DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	**Claim for**
CourierMed, Inc. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
DME MAC, Region C (Contractor)	**** (ALJ Appeal Numbers)

The Medicare Appeals Council (Council) has decided, on its own motion, to review two, substantively identical, Administrative Law Judge's (ALJ's) decisions, each dated July 2, 2009, because there is an error of law material to the outcome of the claims. *See* 42 C.F.R. § 405.1110. At issue are the appellant's claims for Medicare Part B coverage for a surgical dressing which it markets under the name "CD-1000." The appellant submitted 271 claims for coverage of the CD-1000, which it had provided to 135 beneficiaries with end-stage renal disease (ESRD) between October 1, 2007 and September 2, 2008. The ALJ found that the CD-1000 was covered by Medicare because it satisfied the coverage requirements established by section 1862(a)(1) of the Social Security Act (Act). Dec. at 6.[1] The Centers for Medicare & Medicaid Services (CMS) referred the case to the Council, arguing that separate Medicare payment for the dressings at issue was not available because the cost of the CD-1000 was already included in the composite rate paid to the dialysis facility providers, and thus furnishing all necessary catheter-related dressing changes was the responsibility of the dialysis facilities. The appellant responded, asserting that the ALJ decision should be upheld.

[1] Reference to the ALJ decision will be to ALJ Appeal No. 1-426512274.

The Council has carefully considered the record before the ALJ, as well as the CMS memorandum, dated August 27, 2009 and the appellant's memorandum in response, dated September 10, 2009. These memoranda are entered into the record as Exhibit (Exh.) MAC-1 and MAC-2, respectively. As explained below, the Council reverses the ALJ decisions.

BACKGROUND

Medicare provides coverage for beneficiaries diagnosed with ESRD who receive renal dialysis and related services. *See* section 1881 of the Act; Medicare Benefits Policy Manual (MBPM) (CMS Pub. 100-02), Ch. 11; Medicare Claims Processing Manual (MCPM) (CMS Pub. 100-04), Ch. 8 and 42 C.F.R. part 413. Beneficiaries may receive dialysis services either at a facility or in their own home. For beneficiaries who receive services at a facility, the facility is paid a composite rate under the prospective payment system (PPS) to provide all dialysis-related items and services. For patients who receive dialysis services at home, chapter 11, section 40.1 of the MBPM identifies two payment methodologies for ESRD-related items and services:

> **Method I - The Composite Rate**
>
> If a Medicare home dialysis patient chooses Method I . . . the dialysis facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies and home support services. For these services, the facility receives the same Medicare dialysis payment rate as it would for an infacility patient under the composite rate system. . . .
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> **Method II – Dealing Direct**
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> If a beneficiary elects Method II, the beneficiary will deal directly with a single Medicare supplier to secure the necessary supplies and equipment to dialyze at home. The selected supplier (not a dialysis facility) must take assignment and bill the Durable Medical Equipment Regional Carriers (DMERC) [now DME MAC]. The beneficiary is responsible to his or her supplier for unmet Part B deductible and for the 20 percent Medicare Part B coinsurance requirement.

The beneficiaries whose claims are addressed in this decision are those receiving facility-based dialysis or home-based dialysis under payment Method I. The appellant has not provided any evidence that any of the beneficiaries whose claims are at issue were receiving home-based dialysis services under payment Method II.

Most dialysis services are performed either through a shunt or a percutaneous catheter. All of the patients at issue in this case were receiving dialysis services via a catheter. The CD-1000 dressings at issue were generally placed over other dressings to protect the catheter site from moisture, so that the patients could shower and engage in activities which would otherwise risk infection.

The appellant is a provider of durable medical equipment (DME). The appellant billed the 271 claims for the CD-1000 using HCPCS[2] code A6204, thereby defining the item as "a composite dressing, pad size more than 16 square inches, but less than or equal to 48 square inches with any size adhesive border, each dressing." *See* HCPCS 2007, at 36 (Oct. 27, 2006) and HCPCS 2008 at 36 (Dec. 27, 2007). The Region C DME Medicare Administrative Contractor (DME MAC) denied Medicare coverage, both initially and upon redetermination. In virtually each instance, the denials were based upon a finding that the DME MACs had jurisdiction of dialysis supplies and equipment for Method II dialysis patients only. Since "no information has been received that the patient has chosen this method for dialysis, the claim[s] remain denied."

The appellant requested reconsideration by a Qualified Independent Contractor (QIC). The QIC issued two unfavorable, multi-beneficiary decisions. *See* ALJ Appeal No. 1-426512274, Exh. 4 and ALJ Appeal No. 1-423226543, Exh. 3. The QIC denied coverage for a variety of reasons finding that in some cases Part B coverage was not available because a beneficiary was an inpatient, resided in a skilled nursing facility or was in home health care. In other cases, Medicare was not a beneficiary's primary insurer; in one instance the beneficiary was enrolled in a Managed Care Plan. *See* ALJ Appeal No. 1-426512274, Exh. 4

[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.

at 3, 10, 12, 17-19, 21, 23, 53, 76, 80; ALJ Appeal No. 1-423226543, Exh. 3 at 5, 13, 51, 71, 72 and 78. However, pertinent to the issue in this case, in the majority of claims the QIC found that Medicare could not pay for the CD-1000 because payment for those dressings was included in the monthly composite rate which Medicare paid to the outpatient dialysis facility for dialysis-related services and supplies. *See, generally,* ALJ Appeal No. 1-426512274, Exh. 4 and ALJ Appeal No. 1-423226543, Exh. 3.

The appellant requested an ALJ hearing for each unfavorable QIC decision and moved to aggregate the cases. *See, generally,* ALJ Appeal No. 1-426512274, Exh. 5 at 75 and ALJ Appeal No. 1-423226543, Exh. 4 at 1. On June 16, 2009, the ALJ conducted a hearing in both cases at which witnesses for the appellant testified. The ALJ then issued two identical decisions, fully favorable to the appellant. Relying, in part on the guidance provided in Local Coverage Determination (LCD) L11449, the ALJ found that pursuant to prescriptions issued by treating physicians, the appellant had provided twelve dressings per month to each of the beneficiaries and that this number was within the limit prescribed by the LCD. The ALJ determined that the dressings were "for use at home to maintain the wound area of the catheter. . . . [and were] not provided by the dialysis center or connected with any dressing associated with dialysis. . . . The use of the dressings is independent of any occasions during the actual dialysis." Dec. at 6. The ALJ concluded that the claims were sufficiently documented under Section 1833(e) of the Act and that the "services . . . provided to the beneficiaries were reasonable and necessary as required by Section 1862(a)(1) of the Act." *Id.*

The Arguments

CMS asserts, generally, that the ALJ erred in allowing payment solely on the basis that claims met the Act's coverage and documentation requirements. CMS characterizes the determinative issue as whether "payment for surgical dressings used to protect dialysis catheters is included in the composite rate paid to an ESRD facility," and notes that this principle is supported in the program guidance relied upon by both the appellant and the QIC. Further, CMS contends, there is additional error in the ALJ decision because the QIC denied coverage for some claims based upon reasons unrelated to the composite rate issue and the ALJ did not distinguish those decisions. Exh. MAC-1 at 2; *see*

also, ALJ Appeal No. 1-426512274, Exh. 4 at 3, 10, 12, 17-19, 21, 23, 53, 76, 80; ALJ Appeal No. 1-423226543, Exh. 3 at 5, 13, 51, 71, 72 and 78. Assuming for the sake of argument that the appellant could bill for the dressings and they otherwise met coverage requirements, CMS maintains that Medicare could not pay these unfavorable QIC claims. Exh. MAC-1 at 2.

The appellant urges the Council to decline review of this case. The appellant asserts that the record does not support CMS's position that the ALJ committed an error of law "by misunderstanding the issues and providing for payment of all claims regardless of the other issues raised." Rather, the appellant counters, CMS "has ignored the ALJ's analysis and findings, and Appellant's payment, in an effort to fabricate an error of law." Exh. MAC-2 at 2.

The appellant contends that the CMS memorandum neglected to recognize "ESRD Manual sections 50.60.1.2 and 50.60.1.3" which set out program guidance on Medicare coverage of surgical dressings.[3] The appellant notes that this guidance provides that surgical dressings which are not covered incident to the services of a health care practitioner, but are obtained by the patient from a supplier based on a physician's order, are covered under Medicare Part B. The appellant maintains that the CD-1000 is not used for or during dialysis and thus, is a "renal related" rather than a "dialysis related" supply. Exh. MAC-2 at 2-3.

The appellant also notes that CMS' memorandum neglected to discuss the surgical dressing benefit addressed in LCD L11449, which provides that "[d]ressings over a percutaneous catheter or tube (*e.g.,* intravascular, epidural, nephrostomy, etc.) are covered as long as the catheter or tube remains in place. . . ." The appellant argues that CMS' presentation of the law, regulation and policy arguments attempts to confuse, rather than clarify, the issue at hand. The appellant contends that the ESRD facility composite rate applies to dialysis treatment in a dialysis facility. However, the issue to be decided here concerns coverage for surgical dressings, outside the context of the dialysis procedure. Exh. MAC-2 at 2.

Finally, the appellant distinguishes dressings applied in conjunction with dialysis treatment, and included in the

[3] The Council considers these citations to contain typographical errors and understands the appellant's argument to reference MBPM, chapter 11, sections 50.6.1.2 and 50.6.1.3.

composite rate, from the CD-1000. The appellant indicates that each beneficiary received hemodialysis as defined in chapter 11 of the MBPM, but argues that the dressings at issue were not used for dialysis treatment nor provided by dialysis centers. Rather, they were used for "catheter care (regardless of the reason for the catheter) in the home setting." The appellant argues that CMS cited language in the MBPM pertinent to dialysis treatment, but ignored the fact that these supplies were not used for dialysis and the MBPM guidance (chapter 11, section 50.6.1.2) which provides coverage of dressings not covered as incident to dialysis. The appellant concedes the CMS argument that an ALJ must defer to the guidance in the LCD, but contends that this deference is precisely what this ALJ (and others) have done in reading LCD L11449 to permit coverage for these dressings. Exh. MAC-2 at 3.

The appellant also concedes that the QIC decisions denied coverage for CD-1000 claims for reasons other than their inclusion in the composite rate. However, the appellant contends that this is harmless error by the ALJ as Medicare did not pay the appellant for these claims. Exh. MAC-2 at 2-3.[4]

ANALYSIS

The Council finds that the CD-1000 is not separately payable to an independent DME supplier under the circumstances presented here, that is, where the beneficiaries are receiving facility-based dialysis services or home-based dialysis services paid for under Method I.

Chapter 11, section 30 of the MBPM addresses the "Composite Rate for Outpatient Maintenance Dialysis." Specifically, that section provides that the "cost of an item or service is included under the composite rate unless specifically excluded." Section 30 continues, providing examples of facility-furnished items or services included in the composite rate. Included

[4] It is not necessary for the Council to address the findings of the QIC with regard to each of the beneficiaries whose claims were denied by the QIC on a basis other than the composite rate coverage issue addressed in this decision. The referral of this case by CMS was premised on a finding that payment on these other limited claims would have to be overturned if the Council found that the dressings at issue were separately payable outside of the composite rate. However, the Council does not make such a finding, but finds to the contrary.

among those items or services are “Dressing changes.” The associated Policy Article (Surgical Dressings - A24114) provides --

> When dressings are covered under other benefits, there is no separate payment using surgical dressing codes. Payment for any type of dressing in these situations is included in the allowance for other codes. Examples, not all-inclusive, are:
>
> * * *
>
> e. Dressings used with dialysis access catheters (covered under the end stage renal benefit) are included in the composite rate (outpatient facility dialysis) or payment cap (method 1 home dialysis) paid to the dialysis provider.

Surgical Dressings - A24114 at 3. The Council finds that this language is broad and inclusive. First, the section refers to “any type of dressing.” It does not distinguish between primary dressings changed at the time of dialysis versus secondary dressings placed over the primary dressings at that time or later for purposes of showering. Second, it refers to “dressings used with dialysis access catheters.” It does not limit coverage under the composite rate to dressings used during or immediately following the dialysis procedure itself. It simply includes any dressing used with a dialysis access catheter. There is no dispute that the catheters used by the beneficiaries, and covered by the CD-1000 dressings at issue in this case, are dialysis access catheters. Thus, they are covered within the composite rate provided to the dialysis provider.

The essence of the appellant’s position is that the CD-1000 “is a renal related, non-routine, specialized surgical dressing for use at home by the patient for activities posing high risk of infection when prescribed by the patient’s treating physician.” ALJ Appeal No. 1-426512274, Exh. 2 at 5. However, the distinction which the appellant attempts to draw between dialysis-related and renal-related supplies, does not withstand scrutiny. But for the dialysis and related services provided to these beneficiaries, there would be no catheters, no necessary dressing changes over the catheters, and no claims for coverage of the CD-1000.

In arguing that the dressings at issue are not ESRD-related items included within the composite rate, the appellant places great reliance on chapter 11, section 50.6.1.3 of the MBPM, distinguishing between dialysis-related and renal-related services and supplies. Section 50.6.3.1 provides --

> All services, supplies, items, equipment and laboratory services that are related to the dialysis treatment are considered services that are directly related to dialysis. Examples of dialysis-related services include treatment of an infected shunt site, injecting drugs, or routine venipunctures that are necessary to monitor a dialysis patient's condition (*e.g*. blood urea nitrogen and creatinine test). Nondialysis services that are renal-related are services that are either necessary to provide the dialysis treatment or to ensure a desired outcome of the treatment but is not directly related to dialysis itself. An example of a non-dialysis service that is renal-related would be the procedure and supplies related to the insertion of a subclavian or femoral catheter.

However, in contrast to the appellant's position, the MBPM's examples of "renal-related supplies" are those related to the *insertion* of a catheter. Here, there is no dispute that the beneficiaries are already catheterized as, absent an existing catheter, they would otherwise not be receiving dialysis in this manner.

In any event, section 50.6.1.2 provides, in pertinent part, --

> Abandoned, dysfunctional, or multiple access sites are not necessary for dialysis, so wound care of such sites is not the responsibility of the dialysis facility. Access sites that have been placed in a patient who has not yet started dialysis are also not the responsibility of the dialysis facility. Therefore, dressing changes of this nature are not included in the composite rate. . . .
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> * * *
>
> In situations in which a new access has been surgically placed in a patient to enable a dialysis facility to provide dialysis treatment and the

> patient has started dialysis, Medicare would consider this a renal-related service. In this case the patient's surgical wound is relevant to the patient's ongoing dialysis treatment, and the patient is affiliated with a dialysis facility. Therefore, the dressing changes would be part of the home support services provided by the dialysis facility.

Inherent in the above-quoted section of the MBPM is the concept that, while responsible for the wound care at a dialysis site, a dialysis center is not responsible for wound care at an "abandoned, dysfunctional, or multiple access sites . . . not necessary for dialysis" as well as sites where a patient "has not yet started dialysis." By contrast, costs of the surgical dressings on a functional access site are part of the dialysis center's composite rate of reimbursement. Section 50.6.1.2 continues, identifying as renal-related "a new access . . . surgically placed in a patient to enable a dialysis facility to provide dialysis treatment and the patient has started dialysis," in contrast to the dressings provided by the appellant here. In this case, "the . . . wound is relevant to the patient's ongoing dialysis treatment and . . . would be part of the home support services provided by the facility." *Id.*

The appellant's attempt to distinguish the CD-1000 from other dialysis-related care is further undercut by an article written by Sanford Altman, M.D. (***Showering with Central Venous Catheters: Experience Using the CD-1000 Composite Dressing***[5]), and published in the May 2006 edition of *Dialysis & Transplantation*. Dr. Altman is the appellant's Medical Director and a shareholder in SDA Product Inc., the company which produces the CD-1000. *See* Dec. at 4; Exh. MAC-3 and ALJ Hearing CD (June 16, 2009).

In pertinent part, Dr. Altman's article provides that the CD-1000 is designed for --

> patients living with tunneled hemodialysis catheters . . . [for] use when they are engaged in high-risk activities such as showering or working around the yard. . . . The CD-1000 consists of an outer removable tarp that covers an inner composite dressing and pouch. . . . The composite dressing and

[5] Dr. Altman's article, which appears at the appellant's website (http://www.couriermedonline.com/PDF/published.pdf), has been entered into the record as Exh. MAC-3.

> pouch houses the catheter and covers the exit wound site. . . .
>
> . . . Patients were instructed to either apply the dressing over their existing catheter dressing or to remove the catheter dressing and apply the dressing [*i.e.*, the CD-1000] directly over the catheter and exit site. . . .

Exh. MAC-3 at 2.

Finally, the appellant cites chapter 11, section 50.6.1.2 of the MBPM for the proposition that surgical dressings are covered by Medicare. However, the Council is not finding that surgical dressings for these patients are not *covered*, but rather that they are not *separately billable* because they are included within the composite rate.

For the reasons stated above, the Council concludes that the appellant's CD-1000 is not separately billable under Medicare for beneficiaries receiving facility-based dialysis or home-based dialysis covered by the composite rate (Method I). The dressings are covered in the composite rate of Medicare reimbursement for dialysis-related services provided to ESRD facilities. Therefore, the Council reverses the ALJ decisions. Because the denial of separate payment is based on a finding that the dressings are covered under the ESRD composite rate, the basis for denial is not based on medical reasonableness and necessity under section 1862(a)(1) of the Act and, thus, the limitation on liability provisions of section 1879 of the Act are not applicable.

DECISION

It is the decision of the Medicare Appeals Council that the appellant's CD-1000 is covered under the composite rate of Medicare reimbursement for dialysis services. Thus, it is not separately billable for beneficiaries receiving facility-based dialysis or home-based dialysis under the Method I payment

provisions. Therefore, the Council reverses the ALJ's findings of coverage for all claims for coverage.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: November 24, 2009