Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INDIANA 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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Acting Assistant Inspector General
for Audit Services

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Office of Inspector General

http://oig.hhs.gov

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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.

Indiana made incorrect Medicaid payments to providers for full vials of Herceptin that resulted in overpayments of approximately $710,000 (Federal share).

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 Indiana Medicaid program.

OBJECTIVE

Our objective was to determine whether payments made by Indiana 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 Indiana, the Indiana Family and Social Services Administration (the State agency) administers its Medicaid program in accordance with the 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 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.

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

HOW WE CONDUCTED THIS REVIEW

The State agency processed 7,768 outpatient service line items of Herceptin totaling approximately $39 million from January 1, 2009, through December 31, 2014. Of these line items, 381 totaling approximately $3.5 million had unit counts of 44 or 88 that represent billings equivalent to entire multiuse vials.[1]

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 A contains the details of our audit scope and methodology.

FINDINGS

More than half of the Medicaid payments that the State agency made to providers for full vials of Herceptin were incorrect. Of the 381 line items reviewed, 203 (53 percent) were incorrect and included overpayments of $1,036,624 ($710,130 Federal share),[2] or almost a third of total dollars reviewed. The 178 remaining line items were correct.

For chemotherapy drugs, providers bill the State agency using revenue code 636 and the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and units. Additionally, in the case of manually priced J and Q codes such as Herceptin, providers also need to use the corresponding National Drug Code (NDC)[3] (Chapter 8 of the Indiana Health Coverage Programs Provider Manual). According to the Indiana Administrative Code (IAC), the State requires medical records to be of sufficient quality to fully disclose and document the extent of services provided (405 IAC 1-5-1) and may deny payments to providers when services claimed cannot be properly documented (405 IAC 1-1-4).

On nearly all of the incorrect line items, providers reported the units of service for the entire contents of one or two vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered.

[1] Of the 381 line items, 51 had unit counts of 100 or greater. Although these line items did not represent billings equivalent to a full vial, these high-unit items were included because they were likely to be incorrect.

[2] The Federal matching percentage ranged from 66.92 percent to 76.21 percent during our audit period.

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

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.

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS

Incorrect Number of Units of Service

Providers reported incorrect units of service on 200 line items, resulting in overpayments totaling $1,010,083 ($692,112 Federal share). Providers billed Medicaid for entire vials containing 440 milligrams of Herceptin, rather than billing only for the amounts actually administered.

For example, one provider administered 114 milligrams of Herceptin to a patient and billed for 114 units of service (1,140 milligrams). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 114 milligrams is 12.[4] This error occurred on 12 separate occasions for 1 patient; as a result, the State agency paid the provider $347,848 when it should have paid $36,616, an overpayment of $311,232 ($208,287 Federal share).

Unsupported Services

Providers billed Medicaid for three line items for which the providers did not provide supporting documentation. These line items are considered to be in error, resulting in overpayments totaling $26,541 ($18,018 Federal share).

RECOMMENDATIONS

We recommend that the State agency:

- recover the identified overpayments and refund $710,130 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.

[4] 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.

STATE AGENCY COMMENTS

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

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency processed 7,768 outpatient service line items of Herceptin totaling approximately $39 million from January 1, 2009, through December 31, 2014. Of these 7,768 line items, we reviewed 381 totaling approximately $3.5 million. These 381 lines had unit counts of 44 or 88 that represented billings equivalent to entire multiuse vials.[5]

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 the fieldwork for this review from June through September 2015 and contacted 45 providers in Indiana that received the selected Medicaid payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- obtained Medicaid paid claims in which payments were made for HCPCS code J9355 (Herceptin) for service dates during the audit period, from the State agency;
- identified 381 line items in our scope that the State paid to 45 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,
    - whether the medication was administered, and

[5] Of the 381 line items, 51 had unit counts of 100 or greater. Although these line items did not represent billings equivalent to a full vial, these high-unit items were included because they 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);

- coordinated the calculation of overpayments and discussed the results of our review 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 B: STATE AGENCY COMMENTS

Michael R. Pence, Governor
State of Indiana

Office of Medicaid Policy and Planning
MS 07, 402 W. WASHINGTON STREET, ROOM W382
INDIANAPOLIS, IN 46204-2739

April 15, 2016

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

Re: OIG Report No. A-05-15-00035

Dear Ms. Fulcher:

The Indiana Family and Social Services Administration's Office of Medicaid Policy and Planning (Indiana Medicaid) appreciates the opportunity to comment on the draft report of the Office of the Inspector General (OIG) entitled "*Indiana Made Incorrect Medicaid Payments to Providers for Full Vials of Herceptin*", Report No. A-05—15-00035 dated February 23, 2016 and received by the State on February 23, 2016 (Audit Report). The OIG found that 203 of 381 Herceptin Medicaid payments, for which the State claimed Federal financial participation, were paid incorrectly due to provider submitted erroneous charges. The state concurs with these findings.

In October 2015, the OIG provided the State with a spreadsheet containing two hundred three (203) claims included in OIG audit A-05-15-00035. This spreadsheet also included a column for claim amount paid, OIG calculated payment, and overpayment identified for the individual claims and verified by the OIG. Given the information supplied in this spreadsheet, the State and its contractor(s) re-priced the claims based on the documented units of Herceptin used by providers in order to determine any potential overpayments due from providers. Potential overpayments were identified by subtracting the re-priced Indiana Medicaid payment from the original Indiana Medicaid payment received by providers on the originally submitted claim after any and all claim adjustments or voids were taken into consideration. The resulting estimated total overpayment amount identified for all 203 claims involved in the audit was $1,036,623.57, of which the Federal share will be returned.

Beginning in February 2016, based on the information supplied by the OIG and the re-pricing calculations completed by the State and its contractor, Indiana Medicaid Program Integrity began sending out either a Draft Audit Findings (DAF) letter or a Final Audit Findings (FAF) letter to the forty-four (44) providers included within the OIG audit. In the twenty (20) DAF letters, providers are informed of the identified potential errors and provided a form to indicate either their agreement with the audit findings, or their disagreement with the audit findings and request Administrative Reconsideration of the findings. In instances in which the provider agrees with the draft audit findings and returns the provider intent form indicating agreement, the State and its contractor(s) will draft the Final Calculation of Overpayment letter, denoting the amount to be refunded to Indiana Medicaid, as well as any applicable interest assessed against the overpayment amount. In the twenty-four (24) FAF letters, no overpayment is identified against the providers and the provider is informed that the audit process is complete.

In instances in which the provider may disagree with the draft audit findings and requests administrative reconsideration, the State will work with these providers to finalize the audit findings. In these instances, a Response to Request for Administrative Reconsideration letter is prepared, again outlining the audit findings and addressing any issues or concerns raised by the provider in their response to the DAF letter. Providers are again asked to submit the appropriate documentation or applicable arguments to support their appeal of the audit findings. It is our intent to mail all of the initial audit letters (DAFs and FAFs) to providers by June 1, 2016. Enclosed is a copy of the DAF letter for this report.

We are developing a communication reminding providers how to appropriately bill correct amounts of physician-administered drugs. We anticipate this communication will be sent to providers in May 2016. The FSSA PI team is in the early stages of contacting the state's MMIS vendor to determine the feasibility of implementing system audits/edits for identifying multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial. In the interim, FSSA PI will work with the Indiana Medicaid Pharmacy Team to develop a list of physician-administered drugs, and the corresponding number of units in a standard dose vial to develop an algorithm to look for other instances of claims billed for the number of units that corresponds to the units contained in a multi-use vial of the drug. We anticipate this algorithmic review will be initiated June 2016.

We appreciate the opportunity to respond to the OIG's report and your consideration of the information provided in this letter. If you have any questions or require additional information, please contact James Waddick at 317-234-7484 or James.Waddick@fssa.in.gov.

Sincerely,

Joseph Moser

Joseph Moser
Medicaid Director

Enclosures