

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ASHTABULA COUNTY
MEDICAL CENTER
INCORRECTLY BILLED
MEDICARE FOR
LEUPROLIDE ACETATE IMPLANTS**

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



**Stephen Virbitsky
Regional Inspector General**

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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.

EXECUTIVE SUMMARY

BACKGROUND

Leuprolide acetate, a drug used in the treatment of advanced prostate cancer in men and the management of other medical conditions in women and children, may be administered as an implant or an injection. Leuprolide acetate implants are inserted into the patient's upper arm and provide continuous treatment for advanced prostate cancer for 12 months. Providers bill Medicare 1 unit of service for each 65-milligram implant. Leuprolide acetate (for depot suspension) injections are administered to patients using a prefilled syringe that provides treatment for either 1 month (7.5 milligrams), 3 months (22.5 milligrams), 4 months (30 milligrams), or 6 months (45 milligrams). Providers bill Medicare 1 unit of service for each 7.5 milligrams administered. Therefore, leuprolide acetate implants billed for more than one unit or more than once in a 12-month period may represent incorrect billing for the injected drug.

Title XVIII of the Social Security Act established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as implanted and injected drugs. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to process and pay Medicare claims submitted for outpatient services. Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims.

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. CMS assigned HCPCS code J9219 with a narrative description of "leuprolide acetate implant, 65 mg [milligrams]" and HCPCS code J9217 with a narrative description of "leuprolide acetate (for depot suspension), 7.5 mg [milligrams]." CMS has assigned additional HCPCS codes for doses of leuprolide acetate (1 milligram and 3.75 milligrams) that are used in the management of medical conditions in women and children. These doses are not used in the treatment of advanced prostate cancer.

During our audit period (January 1, 2009, through December 31, 2011), Ashtabula County Medical Center (Medical Center) received payments from Medicare totaling \$264,590 for 14 line items for leuprolide acetate implants administered to 7 beneficiaries. Of the 14 line items, 9 were billed for 6 units each and 5 line items were billed for 1 unit each. (After we identified the nine line items billed for six units each, and as a result of our inquiry, the Medical Center brought to our attention four line items billed for one unit each. Subsequently, we identified one additional claim for one unit.) 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 the Medical Center correctly billed and was correctly paid by Medicare for leuprolide acetate implants.

SUMMARY OF FINDING

All of the 14 line items that the Medical Center billed for leuprolide acetate implants were incorrect.

- For each of nine line items, the Medical Center incorrectly billed Medicare for six units of leuprolide acetate implants rather than for three units of leuprolide acetate (for depot suspension) injections, the service actually administered.
- For each of five line items, the Medical Center incorrectly billed Medicare for one unit of service for leuprolide acetate implants, rather than for three units of leuprolide acetate (for depot suspension) injections, the service actually administered.

The Medical Center did not administer any leuprolide acetate implants. Rather, the Medical Center billed Medicare using the incorrect HCPCS code and the incorrect units of service. As a result, it received a total of \$264,590 for the 14 line items instead of the \$6,908 it should have received, an overpayment of \$257,682. At the time of our audit, these overpayments remained outstanding from the Medical Center.

RECOMMENDATIONS

We recommend that the Medical Center:

- refund to the Medicare contractor the \$257,682 in identified overpayments and
- strengthen controls to ensure compliance with Medicare requirements.

MEDICAL CENTER COMMENTS

In response to our audit inquiry, the Medical Center agreed with our finding and described the action it planned to take to correct the errors. The Medical Center's comments are included as the appendix.

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INTRODUCTION

BACKGROUND

Leuprolide acetate, a drug used in the treatment of advanced prostate cancer in men and the management of other medical conditions in women and children, may be administered as an implant or an injection. Leuprolide acetate implants are inserted into the patient's upper arm and provide continuous treatment for advanced prostate cancer for 12 months. Providers bill Medicare 1 unit of service for each 65-milligram implant. Leuprolide acetate (for depot suspension) injections are administered to patients using a prefilled syringe that provides treatment for either 1 month (7.5 milligrams), 3 months (22.5 milligrams), 4 months (30 milligrams), or 6 months (45 milligrams). Providers bill Medicare 1 unit of service for each 7.5 milligrams administered. Therefore, leuprolide acetate implants billed for more than one unit or more than once in a 12-month period may represent incorrect billing for the injected drug.

The Medicare Program

Title XVIII of the Social Security Act established the Medicare program to provide health insurance for people aged 65 and over and individuals with disabilities or permanent kidney disease. Part B of the Medicare program provides supplementary medical insurance for medical and other health services, including outpatient services such as implanted and injected drugs. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to, among other things, process and pay claims submitted for outpatient services. Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims.

Claims for Outpatient 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)¹ code for drugs administered and report units of service in multiples of the units shown in the HCPCS narrative description.

Ashtabula County Medical Center

Ashtabula County Medical Center (the Medical Center) is a not-for-profit acute care hospital located in Ashtabula, Ohio. For most of our audit period, National Government Services was the Medicare Contractor for the Medical Center. In October 2011, CGS Administrators, LLC, assumed full responsibility for the Jurisdiction 15 workload (Ohio and Kentucky), including those claims paid by National Government Services.

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the Medical Center correctly billed and was correctly paid by Medicare for leuprolide acetate implants.

Scope

During our audit period (January 1, 2009, through December 31, 2011), the Medical Center received payments from Medicare totaling \$264,590 for 14 line items for leuprolide acetate implants administered to 7 beneficiaries. In this audit, we did not review entire claims; rather, we reviewed specific line items within the claims.

We limited our review of the Medical Center'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. 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 our fieldwork during May and June 2012 by contacting the Medical Center in Ashtabula, Ohio, and CGS Administrators, LLC, in Columbia, South Carolina.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- analyzed CMS's National Claims History file to identify claims for implanted drugs potentially at risk for noncompliance with selected Medicare billing requirements;
- identified all 14 line items totaling \$264,590 for leuprolide acetate implants (HCPCS code J9219) billed by the Medical Center: 9 line items billed for 6 units each that exceeded the recommended dose and 5 line items billed for 1 unit each;²
- contacted the Medical Center to determine whether the billed units for the selected line items were correct and, if not, why the billed units were incorrect;
- reviewed patient medical records, specifically the physician orders and drug administration records, to verify whether each selected line item was billed correctly;
- coordinated the calculation of overpayments with the Medicare contractor; and
- discussed the results of our review with Medical Center officials.

² After we identified the nine line items billed for six units each, and as a result of our inquiry, the Medical Center brought to our attention four line items billed for one unit each. Subsequently, we identified one additional claim for one unit.

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.

FINDING AND RECOMMENDATIONS

All of the 14 line items that the Medical Center claimed for leuprolide acetate implants were incorrect.

- For each of nine line items, the Medical Center incorrectly billed Medicare for six units of leuprolide acetate implants rather than for three units of leuprolide acetate (for depot suspension) injections, the service actually administered.
- For each of five line items, the Medical Center incorrectly billed Medicare for one unit of service for leuprolide acetate implants, rather than for three units of leuprolide acetate (for depot suspension) injections, the service actually administered.

The Medical Center did not administer any leuprolide acetate implants. Rather, the Medical Center billed Medicare using the incorrect HCPCS code and the incorrect units of service. As a result, it received a total of \$264,590 for the 14 line items instead of the \$6,908 it should have received, an overpayment of \$257,682. At the time of our audit, these overpayments remained outstanding from the Medical Center.

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 Medicare Claims Processing Manual, Pub. No. 100-04 (the Manual), chapter 17, section 90.2.A states: “It is also of great importance that hospitals billing for these products [drugs, biologicals, and radiopharmaceuticals] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity ... that was used in the care of the patient.” Chapter 17, section 70, of the Manual states, “[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” Further, 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.”

MEDICARE BILLING FOR LEUPROLIDE ACETATE

Leuprolide acetate is used for the treatment of advanced prostate cancer in men and the management of other medical conditions in women and children. Leuprolide acetate implants are used to provide continuous treatment for 12 months to patients with advanced prostate cancer. CMS assigned HCPCS code J9219 to this procedure with a narrative description of

“leuprolide acetate implant, 65 mg [milligrams].” Providers bill Medicare for 1 unit of service

Leuprolide acetate (for depot suspension) injections are used to provide continuous treatment for less than 12 months to patients with advanced prostate cancer. CMS assigned HCPCS code J9217 to this procedure with a narrative description of “leuprolide acetate (for depot suspension), 7.5 mg [milligrams].” Leuprolide acetate (for depot suspension) is available in prefilled syringes containing 7.5 milligrams (1-month dose), 22.5 milligrams (3-month dose), 30 milligrams (4-month dose), or 45 milligrams (6-month dose).³ Therefore, providers bill Medicare for one, three, four, or six units of service, respectively, depending on the dose administered.

INCORRECT HEALTHCARE COMMON PROCEDURE CODING SYSTEM CODE

For all 14 line items for leuprolide acetate implants, the Medical Center used the incorrect HCPCS code and incorrect units, resulting in overpayments totaling \$257,682. For each of nine line items, the Medical Center billed Medicare for six units of service using HCPCS code J9219 (leuprolide acetate implant) rather than three units of service using HCPCS code J9217, (leuprolide acetate for depot suspension). For each of the remaining five line items, the Medical Center billed Medicare for one unit of service using HCPCS code J9219 rather than three units of J9217. As a result, the Medical Center received payments totaling \$264,590 for the 14 line items when it should have received only \$6,908, an overpayment of \$257,682. At the time of our audit, these overpayments remained outstanding.

RECOMMENDATIONS

We recommend that the Medical Center:

- refund to the Medicare contractor the \$257,682 in identified overpayments and
- strengthen controls to ensure compliance with Medicare requirements.

MEDICAL CENTER COMMENTS

In response to our audit inquiry, the Medical Center agreed with our finding and described the action it planned to take to correct the errors. The Medical Center’s comments are included as the appendix.

³ CMS has assigned additional HCPCS codes for doses of leuprolide acetate (1 milligram and 3.75 milligrams) that are used in the management of medical conditions in women and children. These doses are not used in the treatment of advanced prostate cancer.

APPENDIX

APPENDIX: MEDICAL CENTER COMMENTS

**Ashtabula County
Medical Center**
ACMC Healthcare System

An affiliate of
 **Cleveland Clinic**

June 29, 2012

Mr. John Carlucci
Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106

Re: A-03-12-00010

Dear Mr. Carlucci,

Upon receipt of your letter dated May 07, 2012, we reviewed the accounts in question and found that we had billed with a cpt/hcpcs code of J9219 incorrectly. We reviewed claims back to 2009 and found four others that were coded incorrectly. We included those along with the nine accounts that were brought to our attention by the Department of Health and Human Services.

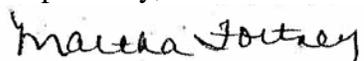
You have since recognized and brought to our attention another account that fell into the same category. I did send that corrected claim to you for review.

Our coding personnel, who is no longer employed at Ashtabula County Medical Center, had erroneously instructed that the cpt/hcpcs code should be J9219 (leuprolide implant). I previously sent those corrected claims reflecting the correct cpt/hcpcs code and number of units for your review.

We have since submitted adjustment claims on all the accounts mentioned.

If you need further information, please do not hesitate to contact me.

Respectfully,



Martha Fortney
Supervisor, Patient Financial Services
p: 440)997-6664

2420 Lake Avenue
Ashtabula, OH 44004

Phone 440.997.2262
Fax 440.997.6644
www.acmchealth.org