

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Kinetic Concepts, Inc.
(Appellant)

(Beneficiaries)

Regional DME Contractors
(Contractors)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Numbers)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated July 2, 2008, concerning Medicare coverage for negative pressure wound therapy (NPWT) devices and associated supplies provided to multiple beneficiaries from May 2, 2005, through January 19, 2007. In his partially favorable decision, the ALJ found that Medicare coverage was appropriate for a subset of the appellant's claims and denied coverage for others. Where the ALJ found that the documentation was insufficient to establish Medicare coverage, the ALJ also concluded that there was no evidence that the appellant had provided the beneficiaries with notice that the items at issue would not be covered by Medicare. Consequently, the ALJ held the appellant liable for the non-covered items. The appellant has asked the Medicare Appeals Council (Council) to review this action as it pertains to the subset of beneficiaries whose therapy was not covered because it extended beyond an initial four-month period and a beneficiary who received canisters in excess of ten a month and, on the ALJ's finding that advance beneficiary notices (ABNs) provided to two beneficiaries were not valid to shift liability for the non-covered items to those beneficiaries.

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 Council enters the following into the record:

- Exh. MAC-1: Appellant's request for review and brief in support of its request for review, dated August 28, 2008.
- Exh. MAC-2: Appellant's "supplement to appeal of [ALJ] decisions," dated September 4, 2008.
- Exh. MAC-3: Council's December 8, 2008, interim letter to the appellant; and appellant's February 2, 2009, response to the Council's interim letter with a "Certificate of Service."

PROCEDURAL MATTERS

In its request for review, the appellant requested an oral hearing before the Council. See Exh. MAC-1. In correspondence dated December 8, 2008, the Council notified the appellant that the Council reviewed its request for an appearance to present oral argument. See Interim Letter, dated December 8, 2008, in Exh. MAC-3. The Council determined that oral argument was not warranted in this case, but granted the appellant the right to submit additional written argument. *Id.* As of the date of this decision, the appellant has not submitted additional written argument.

By a separate action, the Council dismissed the appeal with respect to beneficiaries numbered 54 and 56. The basis for the dismissal was that the request for review, as to these beneficiaries, was not timely filed and the appellant did not offer an explanation of good cause for the late filing. 42 C.F.R. §§ 405.1102(a) and (b), 405.1114.

Also, by another action, the Council remanded to the Office of Medicare Hearings and Appeals the request for review for eleven beneficiaries numbered 27, 31, 32, 33, 35, 36, 39, 40, 43, 44, and 45.¹ The reason for remand was that the Council does not have the ALJ's exhibits associated with the claim files for

¹ The ALJ's decision indicates that only two beneficiaries (39 and 40) were provided ABNs. Dec. at 7-8. The ALJ found both ABNs invalid to shift liability to these beneficiaries. The Council does not now address the merits of the issue of validity of the ABNs provided to these two beneficiaries. Beneficiaries 39 and 40, along with nine others, are the subject of the remand order.

these beneficiaries. Therefore, the Council's decision herein does not apply to these eleven beneficiaries. By the remand order, the Council directed the Office of Medicare Hearings and Appeals to assign the matter, for the eleven beneficiaries, to an ALJ for appropriate action.

On another matter, on the issue of coverage, the appellant, by counsel, specifically requested Council review of the claims for the beneficiaries whose therapy was not covered because it extended beyond an initial four-month period and those who received excess supplies (explicitly characterized by appellant as "Coverage of VAC therapy beyond 4 months" and "Canisters" issues in Exh. MAC-1 at 2). Submitted with Exh. MAC-1 was a list of "categories of claims appealed" in which appellant specified that it is seeking review only on three categories ("beyond 4 months"; "waiver of liability"; "canisters") and, under each category, listed the beneficiaries who are the subject of appeal. The beneficiaries were identified only by their ALJ-assigned numbers.

On September 4, 2008, the appellant's counsel submitted a cover letter stating: "On August 28th, we filed an appeal . . . Enclosed please find a spreadsheet of beneficiary claims appealed. In that appeal, we had listed beneficiaries by number." See Exh. MAC-2. A reasonable reading of the above-quoted statement in the September 4, 2008, cover letter is that the spreadsheet was submitted in September 2008, to provide more specific identifying information because the beneficiaries within the three appealed categories were identified only by their *numbers* in August 28, 2008.

In light of the foregoing, the Council modifies the ALJ's decision only as to the beneficiaries specifically identified in Appendix A to this decision. Also, the focus of the Council's decision herein is on the rationale for the denial of coverage for the therapy and supplies for these beneficiaries and on the categories of claims specifically identified in the August 2008, request for review.

BACKGROUND

The appellant, Kinetic Concepts, Inc. (KCI), is a supplier of durable medical equipment (DME). The specific item of equipment at issue in the present appeal is known as the "Vacuum Assisted Closure" (VAC®) device, which provides negative pressure wound therapy (NPWT) to assist in the healing of chronic wounds. The

appellant is the sole supplier of the VAC device. The VAC device is an electric pump that is capable of generating continuous or intermittent subatmospheric (*i.e.*, vacuum) pressure on the wound being treated. The VAC device (HCPCS Code E2402), which may be prescribed as either a standard or portable model, is used with specialized supplies, including surgical foam dressings (HCPCS Code A6550), canisters for the collection of fluid (HCPCS Codes A6551 and A7000), and tubing (included in HCPCS Code A6550) to connect the dressing and the canister to the pump.

The appellant accepted assignment and submitted claims for reimbursement to the Medicare Durable Medical Equipment Regional Carriers (DMERCs) on the beneficiaries' behalf for monthly rentals of the VAC and for related supplies. Each beneficiary at issue was prescribed the VAC device and supplies to treat chronic wound(s). The DMERCs either denied the appellant's claims or paid the claims and subsequently issued notices of overpayment. Upon redetermination, the DMERCs found that the medical documentation failed to support Medicare coverage of the NPWT and/or the associated supplies. *See, e.g.*, Medicare Appeal Decision, dated March 15, 2007, Claim File 6.²

The appellant then requested reconsideration by a Qualified Independent Contractor (QIC). The QIC decisions upheld the denials on the basis that the beneficiaries did not meet criteria for continuing coverage of NPWT beyond four months or excess canisters. *See, e.g.*, Medicare Reconsideration Decision, dated September 24, 2007, Claim File 6; *see also, e.g.*, Medicare Reconsideration Decision, dated September 24, 2007, Claim File 10. To varying degrees, the QIC decisions relied on Local Coverage Determinations (LCDs), issued by the DMERCs, to govern Medicare coverage of NPWT.³ The QIC decisions also considered the question of financial liability and found the appellant liable in each case. The appellant requested a hearing before an ALJ.

The ALJ's hearing decision was based upon the beneficiaries' documentary medical evidence, as well as argument and testimony offered by the appellant's representative and witnesses. As

² To protect privacy, the ALJ assigned numbers to each beneficiary and referred to each beneficiary by number. The Council will utilize the same numbers assigned by the ALJ and listed in Appendix A to this decision.

³ The QIC decisions refer to LCD numbers L11489, L11500, and L5008, which were issued by different DMERCs, but are substantively similar for the purposes of this analysis.

discussed in the opening paragraph of this decision, the ALJ issued a partially favorable decision, finding, among other things, that Medicare coverage was appropriate for a subset of the appellant's claims and denying coverage for others. Concerning the coverage issue raised in the appellant's request for review, continuation of NPWT beyond an initial four-month period, the ALJ determined:

Certainly, a bare medical opinion that a continuing medical need exists is insufficient. It would also appear that the mere presence of factors *generally* known to delay wound healing is insufficient to extend coverage beyond four months . . . Similarly, the LCD does not appear to provide for continued coverage when *anticipated* intervening factors have delayed the healing process.

Dec. at 6-7 (emphases in original).

APPLICABLE LEGAL AUTHORITIES

Durable Medical Equipment (DME)

Section 1832(a) of the Social Security Act (Act) provides that benefits under Medicare Part B include "medical and other health services." Section 1861(s)(6) of the Act defines "medical and other health services" as including durable medical equipment. Section 1861(n) of the Act lists certain items that are classified as DME. The device at issue is not listed in section 1861(n). However, by its own terms, section 1861(n) is not an exhaustive list of those items that qualify as DME.

Medicare covers DME if it (1) meets the definition of DME; (2) is medically "reasonable and necessary," and (3) the equipment is used in the beneficiary's home. CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual (MBPM), Ch. 15, § 110. Medicare regulations at 42 C.F.R. § 414.202 define DME as equipment that can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. The DMERCs do not dispute that the VAC device meets the definition of DME or that it is primarily used in the home. However, as indicated in the DMERCs' determinations in these cases, the contractors denied coverage for the dates of service at issue, finding that the

devices were not medically reasonable and necessary under Medicare coverage provisions.

Medically Reasonable and Necessary

Section 1862 of the Act provides that:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services -

(1)(A) which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues national coverage determinations (NCDs) that specify whether specific medical items, services, treatment procedures or technologies may be paid for under Medicare. CMS has not issued an NCD addressing the VAC device. In the absence of a specific NCD, the Medicare contractors are responsible for determining whether an item or service is reasonable and necessary.

Pursuant to that authority, each DMERC issued substantially similar LMRPs and LCDs addressing Medicare coverage of the VAC device. See, e.g., Region D LCD, Negative Pressure Wound Therapy Pumps (L11489); Region B LMRP, Negative Pressure Wound Therapy Pumps (L27025).⁴

DISCUSSION

As noted above, the ALJ determined, among other things, that Medicare coverage was appropriate for a subset of the claims at issue. Dec. at 5-10. On the issue of coverage, the appellant requested review of the claims for beneficiaries whose therapy was not covered because it extended beyond an initial four-month period and a beneficiary who received excess canisters (characterized by appellant as "Coverage of VAC therapy beyond 4 months" and "Canisters" issues in Exh. MAC-1 at 2).

⁴ The LMRP for this jurisdiction was converted into a LCD on October 1, 2005, and maintained by National Government Services DME MAC.

Deference to the LMRPs and LCDs

Pursuant to the applicable regulations, ALJs and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a). If the ALJ or the Council declines to follow a policy in a particular case, the decision must explain why the policy was not followed. 42 C.F.R. § 405.1062(b). Accordingly, the Council will give substantial deference to applicable LCDs and LMRPs governing NPWT, as well as to interpretive articles published by the DMERCs, unless there is a compelling, stated reason for not doing so.

Medical Necessity for Treatment beyond Four Months

Each DMERC issued substantially similar LMRPs addressing Medicare coverage of the VAC device. The LMRP is the relevant legal authority for certain beneficiaries, e.g., Beneficiary 6, whose dates of service predates July 1, 2006.

The LMRP provides in pertinent part:

INITIAL COVERAGE

An NPWT pump and supplies are covered when either criterion A (home setting) or B (inpatient setting) is met:

A. Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer, neuropathic (for example diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

OTHER EXCLUSIONS FROM COVERAGE

An NPWT pump and supplies will be denied at any time as not medically necessary if one or more of the following are present:

- The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- Untreated osteomyelitis within the vicinity of the wound;
- Cancer present in the wound;
- The presence of a fistula to an organ or body cavity within the vicinity of the wound.

CONTINUED COVERAGE

C. For wounds and ulcers described . . . above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following:

1. On a regular basis,
 - a. Directly assess the wound(s) being treated with the NPWT pump, and
 - b. Supervise or directly perform the NPWT dressing changes, and
2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

WHEN COVERAGE ENDS

- D. For wounds and ulcers described . . . above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
1. Criteria C1-C2 cease to occur;
 2. In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued.
 3. Any measurable degree of wound healing has failed to occur over the prior month. There must be documented in

the patient's medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from month to month.

4. 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. Coverage beyond 4 months will be given individual consideration based upon required additional documentation.
5. Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

See, e.g., LMRP L27025.

The pertinent LCDs are virtually identical to the LMRP and govern the claims with dates of service on or after July 1, 2006.⁵ Specifically, the LCDs also limit coverage after four months. Under the section entitled, "When Coverage Ends," the relevant LCDs, each indicate that "[f]or wounds and ulcers . . . , an NPWT pump and supplies will be denied as not medically necessary [after] . . . 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound." See, e.g., LCD L11489.

The Council notes that the relevant LMRPs and LCDs are unambiguous in that they each clearly state that coverage for the VAC device ends after four months have elapsed using an NPWT pump in the treatment of any wound and that coverage beyond 4 months will be given individual consideration based upon required *additional documentation*. The LCDs state, in the "Additional Documentation" sections that,

[w]hen NPWT therapy exceeds 4 months on the most recent wound and reimbursement ends, individual

⁵ The appellant asserts that the "revised LCD has a stated effective date of July 1, 2006," and took effect "[a]fter most of the cases at issue here." Exh. MAC-1 at 4. The Council notes that the dates of service for only several of the 19 beneficiaries were before the July 1, 2006, effective date of the relevant LCDs.

consideration for additional months may be sought using the appeals process. Documentation should be submitted with the appeal explaining the special circumstances necessitating the extended therapy time.

See, e.g., "Additional Documentation," LCD L11489.

The Council finds that although the ALJ did not err in his general conclusions concerning coverage of the treatments at issue, he erred in establishing an additional criterion that was not set forth in the applicable LMRPs or LCDs. In interpreting the applicable provisions, the ALJ opined that:

coverage is justified under the rare circumstances where actual medical records documenting the beneficiary's medical condition and the treatment history affirmatively prove that (1) the first four months of treatment resulted in progressive healing, (2) adequate wound healing would have occurred but for *unanticipated* medical developments such as traumatic injury to the wound site; and (3) further treatment would predictably complete the healing process in the near future.

Dec. at 7 (emphasis in original) (footnote omitted).

Before the Council, the appellant asserts that the ALJ erred by limiting coverage beyond the LMRP and LCD guidelines to "rare circumstances" and situations where "unanticipated" intervening events occur. See Exh. MAC-1 at 2-3, 6-7. The Council agrees with the appellant to some extent, in that characterizing the coverage of a service as frequent or rare is not a practical measure. Therefore, the Council does not apply the "unanticipated medical development" test in deciding the claims at issue. However, the Council notes that the legal authorities clearly state that "[c]overage beyond 4 months will be given individual consideration based upon required additional documentation." Thus, the Council finds that the language of both the LMRP and the LCD put the appellant on notice that additional documentation is required to demonstrate medical necessity beyond four months, as continued use would not be covered beyond that point in most cases. That is the test that the appellant must meet in the instant cases.

As an initial matter, consistent with recent Council decisions, the Council notes that the checklist form, generated by the

appellant and completed by an independent medical professional, is adequate to establish medical necessity for the first four months of treatment, assuming that measurable wound healing has occurred in each prior month. Beyond four months, however, the Council finds that the checklist is insufficient to support medical necessity without additional documentation.

The appellant asserts that where continued use of the VAC is supported by a physician's letter of medical necessity, the NPWT should be covered by Medicare. Exh. MAC-1 at 6-7. The appellant further argues that the mere passage of time does not establish the end of NPWT's medical necessity when there is continuous therapeutic benefit established by objective wound measures. *Id.*

Each beneficiary's claim file contains several KCI-generated forms, including the Wound Therapy Progress Report (with monthly wound measurements), one or more Prescription forms, and a Letter of Medical Necessity form. See, e.g., Claim Files 6, 8, 62. However, these forms alone do not explain why the beneficiaries needed to continue their NPWT treatment beyond the fourth month. The forms contain only vague and cursory notes from clinicians, including comments such as

- "Wound has improved. He is not a candidate for any surgery. We have nothing else to offer him." (Claim File 8),
- "to promote wound healing." (Claim File 9),
- "Continue for 1 more month." (Claim File 46), and
- "Wound healing." (Claim File 57).

Similarly, the additional documentation in the file for Beneficiary 20 consists of an inpatient history and physical for an unrelated condition dated more than five months after the date of service at issue. See *** Regional Medical Center, History and Physical, Claim File 20. For Beneficiary 60, the file consists of an initial consultation that took place six months (or more) before the dates of service at issue. See *** of Georgia Consultation, dated March 15, 2006, Claim File 60. Thus, in these cases, the additional documentation does not support or explain why the beneficiary needed to continue NPWT beyond the initial four-month period.

A portion of the claim files does not contain any additional documentation beyond these KCI-generated forms. See, e.g., Claim File 12, 55. In these instances, the Council finds that

the letters of medical necessity and bare statements of this type are insufficient to demonstrate that continuing NPWT treatment beyond a fourth month was medically reasonable and necessary.

Other claim files contain medical documentation in addition to the usual KCI-generated forms. See, e.g., Claim File 50. However, the Council notes that this documentation does not adequately substantiate the appellant's claims. For example, in the case of Beneficiary 50, the record contains three "File Notes" within the "Orthopaedics Clinic Note:"⁶

- He continues on his VAC dressing. He is having it changed three times a week.... It is closing quite nicely at this point. Has a good granulation bed.... We redressed him. (November 1, 2006, Claim File 50).
- He is having a little difficulty with the left side folding in, causing a crease, and then is getting a hypergranulation flap which I think is impeding his closure.... This is trimmed back and we will use a half thickness of the sponge to see if we can minimize this. His VAC dressing was changed. (*Id.*, November 15, 2006).
- He is using his VAC dressing but we have had difficulties with the low cleavage plane for which he gets a little hypertrophic flap in it which seems to be preventing him from healing.... (*Id.*, November 29, 2006).

Further, an NPWT pump and supplies will be denied as not medically necessary when any measurable degree of wound healing has failed to occur over the prior month. The appellant concedes that Beneficiary 50's wound did not show measurable healing, and indeed increased due to a debridement, between cycles 13 and 14. See Wound Therapy Progress Report, Claim File 50; see also *id.* at Reimbursement Rationale, "No improvement in the wound during cycle fourteen was due to a debridement...."

This additional documentation does not support or explain why this beneficiary needed to continue NPWT beyond his initial four month period.

⁶ The Clinic Notes are dated November 1, 15, and 29, 2006. Two dates of service for beneficiary 50 precede the dates of the Clinic Notes. Therefore, those dates of service, October 24 and October 26, 2006 are not covered because the case files lack additional documentation.

The Council concurs with the appellant that "additional documentation" is not explicitly defined in the LCDs in effect during the dates of service at issue. Exh. MAC-1 at 3. However, the Council notes that section 110.1(c)(2) of the MBPM states that:

even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the prescribed item. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which would ordinarily be derived from the use of the equipment?

Thus, the Council finds that the additional documentation required to support treatment beyond four months must be from independent providers, be case specific, contemporaneous with the beginning of the fifth month, explain the special circumstances necessitating the extended time, and justify the expense to the Medicare program based on the therapeutic benefits to the individual beneficiary.

For these reasons, the Council determines that the appellant has not demonstrated that it was medically necessary and reasonable for the beneficiaries to continue NPWT beyond four months. For this reason, the supplies associated with the NPWT for the claims in which they were used in conjunction with non-covered NPWT are also not covered. The Council affirms the ALJ's ultimate conclusion denying Medicare coverage for the dates of service after four months.

The Burden of Production

Section 1833(e) of the Act prohibits payment to any supplier unless "there has been furnished such information as may be necessary in order to determine the amounts due." Section 1862(a)(1) of the Act also prohibits payment for claims that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, "[n]otwithstanding any other provision." Thus, the statute clearly places the burden of substantiating a claim for payment on the entity making the claim. In any event, no LMRP

or LCD may supersede the statutory requirements under section 1862(a)(1) that Medicare coverage and payment may only be made for services that are proven to be medically reasonable or necessary.

The LCDs in effect for services performed on or after July 1, 2006, and identified by the appellant in its request for review (Exh. MAC-1 at 4) as LCDs L1500, L11489, and L5008, clarify the content of the additional information required. They provide that, in cases where NPWT therapy exceeds four months on the most recent wound and reimbursement ends, documentation should be submitted with the appeal explaining the *special circumstances* necessitating the extended therapy time. See Exh. MAC-1 at 4-5; see also, e.g., LCDs L11500 and L27025.

As stated above, the burden is on the appellant to provide additional documentation explaining the special circumstances necessitating the extended therapy time for each particular beneficiary. The Council finds that the appellant has not satisfied its burden by relying on the opinions of the beneficiaries' physicians as expressed on the medical necessity form or in the limited additional medical documentation submitted.

The Council agrees with several United States Circuit Courts of Appeal which have upheld the Secretary's decisions that forms, such as a certificate of medical necessity, signed by a physician, are not conclusive evidence that an item of DME is medically reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act. See *Maximum Comfort v. Secretary of Health & Human Services*, 512 F.3d 1081 (9th Cir. 2007); accord *MacKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4th Cir. 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS*, 468 F.3d 1347 (11th Cir. 2006). In addition, CMS Ruling 93-1, which was issued in response to litigation concerning coverage of Medicare Part A services, provides that no presumptive weight should be assigned to a treating physician's medical opinion in determining the medical necessity of inpatient hospital or skilled nursing facility services. The Ruling adds that it does not "by omission or implication" endorse the application of the treating physician rule to services not addressed in the Ruling.

Thus, the Council reiterates that the checklist form developed by the appellant only supports medical necessity for the first four months of treatment. As clarified by the current LCD, the

burden of coming forward with additional documentation must be satisfied by the appellant during the appeals process, which includes the hearing before the ALJ and review by the Council. See, e.g., LCD 11500. In the present case, the appellant has not produced adequate additional documentation explaining the special circumstances necessitating treatment beyond four months. The Council notes that the appellant did not submit any new evidence with its request for review, nor did it engage in individual arguments for the beneficiaries at issue. Thus, the Council finds that the appellant failed to meet this burden.

Accordingly, for the reasons stated above, the Council finds that the VAC devices and associated supplies for the beneficiaries at issue were not medically reasonable and necessary to treat the beneficiaries' wounds during the periods of service at issue.

Excess Canisters Using a Freedom VAC

The VAC uses detachable canisters to store exudate from wounds. The LCDs state that:

Coverage is provided up to a maximum of 10 canister sets (A6551) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). *For high volume exudative wounds, a stationary pump with the largest capacity canister must be used.* Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary. (Emphasis added.)

The LCDs clearly contemplate that beneficiaries with wounds with a large volume of wound drainage would be using the stationary pump. The appellant specifically appealed the ALJ's disallowance of canisters in excess of the numerical limit specified in the LCD for Beneficiary 65. The ALJ disallowed coverage because the beneficiary was not using the stationary pump but instead was using the portable Freedom VAC pump. ALJ Dec. at 6.

The appellant argues that excess canisters used with a Freedom VAC pump should be covered by Medicare. Exh. MAC-1 at 7-8. The appellant argues that the stationary pump is not portable and that a beneficiary limited to a stationary pump would have his or her movements restricted. *Id.*

The ALJ stated:

The NPWT LCD expressly provides that where more than ten canisters per month are delivered to a beneficiary in order to accommodate wounds producing more than 90 ml. of exudate per day, a "stationary["] pump (not a portable "Freedom" pump which uses smaller canisters) must be used.

Dec. at 6.

The Council agrees with the ALJ. In the absence of a compelling reason not to, the Council gives substantial deference to the applicable LCDs governing NPWT. A beneficiary who has a large volume of exudate needs a determination of medical need for a portable rather than a stationary pump. Without such a determination, the LCD numerical limits on canisters for a beneficiary not using a stationary pump would apply. Accordingly, the Council affirms the ALJ decision that the excess canisters provided to Beneficiary 65 are not covered.

Liability

Section 1879 of the Act provides that a beneficiary or supplier may be liable for the cost of an item or service that is not "reasonable and necessary" based upon prior knowledge of non-coverage. See also 42 C.F.R. §§ 411.400, 411.404 and 411.406. A beneficiary is deemed to have knowledge of non-coverage if the supplier provides a notice to the beneficiary explaining why it believes that Medicare will not cover the item or service. 42 C.F.R. § 411.404(b). A supplier is deemed to have knowledge of non-coverage, in part, when it informs the beneficiary before furnishing the services that the services are not covered. 42 C.F.R. § 411.406(d)(1). A supplier also has actual or constructive knowledge of non-coverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1) and 411.406(e)(3). An Advanced Beneficiary Notice (ABN) must provide a sufficient explanation of a providers belief that an item would not be covered to enable a beneficiary to make an informed consumer decision whether to decline the item or pay for it personally. Medicare Claims Processing Manual (MCPM) (Pub. 100-04) Ch. 30,

§ 40.3.8.

None the beneficiaries *at issue in this decision* had ABNs in their case files. See Dec. at 7-8; footnote 1 above. Thus, the Council finds that the records lack evidence that the beneficiaries had knowledge that Medicare would not cover the NWPT device and/or associated supplies. The Council finds that the supplier had knowledge of non-coverage. For these reasons, the Council concurs with the ALJ and finds the appellant liable for the non-covered claims for all beneficiaries at issue.

DECISION

The Medicare Appeals Council has carefully considered the entire record and finds that NPWT is not covered beyond 4 months without sufficient additional documentation. The burden is on the appellant to explain the special circumstances necessitating extended therapy time.

The Council affirms the ALJ's finding that the treatments and/or associated supplies provided to Beneficiaries 6, 7, 8, 9, 10, 12, 15, 16, 20, 46, 47, 49, 50, 55, 57, 60, 62, 63 and 65 are not covered because the appellant did not meet its burden of documentation or coverage is explicitly disallowed. Further, the excess canisters provided to Beneficiary 65 are not covered.

Finally, the Council affirms the ALJ's finding that the beneficiaries identified above and listed in Appendix A to this decision are not liable for the cost of the noncovered items provided to them.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: June 5, 2009