

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOWER LIMB PROSTHETICS CLAIMS
PAID TO OZARK PROSTHETICS AND
ORTHOTICS WERE NOT ALWAYS
SUPPORTED BY ADEQUATE
DOCUMENTATION**

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Patrick J. Cogley
Regional Inspector General

April 2013
A-07-12-05029

Office of Inspector General

<https://oig.hhs.gov/>

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EXECUTIVE SUMMARY

BACKGROUND

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Social Security Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). The Centers for Medicare & Medicaid Services (CMS) contracts with four DME Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims.

When submitting claims to DME MACs, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes as well as modifiers that indicate left or right limb and a functional level. Each claim can include multiple HCPCS codes, each of which represents a different component of the lower limb prosthetic provided by the supplier. A lower limb prosthetic is an artificial replacement for any or all parts of the leg and provides an individual who has an amputated limb with the opportunity to perform functional tasks, particularly walking, which may not be possible without the device.

DME MACs develop local coverage determinations (LCD) for some covered DMEPOS items. LCDs describe the circumstances for Medicare coverage for lower limb prosthetics and outline the conditions under which DME MACs will cover those devices. LCDs require that some lower limb prosthetics have minimum functional levels to be covered by Medicare.

To be paid for a Medicare DMEPOS claim, the supplier must have on file: (1) written documentation of a verbal order/preliminary written order, (2) a detailed written order, (3) proof of delivery, (4) a beneficiary authorization, (5) information from the treating physician concerning the patient's diagnosis, and (6) any information required for the use of specific modifiers or attestation statements as defined in certain DME policies.

A DMEPOS supplier should also obtain as much documentation from the patient's medical records as it requires to ensure that the coverage criterion for an item has been met. If the information in the patient's medical records does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.

This review was completed as followup work to the Office of Inspector General, Office of Evaluation and Inspections, review, *Questionable Billing by Suppliers of Lower Limb Prostheses*, issued in August 2011.

Kessler Heasley Artificial Limb, also known as Ozark Prosthetics & Orthotics (Ozark), based in Springfield, Missouri, supplies lower limb prosthetics.

OBJECTIVE

Our objective was to determine whether Ozark's paid claims for lower limb prosthetics were supported in accordance with Medicare DMEPOS documentation requirements.

SUMMARY OF FINDINGS

Ozark's paid claims for lower limb prosthetics were not always supported in accordance with Medicare DMEPOS documentation requirements. Of the 99 reviewed beneficiary-days (a beneficiary-day represents claim(s) paid for 1 beneficiary for 1 day) totaling \$1,102,611 in payments, 50 beneficiary-days were supported in accordance with Medicare DMEPOS documentation requirements. However, the remaining 49 beneficiary-days were either not supported or were only partially supported in accordance with Medicare DMEPOS documentation requirements. Specifically, we identified the following deficiencies (10 beneficiary-days had 2 errors each and 2 beneficiary-days had 3 errors each):

- For 46 beneficiary-days, Ozark did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims.
- For 12 beneficiary-days, Ozark's documentation did not support the minimum functional level, as required by the LCD, of the prosthetics for which it had submitted the claims.
- For three beneficiary-days, Ozark submitted claims that included HCPCS codes which, when billed in combination with certain other HCPCS codes, were not reasonable or necessary as required by the LCD.
- For two beneficiary-days, Ozark did not obtain properly completed written orders from physicians before submitting the claims.

Ozark submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. As a result of these errors, Ozark received payments totaling \$67,306 for the 49 beneficiary-days that were not supported in accordance with Medicare DMEPOS documentation requirements during the period January 1, 2009, through December 31, 2011.

RECOMMENDATIONS

We recommend that Ozark:

- refund \$67,306 to the Federal Government for unallowable lower limb prosthetic claims and
- strengthen internal controls by developing and implementing policies and procedures to help ensure that it collects and maintains the required documentation and conforms to the requirements of the LCD.

AUDITEE COMMENTS

In written comments on our draft report, Ozark partially concurred with our findings. Ozark stated that if there is doubt on documentation, Ozark should get credit for having it. Ozark also described procedures it had implemented to allow its staff to know whether required documentation is in place. Additionally, Ozark stated that many of its patients who are initially evaluated at a lower functional level can attain a higher functional level “in a couple of months.”

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing Ozark’s comments, we maintain that our findings and recommendations are valid. The provisions of CMS’s *Medicare Program Integrity Manual*, the *Jurisdiction D DME MAC Supplier Manual*, and the LCD for lower limb prosthetics are very specific as to the requirements that must be met for these types of claims to be allowable, and we continue to believe that the claims we questioned did not conform to these requirements.

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INTRODUCTION

BACKGROUND

Medicare Coverage of Durable Medical Equipment

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, enacted December 8, 2003, CMS contracted with four DME Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. When submitting claims to DME MACs, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes¹ as well as modifiers that indicate left or right limb and a functional level.² Each claim can include multiple HCPCS codes, each of which represents a different component of the lower limb prosthetic provided by the supplier. A lower limb prosthetic is an artificial replacement for any or all parts of the leg and provides an individual who has an amputated limb with the opportunity to perform functional tasks, particularly walking, which may not be possible without the device.

DME MACs develop local coverage determinations (LCD) for some covered DMEPOS items. LCDs describe the circumstances for Medicare coverage for lower limb prosthetics and outline the conditions under which DME MACs will cover those devices. LCDs require that some lower limb prosthetics have minimum functional levels to be covered by Medicare.

This review was completed as followup work to an Office of Inspector General, Office of Evaluation and Inspections, review.³

¹ HCPCS codes are used throughout the health care industry as a standardized coding system for describing and identifying health care equipment and supplies in health care transactions.

² Lower limb prosthetic functional levels are submitted in terms of K-levels. Functional levels range from a K0 (the patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthetic does not enhance his/her quality of life or mobility) through a K4 (the patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills and that exhibits high impact, stress, or energy levels; this level is typical of the prosthetic demands of the child, active adult, or athlete). Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician.

³ *Questionable Billing by Suppliers of Lower Limb Prostheses* (OEI-02-10-00170), issued August 2011.

Medicare Durable Medical Equipment Documentation Requirements

Pursuant to the *Jurisdiction D DME MAC Supplier Manual*, before submitting a claim to the DME MAC, the supplier must have on file: (1) written documentation of a verbal order/preliminary written order, (2) a detailed written order, (3) proof of delivery, (4) a beneficiary authorization, (5) information from the treating physician concerning the patient's diagnosis, and (6) any information required for the use of specific modifiers or attestation statements as defined in certain DME policies.

A DMEPOS supplier should also obtain as much documentation from the patient's medical record as it requires to ensure that the coverage criterion for an item has been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.

Ozark Prosthetics and Orthotics

Kessler Heasley Artificial Limb, also known as Ozark Prosthetics and Orthotics (Ozark), based in Springfield, Missouri, supplies lower limb prosthetics.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Ozark's paid claims for lower limb prosthetics were supported in accordance with Medicare DMEPOS documentation requirements.

Scope

We reviewed a total of \$2,311,483 in DMEPOS claims that Ozark submitted for lower limb prosthetics and that DME MACs paid during the period January 1, 2009, through December 31, 2011.

Our review focused on whether Ozark met Medicare documentation requirements for lower limb prosthetics. We did not conduct a medical review to determine whether the services were medically necessary. However, we communicated with Noridian Administrative Services, LLC (Noridian),⁴ about the allowability of certain HCPCS codes and the LCD for the lower limb prosthetics.

We did not review Ozark's overall internal control structure. We limited our review of internal controls to those related to our audit objective.

We conducted our fieldwork in June 2012 at Ozark's office in Springfield, Missouri.

⁴ Noridian is the DME MAC for Medicare DME Jurisdiction D. Ninety-seven percent of the claims submitted by Ozark were processed and paid by Noridian.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and DME MAC guidance;
- reviewed Ozark's policies and procedures for submitting claims for lower limb prosthetics;
- interviewed staff at Ozark to gain an understanding of its process for billing DMEPOS claims for lower limb prosthetics;
- discussed with staff at Noridian the allowability of lower limb prosthetic claims that contained HCPCS code L7368 (lithium ion battery charger);
- obtained electronic paid claims data for Ozark during the period January 1, 2009, through December 31, 2011;
- selected a sample of 99 paid beneficiary-days⁵ from the 386 paid beneficiary-days during the period January 1, 2009, through December 31, 2011;
- obtained and reviewed the supporting documentation for each beneficiary-day that we reviewed to determine the allowability of the claims; and
- discussed the results of our review with Ozark officials on June 8, 2012.

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

Ozark's paid claims for lower limb prosthetics were not always supported in accordance with Medicare DMEPOS documentation requirements. Of the 99 reviewed beneficiary-days totaling \$1,102,611 in payments, 50 beneficiary-days were supported in accordance with Medicare DMEPOS documentation requirements. However, the remaining 49

⁵ Beneficiary-days are paid DMEPOS claims that were grouped by unique Medicare health insurance code and date of service. Stated differently, a beneficiary-day represents claim(s) paid for 1 beneficiary for 1 day.

We designed this audit with the intent of using statistical sampling. However, the statistical projection resulted in questioned costs that were only slightly higher than the results from the sample items. Therefore, we elected to report only on the results of the 99 sample items that we reviewed. Our reviewed claims consisted of all paid beneficiary-days (28) with claimed costs greater than or equal to \$15,000, along with an additional 71 paid beneficiary-days that were randomly selected from the remaining 358 paid beneficiary-days whose claimed costs were less than \$15,000 but greater than \$1,000.

beneficiary-days were either not supported or were only partially supported in accordance with Medicare DMEPOS documentation requirements. Specifically, we identified the following deficiencies (10 beneficiary-days had 2 errors each and 2 beneficiary-days had 3 errors each):

- For 46 beneficiary-days, Ozark did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims.
- For 12 beneficiary-days, Ozark's documentation did not support the minimum functional level, as required by the LCD, of the prosthetics for which it had submitted the claims.
- For three beneficiary-days, Ozark submitted claims that included HCPCS codes which, when billed in combination with certain other HCPCS codes, were not reasonable or necessary as required by the LCD.
- For two beneficiary-days, Ozark did not obtain properly completed written orders from physicians before submitting the claims.

Ozark submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. As a result of these errors, Ozark received payments totaling \$67,306 for the 49 beneficiary-days that were not supported in accordance with Medicare DMEPOS documentation requirements during the period January 1, 2009, through December 31, 2011.

MEDICARE DOCUMENTATION REQUIREMENTS NOT MET

Necessity of Claim Items Not Substantiated by Medical Records

Chapter 5, section 5.7, of CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the manual), states:

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered ... if the information in the patient's medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved.

Further, Chapter 5, section 5.8, of the manual provides that "[t]he supplier should ... obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met."

For 46 of the 99 beneficiary-days that we reviewed, Ozark did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims (6 beneficiary-days had more than 1 error). Specifically:

- For 25 beneficiary-days, Ozark submitted claims using HCPCS code L7520 (repair prosthetic device, labor component, per 15-minute increments) without sufficient support for the actual repair time used. In accordance with Noridian's Policy Article (A25367) effective January 2011, documentation must exist in the supplier's records indicating the specific adjustment and/or repair performed and the time involved. One unit of service using HCPCS code L7520 represents 15 minutes of labor time; the time reported for this code must be only for actual repair time. Ozark's records did not have sufficient support for the actual repair time involved in these procedures. As a result of these errors, Ozark received overpayments totaling \$5,447.
- For 22 beneficiary-days, Ozark submitted claims using HCPCS code L7368 (lithium ion battery charger). This code is for a replacement charger for a prosthetic that contains electronic components. However, for each of these claims Ozark also billed for a different HCPCS code for a prosthetic that included a battery charger. Accordingly, an additional bill for a replacement battery charger was not allowable unless supported by documentation substantiating its necessity. Ozark's documentation did not contain support for the necessity of a replacement charger. As a result of these errors, Ozark received overpayments totaling \$8,017.
- For five beneficiary-days, Ozark did not maintain sufficient documentation to substantiate the necessity for the items ordered. The HCPCS codes for these items were not included on the physicians' detailed written orders, and those items were therefore not authorized by the physicians. As a result of these errors, Ozark received overpayments totaling \$4,274.

Minimum Functional Level of Claimed Items Not Supported by Documentation

The LCD (L11453) for lower limb prosthetics states that a high-activity knee control frame (HCPCS code L5930) is covered for patients whose functional level is K4.

For 12 of the 99 beneficiary-days that we reviewed, Ozark's documentation did not support the minimum functional level, as required by this LCD, of the prosthetics for which it had submitted claims. Specifically, Ozark was paid for lower limb prosthetic claims that it had submitted using HCPCS code L5930 which required a minimal functional level of K4. These claims were unallowable because the physicians and/or the supplier assessed the beneficiaries as having a K3 functional level. Therefore, these claims did not meet the minimum functional level requirement for HCPCS code L5930. As a result of these errors, Ozark received overpayments totaling \$29,141.

Claims Not Reasonable and Necessary

From the LCD (L11453) for lower limb prosthetics:

- When an above-knee preparatory prosthesis L5590 is provided, the following codes will be denied as not reasonable and necessary: L5610, L5631, L5640, L5642, L5644, L5648, L5705, L5706, L5964, L5980, L5710-L5780, and L5790-L5795.
- When a preparatory below-knee prosthesis L5540 is provided, the following codes will be denied as not reasonable and necessary: L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980.

For 3 of the 99 beneficiary-days that we reviewed, Ozark was paid for lower limb prosthetic claims that included HCPCS codes which, when billed in combination with certain other HCPCS codes, were not reasonable or necessary as required by the LCD. Ozark submitted two claims with the unallowable combination of HCPCS codes L5980 and L5590 and one other claim with the unallowable combination of HCPCS codes L5629 and L5540. Prosthetic substitutions and/or additions of procedures and components are allowable in accordance with the functional level assessment, except for combinations specifically identified in the LCD as not reasonable and necessary. As a result of these errors, Ozark received overpayments totaling \$6,414.

Detailed Written Order Not Obtained Prior to Claim Submission

Chapter 5, section 5.2.3, of the manual provides that a “supplier must have a detailed written order prior to submitting a claim.... [T]he treating physician must ... personally sign and date the order ... if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.”

For 2 of the 99 beneficiary-days that we reviewed, Ozark did not obtain properly completed detailed written orders from physicians before submitting the claims. As a result of these errors, Ozark received overpayments totaling \$14,013.

INADEQUATE INTERNAL CONTROLS

Ozark submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. Specifically, Ozark did not have policies and procedures in place to ensure that it collected and maintained all required documentation for lower limb prosthetic claims and that it billed only for properly supported HCPCS codes and for HCPCS codes that were, according to the LCD, considered reasonable and necessary when billed in combination with other billed HCPCS codes.

OVERPAYMENTS FOR UNSUPPORTED CLAIMS

Of the 99 beneficiary-days that we reviewed, 49 did not comply with the Medicare DMEPOS requirements. Ozark received overpayments totaling \$67,306 for unsupported lower limb prosthetic claims during the period January 1, 2009, through December 31, 2011.

RECOMMENDATIONS

We recommend that Ozark:

- refund \$67,306 to the Federal Government for unallowable lower limb prosthetic claims and
- strengthen internal controls by developing and implementing policies and procedures to help ensure that it collects and maintains the required documentation and conforms to the requirements of the LCD.

AUDITEE COMMENTS

In written comments on our draft report, Ozark partially concurred with our findings. Ozark stated that if there is doubt on documentation, Ozark should get credit for having it. Ozark added that codes were sometimes missed on written detailed orders. Ozark explained that it had implemented several procedures to allow its staff to know whether required documentation is in place, and said that orders will now be checked for missing or inappropriate codes before being sent to doctors' offices. Ozark also noted that if orders are subsequently changed, updated orders will be provided to doctors' offices. Additionally, Ozark stated that many of its patients who are initially evaluated at a lower functional level can attain a higher functional level "in a couple of months." Ozark concluded by saying that procedures would be brought up to standards and kept that way.

Ozark's comments appear in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing Ozark's comments, we maintain that our findings and recommendations are valid. The provisions of CMS's *Medicare Program Integrity Manual*, the *Jurisdiction D DME MAC Supplier Manual*, and the LCD for lower limb prosthetics are very specific as to the requirements that must be met for these types of claims to be allowable, and we continue to believe that the claims we questioned did not conform to these requirements.

APPENDIX

APPENDIX: AUDITEE COMMENTS

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January 31, 2013
Report number: A-07-05029

Mr. Cogley,

This response is to the audit report received for Ozark Prosthetics & Orthotics for the period of January 01, 2009 through December 31, 2011.

Basically I concur with the audit findings, but not all of them. If there is doubt on documentation, the supplier should get credit for having it.

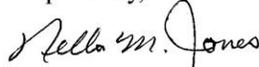
In the last couple of years there have been several procedures implemented that allow the staff to know if the required documentation is in place. There is now documentation in the patient electronic chart as well as a form that allows the staff to know where in the paperwork process each document is at. The form allows monitoring for who checked the documentation, when, and the status of the it. Only after the form is completed/entered into the electronic record is the device/item fabricated/ordered, and then delivered.

On the written detailed orders missing codes, codes were sometimes missed on the code sheet and entered after the Written Detailed Order was sent to the Dr. Now, there are no Written Detailed Orders sent out until after each order is checked for missing or inappropriate codes. Should the order be changed by the practitioner a new Detailed Written Order is sent to the Dr. with explanation and for his signature.

Several of our adult patients are potential K4 patients. They are motivated and anxious to get back to their lives. Many of them work regular jobs, hunt, fish, play golf, tennis, and farm, which make them a high activity patient. These patents are at a K3 when we first evaluate them because they still have to learn the basics of using a prosthesis. Normally in a couple of months, they are up to a K4 and the knee will have to be replaced.

Thank you for your input and suggestions. We will make sure everything is brought up to standards and kept that way.

Respectfully,



Nella M. Jones
Office Manager