Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS MADE TO PROVIDERS IN JURISDICTION 7 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

April 2013
A-06-11-00068

Office of Inspector General

https://oig.hhs.gov

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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 properly stored, 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 review 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.

During our audit period (January 2008 through December 2010), Pinnacle Business Solutions, Inc. (Pinnacle), and Tri-Span Health Services (Tri-Span) were Medicare contractors that processed line items for Herceptin in Jurisdiction 7, which comprised Arkansas, Louisiana, and Mississippi. On November 8, 2011, CMS announced that it had awarded Novitas Solutions, Inc. (Novitas), formerly Highmark Medicare Services, the contract for Jurisdiction H, which includes the former Jurisdictions 7 and 4. Accordingly, Novitas assumed responsibility for claims formerly paid by Pinnacle and Tri-Span, and we have addressed our findings and recommendations to Novitas for review and comments.

The Medicare contractors processed 5,796 line items of Herceptin totaling approximately $10.8 million. Of the 5,796 line items, 1,607 totaling approximately $4.6 million had 44, 88, 132, or 176 units of service that represented billings equivalent to entire multiuse vials. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

OBJECTIVE

Our objective was to determine whether payments that the Medicare contractors made to providers in Jurisdiction 7 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most payments that the Medicare contractors made to providers in Jurisdiction 7 for full vials of Herceptin were incorrect. Specifically, of the 1,607 selected line items, 1,466 (91 percent) were incorrect and had not been identified or refunded by the beginning of our audit. Providers refunded overpayments on 56 line items totaling $92,073 by the beginning of our fieldwork. The 85 remaining line items were correct. Of the 1,466 incorrect line items, 1,344 included

overpayments totaling $1,753,744. As of November 30, 2012, the amount of overpayment for 122 of the 1,466 line items had not been determined because they had not been reprocessed and the correct line payment amounts identified.

For the 1,466 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,455 line items, resulting in overpayments totaling $1,723,294 (the amount of overpayment for 122 of the 1,455 line items has not been determined), and

- did not provide supporting documentation for 11 line items, resulting in overpayments totaling $30,450.

The providers attributed the incorrect payments to clerical errors, chargemaster errors, and billing systems that could not prevent or detect the incorrect billing of units of service. (A provider's chargemaster contains data on every chargeable item or procedure that the provider offers, including a factor that converts a drug's dosage to the number of units to bill and whether to charge for waste.) 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 Novitas:

- recover the $1,753,744 in identified overpayments,

- determine and recover the amount of overpayment for the 122 line items that had not been processed and correct payment amounts identified,

- 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.

NOVITAS SOLUTIONS, INC., COMMENTS

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

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INTRODUCTION

BACKGROUND

Herceptin[1] is a Medicare-covered biological drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes 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. 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 review found that the Medicare contractor's payments for full vials of Herceptin were often incorrect.[2]

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. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as the injection of drugs. 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 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

[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.

description.[4] Multiuse vials are not subject to payment for discarded amounts of the drug. Multiuse vials are typically used for more than 1 date of service and can be stored for up to 28 days. Therefore, a payment for an entire multiuse vial is likely to be incorrect.

Herceptin

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

Claims Processing Contractors

During our audit period (January 2008 through December 2010), Pinnacle Business Solutions, Inc. (Pinnacle), and Tri-Span Health Services (Tri-Span) were Medicare contractors that processed 5,796 line items for Herceptin in Jurisdiction 7, which comprised Arkansas, Louisiana, and Mississippi. On November 8, 2011, CMS announced that it had awarded Novitas Solutions, Inc. (Novitas), formerly Highmark Medicare Services, the contract for Jurisdiction H, which includes the former Jurisdictions 7 and 4. Accordingly, Novitas assumed responsibility for claims formerly paid by Pinnacle and Tri-Span, and we have addressed our findings and recommendations to Novitas for review and comments.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether payments that the Medicare contractors made to providers in Jurisdiction 7 for full vials of Herceptin were correct.

Scope

During our audit period (January 2008 through December 2010), the Medicare contractors processed 5,796 outpatient Part B service line items of Herceptin totaling approximately $10.8 million. Of these 5,796 line items, 1,607 items totaling approximately $4.6 million had unit counts in multiples of 44 (44, 88, 132…) that represented billings equivalent to 1 or more

[4] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

full multiuse vials.[5] In the audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

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.

We conducted our fieldwork from October 2011 through December 2012; it included contacting Pinnacle in Little Rock, Arkansas, and the 43 providers 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 1,607 line items that the Medicare contractors paid to 43 providers;
- contacted the 43 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 administration of the medication for the amount ordered, and
    - the type of solution (BWFI containing 1.1 percent benzyl alcohol or sterile water) used to reconstitute the Herceptin;
- determined an overpayment amount; and
- discussed the results of our review with Novitas on December 20, 2012.

[5] We included 11 of the 1,607 line items because they exceeded $10,000. Although these did not represent billings equivalent to a full vial, these high-dollar items were included because they were likely to be incorrect.

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 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 objectives.

FINDINGS AND RECOMMENDATIONS

Most payments that the Medicare contractors made to providers in Jurisdiction 7 for full vials of Herceptin were incorrect. Specifically, of the 1,607 selected line items, 1,466 (91 percent) were incorrect and had not been identified or refunded by the beginning of our audit. Providers refunded overpayments on 56 line items totaling $92,073 by the beginning of our fieldwork. The remaining 85 line items were correct. Of the 1,466 incorrect line items, 1,344 included overpayments totaling $1,753,744. As of November 30, 2012, the amount of overpayment for 122 of the 1,466 line items had not been determined because they had not been reprocessed and the correct line payment amounts identified.

For the 1,466 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,455 line items, resulting in overpayments totaling $1,723,294 (the amount of overpayment for 122 of the 1,455 line items has not been determined), and

- did not provide supporting documentation for 11 line items, resulting in overpayments totaling $30,450.

The providers attributed the incorrect payments to clerical errors, chargemaster errors, and billing systems that could not prevent or detect the incorrect billing of units of service.[6] 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

Section 1833(e) of the Social Security Act states: "No payment shall be made to any provider of services … unless there has been furnished such information as may be necessary in order to determine the amounts due such provider … for the period with respect to which the amounts are being paid …."

[6] A provider's chargemaster contains data on every chargeable item or procedure that the provider offers, including a factor that converts a drug's dosage to the number of units to bill and whether to charge for waste.

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 23, section 20.3, states that "… 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

Incorrect Number of Units of Service

Thirty-five providers reported incorrect units of service on 1,455 line items, resulting in overpayments totaling $1,723,294. We were unable to determine the amount of overpayment for 122 line items because the line items have not been reprocessed. Providers billed Medicare for full vials of Herceptin containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, one provider administered 180 milligrams (18 units) 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 180 milligrams is 18.[7] On 41 separate occasions, the provider billed for 1 full vial of Herceptin (44 units of service) for each patient dose, rather than the amount administered. As a result, the Medicare contractor paid the provider $91,726 when it should have paid $37,279, an overpayment of $54,447.

As a result of these unit-of-service errors, the Medicare contractors paid 35 providers a total of $4,193,577 when they should have paid $2,055,437, overpayments of $1,723,294. The amount of overpayment for 122 line items with original payment amounts totaling $414,846 had not been determined as of November 30, 2012.

Unsupported Services

Four providers billed Medicare for 11 line items for which the providers did not provide adequate documentation to support that a patient received treatment. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined $30,450 in overpayments that they received.

[7] 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

Providers attributed the incorrect payments to clerical errors, chargemaster errors, and 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*[8] and disclose any overpayments.

RECOMMENDATIONS

We recommend that Novitas:

- recover the $1,753,744 in identified overpayments,
- determine and recover the amount of overpayment for the 122 line items that had not been reprocessed and correct payment amounts identified,
- 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.

NOVITAS SOLUTIONS, INC., COMMENTS

In written comments on our draft report, Novitas concurred with our recommendations and described corrective actions that it had taken or planned to take. Novitas' comments are included in their entirety as the Appendix.

[8] 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: NOVITAS SOLUTIONS, INC., COMMENTS

NOVITAS
SOLUTIONS

Sandy Coston
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March 13, 2013

Ms. Patricia Wheeler
Regional Inspector General
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, TX 75242

Reference: Report # A-06-11-00068

Dear Ms. Wheeler,

We received the US Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled, *"Medicare Contractors' Payments to Providers in Jurisdiction 7 for Full Vials of Herceptin Were Often Incorrect"* and reviewed the findings and recommendations. We appreciate the opportunity to review and provide comments prior to release of the final report.

In the draft report, you outlined three recommendations that we have addressed as follows:

Recommendation:

Recover the $1,753,744 in identified overpayments and determine and recover the amount of overpayment for the 122 line items that had not been reprocessed and correct payment amounts identified.

Response:

Novitas concurs with the recommendation and will initiate claims history adjustments, on claims that providers have not already adjusted and recover overpayment per CMS guidelines.

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Fax: 904-361-0372

Recommendation:

Implement a system edit that identifies for review line items for multiuse-vial drugs with units of service equivalent to one or more entire vials.

Response:

Novitas concurs with the recommendation and will institute a service-wide, prepayment edit on HCPCS J9355 billed in multiples of 44.

Recommendation:

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

Response:

Novitas concurs with the recommendation and will incorporate the results of this audit into its provider education activities (e.g. Medicare presentations and published articles.)

Again, we appreciate the opportunity to review and provide comments prior to release of the final report. If you have any questions regarding our response please contact Mr. Gregory W. England at (904) 791-8364.

Sincerely,

Sandra L. Coston

Sandra L. Coston

cc: David Vaughan, Vice President & JH Project Manager
Gregory England, Director Internal Audit