DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE

In the case of	**Claim for**
Kinetic Concepts Inc. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
DMERC Region A DMERC Region B DMERC Region C DMERC Region D (Contractors)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision unfavorable to the appellant dated November 8, 2007. The ALJ held that the appellant's claims for negative pressure wound therapy (NPWT) devices and associated supplies provided to 47 beneficiaries between January 5, 2006, and October 30, 2006, were not reasonable and necessary and, therefore, not entitled to Medicare coverage. Specifically, the ALJ determined that the appellant-designed checklist form associated with each beneficiary's claim file did not contain sufficient medical information to support Medicare coverage. The ALJ found there was no evidence that the appellant had provided the beneficiaries satisfactory written notice that the items in issue would not be covered by Medicare. Consequently, the appellant was liable for the non-covered charges in the claims at issue. *See* Dec. at 9-10; *see also* Appendix C to ALJ Decision (Wound Failure to Heal Status Table).

The appellant has asked the Medicare Appeals Council to review this action as it pertains to claims for 46 beneficiaries.[1] The Council has entered the appellant's request for review into the record as Exhibit (Exh.) MAC-1.

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).

For the reasons stated below, the Council disagrees with the ALJ's analysis regarding the sufficiency of KCI's checklist forms. As explained more fully below, the Council hereby vacates the hearing decision as it pertain to the claims involving the 46 beneficiaries for whom the appellant properly requested review and remands this case to an ALJ for further proceedings, including a new decision. *See* 42 C.F.R. §§ 405.1108(a) and 405.1128(a). The Council further notes that in the case caption to his decision the ALJ identifies "Multiple . . . Beneficiaries and 83 Dates of Service/claims." However, Appendix C to the ALJ Decision (Wound Failure to Heal Status Table) identifies 122 dates of service. Thus, there is an apparent inconsistency in the number of claims at issue in this case which must be resolved on remand.

BACKGROUND

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

[1] Following submission of its January 8, 2008 Request for Review, the Council notified the appellant that, pursuant to 42 C.F.R. §§ 405.906 and 405.1106 it was required to notify the beneficiaries of its request for review. *See* Council's Letter to Appellant's Representative (May 29, 2008); *see also* Council's Letter to Appellant's Representative (February 5, 2008). In response, the appellant demonstrated to the Council that it had notified 46 of the 47 beneficiaries involved in the ALJ decision of its request for review. *See* Appellant's Letter to the Council (June 27, 2008). Beneficiary R.G. was not notified of the appellant's request for review. Therefore, the Council takes no action on that claim and the decision of the ALJ remains the final agency action. The Council's Order here addresses the remaining claims for the forty-six beneficiaries notified of the appellant's request for review.

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),[2] 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 Code A6551) and tubing (included in HCPCS Code A6550) to connect the dressing and the canister to the pump.

Each of the forty-seven beneficiaries was prescribed a NPWT to treat a chronic wound or wounds. KCI accepted assignment and submitted claims for reimbursement on behalf of the beneficiaries for monthly rentals of the VAC and for associated supplies to the Medicare Durable Medical Equipment Regional Carriers (DMERC) for Regions A, B, C and D. The DMERCs issued initial determinations denying the claims. KCI requested review and the DMERCs issued redeterminations upholding the initial denials.

KCI then requested reconsideration by a Qualified Independent Contractor (QIC). The QIC decisions also upheld the denials on the grounds that either: (1) the beneficiary did not meet the criteria for continuing coverage of NPWT during the first four months of treatment, (2) the beneficiary did not meet criteria for continuing coverage of NPWT beyond four months, or (3) the quantity of supplies provided to the beneficiary exceeded the monthly coverage limits. To varying degrees, both the review determination and the QIC decisions relied on the provisions of the Local Coverage Determinations (LCDs) issued by the DMERCs governing Medicare coverage of NPWT.[3] The LCD is discussed in more detail below. The QIC decisions also considered the question of financial liability and held KCI liable in all cases.

KCI timely requested a hearing before an ALJ. Following a November 7, 2007, hearing in which the appellant offered testimony, the ALJ issued the decision in dispute. The ALJ concluded that the claims for NPWT and related supplies provided by the appellant to multiple beneficiaries on multiple dates of

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[2] The Healthcare Common Procedure Coding System (HCPCS) is a coding system developed by the Centers for Medicare & Medicaid Services (CMS) for processing, screening, identifying, and paying Medicare claims. *See* 42 C.F.R. §§ 414.2 and 414.40.

[3] The DMERCs LCDs are identical in substance. For ease of reference, the Council cites specifically to LCD L11500, issued by one DMERC.

service were not covered under Part B of Title XVIII of the Social Security Act (Act). Specifically, the ALJ found that the forms and checklists used to document and demonstrate the results or outcome of NPWT did not provide the level of detail required by the LCD. The ALJ further found that there was no medical documentation in the record to substantiate, or provide further elaboration upon, the information summarized in the appellant's forms. The ALJ reasoned that since there was insufficient information to support the claims at issue, his decision need not address whether the record supports continued therapy as reasonable and necessary. Dec. at 8-9. The ALJ then considered the issue of the liability for the non-covered services pursuant to section 1879 of the Act. The ALJ concluded that, in the absence of valid Advance Beneficiary Notices (ABNs) the appellant was liable for the cost of the non-covered services in each claim at issue. *Id.* at 9-10 and Appendix C to ALJ Decision (Wound Failure to Heal Status Table).

In its request for review, the appellant asserted that it had no notice that additional documentation was needed or would be critical to the ALJ review and that the ALJ had imposed a much higher standard for documentation not supported by the LCD. The appellant asserted that the ALJ's categorical refusal to consider medical documentation in the record meant that the ALJ's decision was not based upon independent consideration of the facts based upon the record as a whole. The appellant also contended that the ALJ decision constituted a contravention of the LCD for negative pressure wound therapy.[4] Exh. MAC-1 at 3-8.

ANALYSIS

I. Deference should be provided to the LCD

Pursuant to the applicable regulations: "ALJs and the MAC [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

[4] The appellant made a general request for a "transcript of the appeal" pursuant to 20 C.F.R. § 404.974 and the opportunity to make oral argument pursuant to 20 C.F.R. §§ 404.975 and 404.976. Exh. MAC-1 at 1-2. The regulations at 20 C.F.R. subpart J (sections 404.900 through and 404.999d) are inapplicable to these claims. *See* 70 Fed. Reg. 11420, 11425 (Mar. 8, 2005); *see also* 42 C.F.R. § 405.1100 *et seq*. As the Council is remanding these claims to the ALJ for further action, there is no need to address the substantive aspects of the appellant's request.

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 under the newer appeals regulations, the decision must explain why the policy was not followed. 42 C.F.R. § 405.1062(b). Accordingly, the applicable LCDs governing negative pressure wound therapy will be given substantial deference from the Council in the absence of a compelling reason not to, as will interpretive articles published by the DMERCs.

II. The Checklist Forms Sufficiently Establish Medical Necessity for Continuing Coverage in the First Four Months of NPWT

The DMERCs' policy on NPWT coverage establish certain criteria for determining whether continued treatment of a wound with NPWT is medically necessary.

Specifically,

> C) [f]or wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following: (1) [o]n a regular basis, a) [d]irectly assess the wound(s) being treated with the NPWT pump, and b) [s]upervise or directly perform the NPWT dressing changes, and 2) [o]n 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.

LCD L11500, at 5.

The checklist forms that KCI developed include documentation of specific clinical observations, including wound measurements, in support of the criteria established for continuing coverage in the first four months of treatment. A treating healthcare provider unaffiliated with KCI completes the forms. As such, the forms sufficiently establish medical necessity without the need to consult underlying clinical records as a routine matter. For instance, the "Monthly Wound Progress Form for Negative Pressure Wound Therapy," on its face, contains all of the information required to support continuing coverage in the first four months of treatment under the specific criteria of the LCD.

The Council's decision that the checklist forms in this case sufficiently establish medical necessity for continuing coverage during the first four months of treatment in the absence of underlying clinical records does not represent a departure from its holding In the case of Maximum Comfort (June 11, 2003). In that case, the Council determined that certificates of medical necessity ("CMNs") failed to establish medical necessity and that additional documentation was required. In contrast to the forms that KCI developed here, the CMNs at issue in Maximum Comfort did not require certifying physicians to provide clinical data in support of the certifications. Moreover, the Council's decision pointed out that CIGNA Healthcare, the designated DMERC, had instructed Maximum Comfort, through manuals and newsletters, that it should retain supporting clinical documentation substantiating any equipment claims. Accordingly, the Council held that Maximum Comfort knew, or should have known, that its claims were not supported by sufficient documentation. The Ninth Circuit recently upheld the Council's reasoning as reasonable and entitled to *Chevron* deference. *See* Maximum Comfort, Inc. v. Leavitt, No. 05-15832 (9th Cir. Dec. 21, 2007) (upholding MAC decision and remanding case to lower court).

As mentioned above, the KCI checklist forms contain clinical data that each patient's healthcare provider recorded. The checklist contains the information that the LCD requires to establish medical necessity. Moreover, the LCD explicitly states:

> The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the patient's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of the NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the patient's medical records may be requested by the DMERC in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement).

LCD L11500, at 9.

Therefore, the Council can reasonably distinguish the KCI checklist forms from the CMNs of Maximum Comfort, because the KCI checklists go well beyond the minimal information that the CMNs in Maximum Comfort provided. Accordingly, the ALJ should have proceeded to consider the merits of the individual claims on appeal.

III. The Checklist Forms Sufficiently Document Healing

The LCD provides that "[w]ound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound." LCD L11500, at 4 and 6.

Accordingly, the LCD clearly specifies what constitutes wound healing. The checklist forms contain documentation of the quantitative measurements of wound surface area and depth. For this reason, the forms should contain sufficient data from which to determine whether "wound healing" as the LCD defined has occurred.

At least eleven of the forty-six beneficiary claim files require resolution of the question of whether, during the first four months of NPWT use, there was measurable wound healing during the previous month in order to justify continued use of NPWT during the month of service at issue. On remand, the ALJ will decide whether during the first four months of NPWT therapy the medical evidence supports a finding that measurable wound healing occurred during the previous month.

IV. The Checklist Forms Do Not Sufficiently Support Medical Necessity for Treatment Beyond Four Months

Under the section entitled, "When Coverage Ends," the LMRP sets forth, in part, 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." As discussed above, the Council has found that the checklist form is adequate, as an initial matter, 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 should not presume that the checklist forms sufficiently support medical necessity. The LMRP clearly states that "[c]overage beyond 4 months will be given individual consideration based upon required additional documentation." Clearly, KCI was put on notice that additional documentation was required beyond four months, as continued use would not be covered in most cases.

At least eleven of the forty-six beneficiary claim files at issue raise the question of medical necessity for NPWT beyond four months of use. On remand, the ALJ will decide whether medical necessity for continued treatment and excessive supplies has been established.

V. Shallow Wounds

At least twenty-five of the forty-six beneficiary claim files at issue involve the question of whether NPWT is medically reasonable and necessary for treatment of shallow wounds. The LCD does not directly address the depth of wounds that are appropriate for treatment with NPWT. The DMERCs published Medicare Advisory articles in which they opined that "if the depth of a wound is less than 0.5 cm, then it would generally not be appropriate to continue use of the device." The Council rejects a blanket assertion that the use of NPWT with shallow wounds is never covered. Additional documentation may be necessary to determine whether a treatment of a shallow wound is, in fact, medically necessary, and KCI bears the burden in each instance of proving that treatment of the shallow wound is medically necessary. On remand, the ALJ will decide whether NPWT was medically reasonable and necessary to treat the shallow wounds at issue in these claims.

VII. Liability

The ALJ also concluded that, in the absence of valid ABNs the appellant was liable for the cost of the non-covered services in each claim at issue. Dec. at 9-10; Appendix C to ALJ Decision (Wound Failure to Heal Status Table). If the ALJ concludes on remand that some or all of the services at issue are not covered, the ALJ should again apply the limitation on liability provisions of section 1879 of the Act.

VIII. Remand

Based on the preceding analysis, the Council remands the claims for the 46 beneficiaries, for whom appellant properly sought review, to the ALJ for consideration of the availability of Medicare coverage for the equipment and supplies at issue. The Council notes that the ALJ analysis pertaining to the single claim for beneficiary E.M.R. resulted in a denial of coverage based upon the beneficiary's residence in a skilled nursing facility on the claimed date of service, May 2, 2006. *See* Appendix C to ALJ Decision (Wound Failure to Heal Status Table); *see also* Claim File 34. The ALJ's analysis was consistent with that of the QIC and the Region A DMERC. *See* Claim File 34. The Council notes that the ALJ's analysis for this claim would appear to be correct. However, for the appellant's administrative convenience, the Council will defer judgment on this claim pending the ALJ's review of the entire block of remaining claims involved in this remand order.

CONCLUSION

The Council finds that the forms and checklists used contain the information that the LCD required to establish medical necessity in the first four months of NPWT. Moreover, the appellant has submitted medical documentation relating to medical necessity of NPWT both prior to and beyond four months. Accordingly, the Council vacates the November 8, 2007, ALJ decision and remands the appeal to an ALJ for a new hearing and appeal.

ORDERS ON REMAND

On remand:

- The ALJ shall notify all parties of the issues and afford all parties the opportunity for a hearing.
- The ALJ will identify, specifically, the number of claims at issue in the decision.
- The ALJ will issue a new decision in which all findings of fact or conclusions of law are referenced to specific evidence in the record.

- The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Thomas E. Herrmann
Administrative Appeals Judge

Date: October 28, 2008