Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OHIO MADE INCORRECT MEDICAID PAYMENTS 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.

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Office of Inspector General

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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.

Ohio made incorrect Medicaid payments to providers for full vials of Herceptin that resulted in overpayments of approximately $91,000 (Federal share) over 3 years.

INTRODUCTION

WHY WE DID THIS REVIEW

Herceptin, also known as trastuzumab, is a Medicaid-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. Previous Office of Inspector General reviews found that overpayments were made on Medicare claims for full vials of Herceptin. Specifically, of the line items we reviewed, 77 percent were incorrect and included overpayments of about $24.2 million.

On nearly all of the incorrect line items in previous reviews, the providers reported the units of service for the entire content of one or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. Because of the significant error rate in the Medicare program, we expanded our review of Herceptin billing to State Medicaid programs, including the Ohio Medicaid program.[1]

OBJECTIVE

Our objective was to determine whether payments made by Ohio Medicaid to providers for full vials of the drug Herceptin were in accordance with applicable State and Federal regulations.

BACKGROUND

The Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the Medicaid program. In Ohio, the Department of Medicaid (the State agency) administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

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 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.

Providers bill the State agency using the appropriate Healthcare Common Procedure Coding System (HCPCS) code and the appropriate quantity of the drug administered. The number of units billed should correspond to the quantity of Herceptin actually administered to the patient. The HCPCS code for Herceptin is J9355, with a description of "injection, trastuzumab 10 mg."

[1] See Appendix A for related Office of Inspector General reports.

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

In Ohio, Herceptin is reimbursed on a cost-to-charge basis for provider-administered pharmaceuticals up to the maximum allowable cost as determined for the Medicare program. Medicaid providers are required to keep the records necessary to establish that conditions of payment for Medicaid covered services have been met[2] and that the claim has the appropriate HCPCS codes,[3] National Drug Code (NDC),[4] and quantity of the drug administered. The number of units billed should correspond to the quantity of Herceptin actually administered to the patient.

HOW WE CONDUCTED THIS REVIEW

The State agency processed 5,470 outpatient service line items of Herceptin totaling approximately $10 million from January 1, 2012, through December 31, 2014. Of these line items, 248 (totaling approximately $778,000) had unit counts of 44, 88, or 132, which represent billings equivalent to entire multiuse vials.[5] 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.

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.

Appendix B contains the details of our audit scope and methodology.

FINDINGS

Over half of the Medicaid payments that the State agency made to providers for full vials of Herceptin were incorrect. Of the 248 line items reviewed (totaling $778,073), 135 (54 percent) were incorrect and resulted in overpayments of $141,654 ($90,580 Federal share).[6] The 113 remaining line items were correct.

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[2] Chapter 5160-1-27(A) of the Ohio Administrative Code.

[3] Chapter 5160-1-19(C)(1) of the Ohio Administrative Code.

[4] The NDC serves as a universal product identifier for drugs using a unique three-segment number.

[5] Of the 248, we included 4 line items with high unit counts that did not represent billings equivalent to full vials but were likely to be incorrect.

[6] The Federal matching percentage ranged from 63.02 percent to 64.15 percent during our audit period.

On all of the incorrect line items, providers reported the units of service for the entire contents of one or more vial(s), each containing 440 milligrams of Herceptin, and billed Medicaid for the entire vials rather than the amounts actually administered.

For example, one provider administered 144 milligrams of Herceptin to a patient and billed for 144 units of service (1,440 milligrams). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 mg), the number of units to be reported for 144 milligrams is 15.[7] This error occurred on 2 separate occasions for 1 patient; as a result, the State agency paid the provider $4,493 when it should have paid $468, an overpayment of $4,025.

The providers attributed the incorrect payments to clerical and billing systems errors that could not prevent or detect the incorrect billing units of service. The State agency made these incorrect payments because it did not have sufficient edits in place during our audit period to prevent or detect the overpayments.

RECOMMENDATIONS

We recommend that the State agency:

- recover the identified overpayments and refund $90,580 to the Federal Government,
- 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.

STATE AGENCY COMMENTS

In written comments to our draft report, the State concurred with our recommendations and provided information on actions that it plans to take to address our recommendations. The State agency's comments are included in their entirety as Appendix C.

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

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Louisiana Made Incorrect Herceptin Payments to Medicaid Providers	A-06-15-00037	08/02/2016
New York Improperly Claimed Federal Medicaid Reimbursement for the Drug Herceptin Over a 3 Year Period	A-02-15-01013	07/27/2016
Indiana Made Incorrect Medicaid Payments to Providers for Full Vials of Herceptin	A-05-15-00035	05/16/2016
Most Medicaid Payments Oklahoma Made to Providers for Full Vials of Herceptin Were Correct	A-06-15-00023	10/15/2015
Most Medicaid Payments Arkansas Made to Providers for Full Vials of Herceptin Were Incorrect	A-06-14-00032	07/27/2015
Most Medicaid Payments Texas Made to Providers for Full Vials of Herceptin Were Incorrect	A-06-14-00042	06/04/2015
Most Medicaid Payments the State of Illinois Made to Providers for Full Vials of Herceptin Were Incorrect	A-05-14-00023	02/02/2015

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency processed 5,470 outpatient service line items of Herceptin totaling approximately $10 million from January 1, 2012, through December 31, 2014. Of these line items, we reviewed 248 totaling approximately $778,000. These 248 lines had unit counts of 44, 88, or 132, which represented billings equivalent to entire multiuse vials.[8]

We limited our review of the State agency's internal controls to those that were applicable to the selected payments because our objective did not require an understanding of all internal controls over the submission and processing of claims.

We conducted our audit work from February 2015 through September 2016 and contacted 23 providers in Ohio that received the selected Medicaid payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- obtained from the State agency Medicaid paid claims in which payments were made for HCPCS code J9355 (Herceptin) for service dates during the audit period;
- identified 248 line items in our scope that the State paid to 23 providers;
- contacted providers that received Medicaid 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 the medication,
    - the fact that the medication was administered, and

[8] Of the 248, we included 4 line items with high unit counts that did not represent billings equivalent to full vials but were likely to be incorrect.

- the type of solution that was used to reconstitute the Herceptin (BWFI containing 1.1 percent benzyl alcohol or sterile water);

- calculated the revised payment amounts for incorrect claim lines; and

- discussed the results of our review and coordinated overpayment amounts with the State agency.

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.

APPENDIX C: STATE AGENCY COMMENTS

Ohio
Department of Medicaid
John R. Kasich, Governor
Barbara R. Sears, Director

February 9, 2017

Sheri Fulcher
Office of Inspector General
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Dear Ms. Fulcher:

Thank you for the opportunity to respond to the draft report issued by the OIG regarding their review of Ohio's Herceptin claims.

The Ohio Department of Medicaid's (ODM) informal comments are the following:

Page 2/Findings – ODM would like to clarify that only 4.5% of total Herceptin claims paid during the period under audit were billing equivalents to entire multiuse vials (5,470/248). While ODM agrees that 135 claims reviewed were incorrect, this accounts for only 2.5% of all Herceptin claims paid during the period under audit. Furthermore, 108 of the 135 incorrect claims were made by the same provider and additional education has been delivered to that provider.

Page 3/Recommendation #1 – ODM has already recovered $71,591.88 (federal share) of the identified overpayments prior to the issuance of the draft report. ODM will work with providers to recover the additional $18,988.12 (federal share) of the identified overpayments and refund it to the federal government.

Page 3/Recommendation #2 – ODM will include within the ODM program integrity's agency risk assessment claims paid for full vials of Herceptin.

Page 3/Recommendation #3 – ODM will include the billing of full vials of Herceptin and the results of the OIG audit in the upcoming provider education activities and trainings.

ODM appreciates the OIG's review and recommendations. Thank you for the opportunity to review and provide informal comments on the draft report. Please let me know if you have questions or need additional information.

Sincerely,

/John Maynard/

John Maynard
Bureau of Program Integrity Director

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