Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS' PAYMENTS MADE TO PROVIDERS CURRENTLY ASSIGNED TO JURISDICTION 4 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-06-12-00001

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 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 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 (CMS) administers the program.

In August 2007, CMS announced that it had awarded to TrailBlazer Health Enterprises, LLC (TrailBlazer), the Medicare administrative contractor (MAC) contract for Jurisdiction 4, which includes Colorado, New Mexico, Oklahoma, and Texas.

Historically, Wisconsin Physicians Service Insurance Corporation (WPS) processed a workload that included providers who fell under the geographic jurisdiction of all 15 MACs (WPS Legacy workload). In October 2010, CMS transferred certain providers in the WPS Legacy workload from WPS to TrailBlazer. The transferred providers included providers located in Jurisdiction 4, as well as Qualified Chain Providers with home offices in Jurisdiction 4.

To process providers' claims for outpatient services, 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.

During our audit period (January 1, 2008, through December 31, 2010), TrailBlazer and WPS (contractors) processed 9,136 line items for Herceptin totaling approximately $18.2 million. Of these 9,136 line items, 1,701 totaling approximately $4.7 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 the specific line items within the claims that met these criteria.

OBJECTIVE

Our objective was to determine whether payments that the Medicare contractors made to providers currently assigned to Jurisdiction 4 for full vials of Herceptin were correct.

SUMMARY OF FINDINGS

Most payments that the Medicare contractors made to providers currently assigned to Jurisdiction 4 for full vials of Herceptin were incorrect. Specifically, of the 1,701 selected line items, 1,349 (79 percent) were incorrect and included overpayments totaling $1,777,877, or more than one-third of total dollars reviewed. The providers had not identified or refunded these overpayments by the beginning of our audit. The providers associated with six of the line items refunded overpayments totaling $6,819 before our fieldwork. The remaining 346 line items were correct.

For the 1,349 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,328 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,718,904, and

- did not provide supporting documentation for 21 line items, resulting in overpayments totaling $58,973.

Providers attributed the incorrect payments to clerical errors, chargemaster errors, or inadvertently billing for drug waste because they did not identify the drug as a multiuse-vial drug. (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 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.

RECOMMENDATIONS

We recommend that TrailBlazer:

- recover the $1,777,877 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.

TRAILBLAZER HEALTH ENTERPRISES, LLC, COMMENTS

In written comments on our draft report, TrailBlazer stated that it had processed all 1,349 claim lines requiring adjustment and recovered the $1,777,877 owed to the Medicare program. Also, TrailBlazer stated that it did not have sufficient time to create, test, and implement edits because of the transfer of the Jurisdiction 4 MAC Part A workload to Novitas Solutions, Inc., and that it would forward this report to Novitas. Finally, TrailBlazer said that it provides education materials related to drugs and biologicals on its Web site. TrailBlazer's comments are included in their entirety as the Appendix.

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TRAILBLAZER HEALTH ENTERPRISES, LLC, COMMENTS

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 review[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.

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[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 10mg." An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for Medicare billing.

Claims Processing Contractors

In August 2007, CMS announced that it had awarded to TrailBlazer Health Enterprises, LLC (TrailBlazer), the MAC contract for Jurisdiction 4, which includes Colorado, New Mexico, Oklahoma, and Texas.[5]

Historically, Wisconsin Physicians Service Insurance Corporation (WPS) processed a workload that included providers who fell under the geographic jurisdiction of all 15 MACs (WPS Legacy workload). In October 2010, CMS transferred certain providers in the WPS Legacy workload from WPS to TrailBlazer.[6] Accordingly, we have addressed our findings and recommendations to TrailBlazer for review and comment.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether payments that the Medicare contractors made to providers currently assigned to Jurisdiction 4 for full vials of Herceptin were correct.

Scope

During our audit period (January 2008 through December 2010), the contractors processed 9,136 outpatient Part B service line items of Herceptin totaling approximately $18.2 million. Of these

[5] TrailBlazer also processed Herceptin claims for three providers in Louisiana. These providers are Qualified Chain Providers, a designation for providers located over a large geographic area that belong to multiple MAC jurisdictions. A Qualified Chain Provider has the option to move all of its providers, regardless of geographic location, to the MAC that covers the State in which the Qualified Chain Provider's home office is located.

[6] The transferred providers included providers located in Jurisdiction 4, as well as Qualified Chain Providers with home offices in Jurisdiction 4.

9,136 line items, 1,701[7] items totaling approximately $4.7 million had 44, 88, 132, or 176 units of service that represented billings equivalent to entire multiuse vials.

We limited our review of the 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 July 2012 and included contacting TrailBlazer in Dallas, Texas, and the 75 providers in California, Colorado, Kentucky, Louisiana, Maryland, New Mexico, North Carolina, Oklahoma, Tennessee, and Texas 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 1,701 line items that the contractors paid to 75 providers;
- contacted the 75 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 TrailBlazer; and
- discussed the results of our review with TrailBlazer on August 7, 2012.

[7] One of the 1,701 line items was included because it exceeded $10,000. While this did not represent a billing equivalent to a full vial, this high-dollar item was included because it was 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 objective.

FINDINGS AND RECOMMENDATIONS

Most payments that the Medicare contractors made to providers currently assigned to Jurisdiction 4 for full vials of Herceptin were incorrect. Of the 1,701 selected line items, 1,349 were incorrect and included overpayments totaling $1,777,877 that the providers had not identified or refunded by the beginning of our audit. Providers refunded overpayments on six line items totaling $6,819 before our fieldwork. The remaining 346 line items were correct.

For the 1,349 incorrect line items that had not been refunded, providers:

- reported incorrect units of service on 1,328 line items with unit counts that represented full multiuse vials, resulting in overpayments totaling $1,718,904, and

- did not provide supporting documentation for 21 line items, resulting in overpayments totaling $58,973.

Providers attributed the incorrect payments to clerical errors, chargemaster[8] errors, or inadvertently billing for drug waste because they did not identify the drug as a multiuse-vial drug. The 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 …."

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

[8] 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.

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

Incorrect Number of Units of Service

Providers reported incorrect units of service on 1,328 (78 percent) of the 1,701 line items reviewed, resulting in overpayments totaling $1,718,904 (37 percent) of the $4,699,671 total dollars reviewed. Providers billed Medicare for entire vials containing 440 milligrams of Herceptin, rather than billing only for the amount actually administered.

For example, one provider administered 180 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 180 milligrams is 18.[9] This error occurred on 59 separate occasions for 1 patient; as a result, the Medicare contractor paid the provider $125,692 for this patient when it should have paid $51,299, an overpayment of $74,393.

Unsupported Services

The providers associated with 21 line items did not provide adequate documentation to support that a patient was seen or received treatment. The providers agreed to cancel the claims associated with these line items or file adjusted claims and refund the combined $58,973 in overpayments that they received.

CAUSES OF INCORRECT MEDICARE PAYMENTS

Providers attributed the incorrect payments to clerical errors, chargemaster errors, or inadvertently billing for drug waste because they did not identify the drug as a multiuse-vial drug. 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*[10] and disclose any overpayments.

[9] 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.

[10] 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.

RECOMMENDATIONS

We recommend that TrailBlazer:

- recover the $1,777,877 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.

TRAILBLAZER HEALTH ENTERPRISES, LLC, COMMENTS

In written comments on our draft report, TrailBlazer stated that it had processed all 1,349 claim lines requiring adjustment and recovered the $1,777,877 owed to the Medicare program. Also, TrailBlazer stated that it did not have sufficient time to create, test, and implement edits because of the transfer of the Jurisdiction 4 MAC Part A workload to Novitas Solutions, Inc., and that it would forward this report to Novitas. Finally, TrailBlazer said that it provides education materials related to drugs and biologicals on its Web site. TrailBlazer's comments are included in their entirety as the Appendix.

APPENDIX

APPENDIX: TRAILBLAZER HEALTH ENTERPRISES, LLC, COMMENTS

MEDICARE

October 30, 2012

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

Report Number: A-06-12-00001

Dear Ms. Wheeler:

We received the October 2, 2012, draft report entitled "Medicare Contractors' Payments Made to Providers Currently Assigned to Jurisdiction 4 for Full Vials of Herceptin Were Often Incorrect." In the draft report, the OIG recommended that TrailBlazer:

- Recover $1,777,877 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.

Please consider the following responses to these recommendations for inclusion in the final report:

Recovery of Overpayments: Prior to the conclusion of this audit, TrailBlazer processed all 1,349 claim lines requiring adjustment and recovered the $1,777,877 due the Medicare program.

Implement or Update System Edits: Due to the transfer of the J4 MAC Part A workload to Novitas Solutions, Inc. (Novitas), on October 29, 2012, there is insufficient time to create, test and implement edits as outlined in the draft audit report. TrailBlazer will forward this report to Novitas so that they can ensure the desired edits are implemented in their system.

Provider Education Activities: TrailBlazer provides a Drug and Biologicals Web Page on the TrailBlazer Web site. This page serves as a centralized repository for educational references for drugs and biologicals.
http://www.trailblazerhealth.com/Specialty%20Services/Drugs%20and%20Biologicals/default.aspx?DomainID=1

The following job aids to assist providers with proper claim submission for drugs and biologicals are available on the TrailBlazer Web site.

- Drug Wastage
  http://www.trailblazerhealth.com/Publications/Job%20Aid/Drug%20Wastage.pdf
- Drug and Biologicals Coding Tips
  http://www.trailblazerhealth.com/Publications/Job%20Aid/DrugsandBiologicalsCodingTips.pdf

An article titled "Billing for Drug Wastage" was posted to the TrailBlazer Web site on February 27, 2012.
http://www.trailblazerhealth.com/Tools/Notices.aspx?ID=14256

The article below highlighting these OIG findings posted to the TrailBlazer Web site on October 12, 2012, and was distributed via listserv for future exposure.
http://www.trailblazerhealth.com/Tools/Notices.aspx?ID=15100

If you have any questions regarding our response, please contact me.

Sincerely,

/s/ Melissa Halstead Rhoades

Melissa Halstead Rhoades
Area Director & Medicare CFO

cc: Susan Oken, J4 MAC Contracting Officer's Representative, CMS
Gil R. Glover, President & Chief Operating Officer, TrailBlazer
Scott J. Manning, Vice President, Financial Management Operations, TrailBlazer
Kevin Bidwell, Vice President & Compliance Officer, TrailBlazer