51 separate occasions for 1 patient; as a result, the Medicare contractor paid the provider $233,339 when it should have paid $149,972, an overpayment of $83,367.

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. The Medicare contractors 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 CGS Administrators:

- recover the $1,151,915 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.

CGS ADMINISTRATORS' COMMENTS

In written comments on our draft report, CGS Administrators agreed with our findings and recommendations and stated that it would ensure that all overpayment claims identified in the audit are adjusted and finalized for payment recovery. CGS Administrators said it would reconcile all adjusted claims and recoupments to verify all overpayments are settled in full. Additionally, CGS Administrators implemented a specific prepay edit to correct future overpayments effective October 17, 2012, and posted a related notification article on its Web site. Finally, CGS Administrators outlined steps that it is taking to address aberrant billing for Herceptin in its educational sessions with providers.

CGS Administrators' 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: CGS ADMINISTRATORS' COMMENTS

Steven B. Smith
President & COO
CGS Administrators, LLC

Two Vantage Way
Nashville, TN 37228
Telephone: 615-244-5600
Steve.Smith@bcbssc.com

November 5, 2012

Report Number: A-05-12-00017

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

Dear Ms. Fulcher:

This letter is in response to the recent Office of Inspector General (OIG) draft report entitled *Medicare Contractors' Payments in Jurisdiction 15 for Full Vials of Herceptin Were Often Incorrect*. We appreciate the feedback your review provided and are committed to continuously improving our service to the Medicare beneficiaries and providers we serve.

As stated in the report, CGS Administrators (CGS) assumed full responsibility as the Medicare contractor for Jurisdiction 15 (Ohio and Kentucky) effective October 17, 2011. During the audit period (January 2008 through December 2010), National Government Services was the fiscal intermediary for Ohio and Kentucky and processed 11,249 line items totaling approximately $20.6 million for Herceptin. Of these 11,249 line items, 1,096 had unit counts in multiples of 44, which represent billings equivalent to 1 or more full multiuse vials of Herceptin. The OIG reviewed 1,073 line items totaling approximately $3.1 million. The OIG did not review 23 line items associated with 1 provider that is no longer in business. In this audit the OIG did not review entire claims; rather, reviewed specific line items within the claims that met the criteria.

Of the 1,073 selected line items, 916 (85 percent) were identified by OIG as incorrect and included overpayments totaling $1,151,915. These providers had not identified or refunded these overpayments by the beginning of the audit. Thus the following recommendations were presented to CGS Administrators:

- recover the $1,151,915 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.

Summary of actions taken by CGS:

- **Recover the $1,151,915 identified overpayments.**

CGS Administrators' Response:
CGS will ensure all overpayment claims identified in the audit are adjusted and finalized for payment recovery. As part of the OIG audit process, providers are notified and allowed to submit claim corrections for units initially billed, resulting in a recovery action initiated by provider. As a result, the amount of recovery initiated by CGS may vary from the original OIG recovery amount identified in the draft report. CGS will reconcile all adjusted claims and recoupments to verify that all overpayments are settled in full.

- **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**

  CGS Administrators' Response:
  CGS established a service specific prepay edit with an effective date of 10/17/12. Per IOM requirements, a related notification article was posted to the web on same day as effective date http://cgsmedicare.com/parta/pubs/news/2012/1012/707.html

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

  CGS Administrators' Response:
  - Correct coding has been and continues to be discussed in each educational session. In our upcoming Ask the Contractor Teleconference (ACT), plans are established to provide education related to billing Herceptin.

  - Based on data analysis, a comparative billing report (CBR) is being developed and will be posted to the CGS web site by 11/16/12. Each provider will be ranked. The ranking number will be shared only with the corresponding provider.

  - Effectiveness of prepay complex reviews will be assessed within three months of the edit effective date, or by the end of the first quarter of Option Year 2, whichever is greater. This data will be used to identify provider aberrancy in billing Herceptin. An education letter will be mailed to those providers identified as having billing issues. The individual provider specific CBR will also accompany this letter.

  - Data from the CBR report will be used to establish a basis for edit effectiveness reviews across other business segments within the J15 contract.

Thank you for providing CGS Administrators with the opportunity to offer feedback regarding your review. If you have any questions, please do not hesitate to contact me.

Sincerely,

Steven B. Smith
President & COO