DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-2009-1249

In the case of	**Claim for**
OJ Medtech, Inc. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
CIGNA Government Services (Contractor)	**** (ALJ Appeal Number)

On June 10, 2009, the Administrative Law Judge (ALJ) issued a partially favorable decision concerning Medicare's coverage of a segmented pneumatic compression device with calibrated gradient pressure (HCPCS Code E0652)[1] furnished to the beneficiary on September 17, 2008. The ALJ determined that the appellant had not provided sufficient documentation to demonstrate the medical necessity of the item as billed, but allowed payment for the least costly medically appropriate alternative. Dec. at 2, 7. The ALJ also found the Advanced Beneficiary Notice (ABN) on file defective, and thus, held the appellant liable for the non-covered costs. *Id.* at 8. The appellant has asked the Medicare Appeals Council (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).

As set forth below, we reverse the ALJ's decision and grant Medicare coverage for the device as originally billed.

[1] The Centers for Medicare & Medicaid Services (CMS) has developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a).

As a preliminary matter, we must address the appellant's submission of additional documentation, which include copies of medical records and copies of two photographs, with its timely-filed request for review dated August 10, 2009. By letter dated November 13, 2009, the appellant clarified that "the additional evidence that was submitted was a picture of [the beneficiary]'s arm. This picture was not included in the previous appeal requests." However, the copies of the two photographs submitted with the request for review appear to be additional copies of the two photographs (also photocopies) that are of record as Exh. 2, pages 48 and 49. As for the medical records submitted with the request for review, they, too, are duplicative of the evidence previously admitted into the record, and the appellant did not explain whether these items constituted new evidence. Thus, the Council finds that there is no good cause to admit these items and excludes them, and all of the additional documentation submitted with the request for review, as duplicative of evidence already contained in the record, pursuant to 42 C.F.R. § 405.1122(c). We enter the remaining portions of the appellant's request for review into the record as Exh. MAC-1, pages 1-3.

BACKGROUND AND PROCEDURAL HISTORY

The appellant billed Medicare for a segmented pneumatic compression device with calibrated gradient pressure furnished to the beneficiary on September 17, 2008, utilizing the HCPCS code E0652. Exh. 1 at 20. The Medicare contractor denied coverage for this item initially. *Id.*

Upon redetermination, the contractor issued a partially favorable determination and allowed coverage for the item at a downcoded level, that of HCPCS code E0651, as the least costly medically appropriate alternative. *Id.* at 19. The contractor took this action because the file contained "no indication of a failed trial of other pneumatic compressors. Pain and sensitivity alone does not show medical necessity for full payment of the higher equipment." *Id.* at 13, citing its Local Coverage Determination (LCD) on Pneumatic Compression Devices (L5017).[2] The contractor's redetermination is internally inconsistent regarding liability; it held both beneficiary and the appellant liable for the non-covered charges. *Id.* at 13-14.

[2] The version of LCD L5017 in effect on the date of service at issue is available on the CMS website at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5017&lcd_version=26&show=all (last visited Feb. 17, 2010).

On appeal, the Qualified Independent Contractor (QIC) upheld the contractor's partially favorable coverage determination. *Id.* at 3-6. The QIC determined that the ABN on file was invalid because it did not give "the beneficiary a reasonable idea of the [anticipated] denial reason so [she] can make an informed consumer decision" about purchasing the device. *Id.* at 4. Thus, the QIC waived the beneficiary's liability and held the appellant liable for the non-covered costs. *Id.*

The appellant then requested an on-the-record review by an ALJ and waived its right to a hearing. Exh. 1 at 1. As noted above, the ALJ issued a partially favorable decision, finding that the appellant had not provided sufficient documentation to demonstrate the medical necessity of the item as billed and allowing payment for the least costly medically appropriate alternative, or E0651. Dec. at 7. The ALJ also found the ABN on file defective, and thus, held the appellant liable for the non-covered costs. *Id.* at 8.

Before the Council, the appellant disagrees with the ALJ's decision and states that the beneficiary "has had breast cancer which has resulted in her developing lymphedema. She has tried conservative treatments such as physical therapy, compression garments, elevation, massage, diet, and exercise. Due to scarring and fibrotic tissue in the axilla area she could not tolerate the E0651 pump." Exh. MAC-1 at 3.

DISCUSSION

CMS has issued a National Coverage Determination (NCD) regarding Medicare's coverage of pneumatic compression devices. *See* NCD Manual, Pub. 100-03, Ch. 1, Part 4 at § 280.6 (Pneumatic Compression Devices).[3] By regulation, NCDs are binding on both ALJs and the Council. 42 C.F.R. § 405.1060.

As pertinent to this case, the NCD states:

> Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The

[3] The NCD Manual is available at http://www.cms.hhs.gov/manuals (last visited Feb. 17, 2010).

trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb. The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression.

* * *

Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.

The determination by the physician of the medical necessity of a pneumatic compression device must include:

1. The patient's diagnosis and prognosis;

2. Symptoms and objective findings, including measurements which establish the severity of the condition;

3. The reason the device is required, including the treatments which have been tried and failed; and

4. The clinical response to an initial treatment with the device.

The clinical response includes the change in pretreatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.

The only time that a segmented, calibrated gradient pneumatic compression device (HCPCS code E0652) would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented

> appliance or a segmented compression device without manual control of pressure in each chamber.

NCD at § 280.6.

In addition, the applicable LCD repeats the coverage criteria set forth in the NCD and elaborates:

> When a segmented device with manual control of the pressure in each chamber (E0652) is ordered and provided, payment will be based on the allowance for the least costly medically appropriate alternative, E0651, unless there is clear documentation of medical necessity in the individual case. Full payment for code E0652 will be made only when there is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression treatment using a non-segmented device (E0650) with a segmented appliance/sleeve (E0671-E0673) or a segmented device without manual control of the pressure in each chamber (E0651).

LCD L5017.

While the Council is not bound by a contractor's LCD, we give substantial deference to one where applicable. 42 C.F.R. § 405.1062(a). If the Council declines to follow an LCD in a particular case, the rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b). We have no reason to depart from the language of the applicable LCD in this case.

After carefully reviewing the record, we find that the medical documentation in evidence satisfies the coverage criteria set forth in both the applicable NCD and LCD. Specifically, the evidence demonstrates that the beneficiary developed lymphedema in her right arm following a radical mastectomy in December 2001. Exh. 2 at 14, 31-33. The notes from her physician's office reveal that the beneficiary experienced right arm swelling as early as December 2001, and that she received several referrals to physical therapy for treatment over the years, beginning in 2002. *Id.* at 6-10, 32-39. The file also contains physical therapy evaluations and progress notes from various treatment episodes in 2003, 2006, and the latest, July 2007. *Id.* at 20-24, 42-46. The therapy included exercises, massage, and use of a compression garment. *Id.* In March 2006, the beneficiary reported to her physician that massage therapy

was not alleviating her swelling. *Id.* at 37. The condition continued, as noted when beneficiary contacted her physician's office to inquire about additional physical therapy and a garment for her arm in May 2007. *Id.* at 39.

The record also reveals that the beneficiary visited her physician on July 8, 2008. *Id.* at 41. In his visit note, the physician states that he:

> had a long discussion with [the beneficiary] today about the lymphedema in her arm. It is very debilitating to her. She has been to physical therapy twice, as well as a sleeve. I think that we should try to get her a pneumatic compression device, and we will work on that. Other than that, I will see her back in six months, with her bilateral mammogram.

Id. After this visit, and prior to the date of service at issue, the physician explained to the appellant by letter dated August 19, 2008, that the beneficiary had undergone several conservative treatments over the preceding seven years, including physical therapy, exercises, compression garments, massage, wraps, and even antibiotics when needed. *Id.* at 4. He concluded that "[a]ll of the above treatments have proven to be ineffective with no relief of the swelling and pain in this arm." *Id.* at 5.

The record also contains a form entitled "Addendum to 04.03B Lymphedema Pump" and signed by the physician, which reports that the beneficiary had decreased pain and increased mobility for several months after each prior treatment, but then her pain and mobility issues would return. *Id.* at 47. The NCD allows coverage of pneumatic compression devices "if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial." NCD at § 280.6. Neither the NCD, nor the LCD, require the four-week trial of conservative therapy to immediately precede the device's use. Therefore, we find that the clinical evidence, taken as a whole, supports the physician's statement that the beneficiary tried other, more conservative therapies during the intervening seven years between the onset of her lymphedema and the date of service at issue, and that significant symptoms remained.

The NCD requires that the device be used "with appropriate physician oversight," including "a treatment plan defining the pressure to be used and the frequency and duration of use" and "ongoing monitoring of use and response to treatment." NCD at § 280.6. Here, the physician set forth a specific treatment plan for the beneficiary, to "use the compression pump at 60mmHG distally to 30mmHG proximally for a period of 1 hour twice a day." Exh. 2 at 5. The record includes pre- and post-treatment measurements from the beneficiary's initial treatment indicating a decrease in circumference, especially in the bicep. *Id.* at 11. There is no evidence of record to suggest that the device at issue was used without appropriate physician oversight.

The LCD is clear that "[f]ull payment for code E0652 will be made only when there is documentation that the individual has unique characteristics that prevent satisfactory pneumatic compression treatment using" the least costly medically appropriate alternative. LCD L5017. In this instance, the beneficiary's physician has explained that:

> The multi-chamber sleeve is important because of the ability to bypass the sensitive axilla area, its short cycle (which reduces the risk of pressure injury) and non-invasive milking action. This multi-chamber sleeve allows for more controlled bypass of sensitive scarring, lessening the pain and increasing compliance of treatment.

Exh. 2 at 5. We find the beneficiary's total condition, including her post-surgical status with sensitive scarring in the same area requiring treatment, is sufficient to satisfy the LCD's requirement of having "unique characteristics that prevent satisfactory pneumatic compression treatment" using the least costly medically appropriate alternative. LCD L5017.

Thus, we conclude that the clinical documentation in evidence supports the conclusion that the segmented pneumatic compression device with calibrated gradient pressure (E0652) furnished to the beneficiary was reasonable and necessary for the treatment of her medical condition.

DECISION

It is the decision of the Medicare Appeals Council that the pneumatic compression device at issue was reasonable and necessary for the treatment of the beneficiary's condition, and thus, is covered by Medicare. The appellant is entitled to payment at the E0652 level.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: February 19, 2010