

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Claim for

Kohll's Pharmacy
& Homecare, Inc.

(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiary)

(HIC Number)

Noridian Administrative
Services

(Contractor)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated May 12, 2009, which concerned Medicare coverage for 240 units of zinc paste impregnated bandages (A6456) (surgical dressings) provided by the appellant to the beneficiary on June 30, 2008. The ALJ denied coverage for the surgical dressings, on the ground that the documentation did not show they were medically reasonable and necessary, and held that the provider (but not the beneficiary) is liable for the costs of the noncovered supplies. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c). The appellant's request for review will be made a part of the record as Exhibit (Exh.) MAC-1. For the reasons forth below, the Council modifies the ALJ's decision.

Background and Appellant's Contentions

The medical records in this case (submitted at the ALJ hearing level) show that on June 24, 2008, the beneficiary's physician observed that the beneficiary had wounds from venous stasis ulcer disease that had healed, but still had multiple small punctate ulcers, and edema causing those small wounds not to heal. Exh. 10 at 3. The doctor prescribed Unna boots (requiring the zinc impregnated dressings), to be applied twice a week for one month to the beneficiary's bilateral lower extremities. *Id.* at 19. One month later, the physician's notes show that the beneficiary's punctate ulcers had healed and the edema was much decreased. *Id.* at 4.

The contractor denied Medicare coverage for the dressings (Exh. 7 at 3-7), as did the Qualified Independent Contractor (QIC) (Exh. 9 at 1-4). The QIC explained that the claim could not be considered further without medical records, and also referred the appellant to the Region A Local Coverage Determination (LCD) "L11471 Surgical Dressings." *Id.* at 2.¹ On December 23, 2008, the appellant sought ALJ review (waiving a hearing), and supplied the relevant medical records from the physician. Exh. 10 at 1-4.

On May 12, 2009, the ALJ denied the appellant's claim for Medicare coverage of the surgical dressings. The ALJ's denial was based on two grounds. First, the ALJ found that the appellant had not provided a good cause statement for submitting supporting medical records from the physician after the Qualified Independent Contractor (QIC) reconsideration stage, and that therefore the medical records would not be considered. Dec. at 2-3, 4, 5-7, *citing* 42 C.F.R. §§ 405.1018(c) and 405.1028. Second, the ALJ found that the documentation in the record did not support the necessity of the type and quantity of the surgical dressings provided. Dec. at 6. The ALJ noted that the physician's order called for the application of an Unna boot to the beneficiary's bilateral lower extremities twice a week for one month. *Id.*; see Exh. 3 at 1 (physician's order). The original claim was for 240 units of surgical dressings at \$528. *Id.* The amended claim was for 160 units at \$352. *Id.* In addition, the ALJ determined that the appellant is liable for the noncovered charges because it knew or should have known that Medicare would not cover the surgical dressings, and that the beneficiary is not liable. Dec. at 6-7.

¹ It appears, however, that the correct LCD number is L11460.

In its request for review, the appellant contends that the information the contractor provided did not state that documentation submitted after the QIC reconsideration stage required a demonstration of good cause. Exh. MAC-1. The appellant states that it provided medical records at the ALJ stage (Exh. Exh. 10 at 1, 3, and 4) because the QIC reconsideration said they were required (Exh. 10 at 6).

The appellant also contends that it made efforts to clarify the quantity of surgical dressings provided. The appellant states that it submitted a corrected Health Insurance Claim Form, reducing the charges from \$528 for 240 units (Exh. 4 at 2) to \$352.00 for 160 units (Exh. 7 at 8), and that it explained to the clerk that the amount dispensed was 16 packages of 10 each (equaling 160 units). Exh. MAC-1.

After reviewing the record and the appellant's contentions, the Council concludes that the ALJ erred in excluding the medical evidence submitted by the appellant following the QIC reconsideration, for the reasons explained below. The Council also concludes that the surgical dressings at issue here are not covered by Medicare, because the applicable Policy Article (A23903 Surgical Dressings) does not cover their use for wounds that are neither surgical nor debrided. Each of these points is discussed below.

Appellant's Submission of Medical Records at the ALJ Level

The Council finds that the appellant did have good cause for submitting medical records as additional evidence at the ALJ level of appeal. Appellant explained that it did not have reason to think that the medical records were required until the QIC reconsideration stated that they were needed to show medical necessity. See Exh.9 at 2 (QIC reconsideration); see also LCD L11460 ("This documentation [patient's medical records] must be available to the DMERC upon request. . . . This [clinical information] does not have to be routinely submitted with each claim.") (Emphasis added.) (Exh. 2 at 21-22.).

Because the QIC reconsideration stated that the medical records should be submitted, and they had not been previously requested or required, the appellant had good cause to submit them to the ALJ, and has good cause to submit them to the Council. The regulations provide for an appellant to make a statement of good

cause, explaining in writing to the ALJ or the Council why the documents are being submitted at this point and should be considered. See 42 C.F.R. §§ 405.1018(c), 405.1028, and 405.1122(c). It appears that the appellant did not provide a written good cause statement to the ALJ. See Exh. 10 at 1 (request for ALJ hearing, stating simply that medical records are attached). However, based on the QIC's reconsideration statement that medical records were required, the Council determines that good cause exists for the submission of medical records at the ALJ and Council levels. 42 C.F.R. § 405.1122(c).

The Applicable CMS Policy Article for Surgical Dressings Does Not Provide Medicare Coverage for Their Use in This Case

Medicare is a program of defined benefits. Congress has defined in the Medicare statute which kinds of medical services and supplies will be covered, under what type of conditions, and which ones will not. Definitions of coverage are also contained in the Medicare regulations, in National Coverage Determinations developed by the Centers for Medicare and Medicaid Services (CMS), and in Local Coverage Determinations and Policy Articles developed by the Medicare contractors.²

The Policy Article that applies in this case, for Surgical Dressings, is A23903. It provides for Medicare coverage of surgical dressings when one of the following criteria is met:

- 1) The dressings are required for the treatment of a wound caused by, or treated by, a surgical procedure; or
- 2) The dressings are required after debridement of a wound.

Id. at 2 (Exh. 2 at 2). In this case, the wounds that were treated with surgical dressings were not wounds caused or treated by a surgical procedure, or wounds requiring a dressing after debridement. Therefore, the cost of the surgical dressings in this case is not covered by Medicare.

This is not to say that the use of these dressings for the punctate wounds was not medically appropriate. In fact, the medical documentation cited above appears to show that the treatment was effective. However, as stated above, the Medicare

² Local Coverage Determinations and Policy Articles are available on the Medicare Coverage Database at: <http://www.cms.hhs.gov/MCD/overview.asp>

program is authorized to cover only a defined set of supplies and services, in a defined set of medical conditions. The use of these dressings for this purpose is not covered by the applicable Medicare Policy Article (A23903).

Liability for the Noncovered Costs

The Medicare Program Integrity Manual (MPIM) provides that if a contractor requests additional documentation (as both the contractor and the QIC did in this case), and receives documentation that shows that the benefit category requirement (here, Surgical Dressings) is present but is defective (here, because the Policy Article requirements were not met), then for purposes of determining liability coverage should be denied on the grounds that the services or supplies are not reasonable and necessary. CMS Pub. 100-8, MPIM, Chapter 3, Section 3.4.1.2.E ("Distinguishing between Benefit Category, Statutory Exclusion and Reasonable and Necessary Denials").³

In this case, where coverage of the supplies is therefore denied on the ground that the supplies are not reasonable and necessary, Section 1879 of the Act applies to determine the respective liabilities of the appellant (supplier) and the beneficiary. Pursuant to Section 1879, the appellant, who has access to information from multiple sources about the Medicare program and its coverage provisions, could have known or have reasonably been expected to know that these supplies would not be covered for this use. Therefore, the appellant is liable for the noncovered costs of these surgical dressings. The beneficiary, however, is not liable for the noncovered costs because she could not have known or have reasonably been expected to know that these supplies would not be covered for this use.

DECISION

The Council modifies the ALJ's decision. The Council finds there is good cause to admit into evidence and to consider the medical records furnished by the appellant at the ALJ appeal level. The Council concludes that the surgical dressings for the treatment of punctate venous ulcers in this case are not

³ The Medicare Manuals, including the Medicare Program Integrity Manual, are also available online at: <http://www.cms.hhs.gov/Manuals/IOM/list.asp>

covered by Medicare, because the applicable Policy Article (A23903) does not provide for coverage. The appellant is liable for the noncovered costs; the beneficiary is not liable.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ M. Susan Wiley
Administrative Appeals Judge

Date: September 30, 2009