

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-1177

In the case of

Claim for

MP Totalcare/CCS Medical
(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiaries)

(HIC Numbers)

DME MAC Jurisdictions C & D
(Contractors)

(ALJ Appeal Numbers)

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated January 26, 2011, because there are errors of law material to the outcome of the claims. The ALJ issued a decision concerning Medicare coverage for the appellant's claims for surgical dressings (trade name Kerlix AMD). Most of the claims were billed using HCPCS¹ code A6266 and furnished to 34 beneficiaries between October 23, 2009, and January 29, 2010. The ALJ determined that where the treating physician specifically ordered the precise quantities of the surgical dressings at issue, the dressings as supplied were medically reasonable and necessary for the beneficiaries and, thus, covered by Medicare.² The ALJ covered the dressings at issue and therefore did not address liability. Exh. MAC-1 at 5.

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). HCPCS Code A6266 denotes "Gauze, impregnated, other than water, normal saline, or zinc paste, sterile, any width, per linear yard."

² The ALJ denied coverage for the dressings furnished to one beneficiary, L.W. Dec. at 8. The request for hearing for another beneficiary, L.C., was

The Council enters the following into the record:

- The memorandum of referral for the Council's own motion review filed by the Centers for Medicare & Medicaid Services (CMS), dated March 24, 2011, as Exh. MAC-1;
- The appellant's exceptions to CMS' memorandum of referral for the Council's own motion review, in duplicate, dated April 14, 2011, and April 15, 2011, as Exh. MAC-2;
- LCD L11460, *LCD for Surgical Dressings*³, as Exh. MAC-3; and
- Policy Article A23903, *Local Coverage Article for Surgical Dressings*, as Exh. MAC-4.

For the reasons explained below, the Council does not admit into the record the appellant's rebuttal to CMS' memorandum for own motion review, dated May 4, 2011. CMS' memorandum for own motion review is dated March 24, 2011. Exh. MAC-1. As stated on CMS' notice to the appellant,

You are not required to take any further action. However, you may file exceptions to our referral by submitting written comments to the [Council] within 20 days of receiving this notice. The Council will assume you received this notice five days after the date stated at the top of this page, unless you show that you actually received it late.

Exh. MAC-1 at 11; see also 42 C.F.R. § 405.1110(b)(2). In response, the appellant filed a brief, by facsimile on April 14, 2011, and, a duplicate copy, by expedited mail, on April 15, 2011. Exh. MAC-2. By correspondence dated May 4, 2011, the appellant's attorney acknowledged that the original rebuttal,

withdrawn. Attachment 1 to ALJ Dec. The CMS referral does not address beneficiaries L.W. and L.C. One beneficiary addressed in the referral (R.M.) has two dates of service. See Appendix A.

³ The Noridian Administrative Services *LCD for Surgical Dressings* (L11460), and the accompanying Policy Article (A23903), *Local Coverage Article for Surgical Dressings*, in effect during the dates of service at issue, are available at: <http://www.cms.gov/medicare-coverage-database/>. As CMS notes, also pertinent to this case is LCD L11449, issued by CIGNA Government Services, the contents of which are substantially similar to that in LCD L11460. Exh. MAC-1 at 6, n.3.

dated April 14, 2011, contained argument for beneficiaries who were not the subject of the ALJ's decision for which CMS requested the Council's own motion review. In the May 4, 2011 supplement, the appellant asks the Council to "replace the prior summary with the one attached to this letter". The Council notes that the appellant's May 4, 2011 argument for the beneficiaries at issue was received well after the 20-day response period. 42 C.F.R. § 405.1110(b)(2). The Council also notes that the May 4, 2011 supplement does not contain revisions to its original arguments, but wholly supplants all beneficiary-specific arguments in its timely, April 14, 2011 brief. For these reasons, the appellant's untimely, May 4, 2011 filing is excluded from the record and will not be considered to decide this case, but will be marked Exh. MAC-5 for identification purposes. The Council will consider only the general arguments in the appellant's April 14, 2011 submission.⁴

BACKGROUND

Kerlix® Dressings (A6226)

The majority of the appellant's cases arise from claims for Medicare coverage of Kerlix® dressings to treat and/or prevent wound infection, billed using HCPCS code A6266. Initially and upon redetermination, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs)⁵ denied these claims, either in part or in full, based on the quantities billed; and in most cases, downcoded the claims to 30 or 31 units⁶ per wound of non-impregnated sterile roll gauze (A6446).⁷ See, e.g., Beneficiary L.H. Claim File (L.H.) Exh. 3. On reconsideration, the Qualified Independent Contractor (QIC) issued an unfavorable determination in each case, finding that the appellant was not

⁴ The beneficiary-specific arguments in the April 14, 2011 and the May 4, 2011 filings share some commonalities. Two beneficiaries are addressed in both lists, but the dates of service differ between the two filings. It is evident that the April 14, 2011 filing did not address the beneficiaries and the corresponding dates of service addressed in the ALJ's decision at issue.

⁵ The claim for beneficiary G.Mi. was processed by CIGNA Government Services, the DME MAC for Jurisdiction C. The other beneficiary claims at issue were processed by Noridian Administrative Services, the DME MAC for Jurisdiction D.

⁶ Corresponds to the number of days in a given month.

⁷ HCPCS A6446 is defined as a "conforming bandage, non-elastic, knitted/woven, sterile, width greater than or equal to three inches and less than five inches per yard".

entitled to any additional payment and held the appellant liable⁴ for any non-covered items. *See, e.g., id., Exh. 2.*

The appellant requested a hearing before an ALJ. The hearing office assigned individual docket numbers for each beneficiary claim and, on January 19, 2011, the ALJ conducted a consolidated telephonic hearing. *See, e.g., id., Dec. at 4; reference also Hearing CD 09:01:59-09:02:45.*

The ALJ reviewed medical literature provided by the appellant concerning the surgical dressing at issue and determined that the medical literature either lacked references to the dressing as a secondary dressing or did not specifically mention the specific type of dressing. *Dec. at 5-6.* Further, the ALJ evaluated the attestations of treating physicians and found only one relevant to the issue in this case, Dr. H.'s attestation, and then only anecdotally. *Id. at 6.* However, the ALJ further determined that "when a medical treatment provider specifically orders a medical product, it is not the responsibility of the supplier, here [the appellant], to be the entity for determining whether its use is medically reasonable and necessary". *Id.* Accordingly, in the cases where the treating physician specifically ordered the impregnated dressings by "[antimicrobial dressing] (AMD) gauze," or by their brand names "Bioguard" or "Kerlix®," the ALJ determined the dressings were reasonable and necessary and "should be paid by Medicare". *Id. at 7-11.*

Alginate Dressings (A6197)

The claims for beneficiaries G.Mi. and G.V. concern alginate dressings billed using HCPCS code A6197.⁸ Initially, and upon redetermination, the DME MAC denied these claims. *See, e.g., Beneficiary G.Mi. File (G.Mi.) Exh. 3.* Upon reconsideration, the QIC determined that the medical documentation did not support the frequency at which the dressings were prescribed. *See, e.g., G.Mi. File, Exh. 2 at 2.* The ALJ determined that the applicable records for both beneficiaries contain a prescription from the treating physician; thus, the claims are payable by Medicare. *Dec. at 8, 10.*

As stated above, CMS referred the ALJ's January 26, 2011 decision for the Council's own motion review. *Exh. MAC-1.* CMS' position is that the ALJ erred in allowing Medicare coverage for

⁸ HCPCS A6197 is defined as "alginate or other fiber gelling dressing, wound cover, sterile pad, size 16 square inches or more but less than or equal to 48 square inches, each dressing".

the dressings simply because a physician ordered the supplies at⁵ issue and did not base his decision on the record before him. Exh. MAC-1 at 5-9; see also 42 C.F.R. § 405.1046(a). CMS also contends that the ALJ did not give substantial deference to the applicable local coverage determination (LCD) or explain why he chose not to do so. Exh. MAC-1 at 2; see also 42 C.F.R. §§ 405.1062(a) and (b). CMS states that the ALJ additionally made errors of law material to the outcome of the claims by not requiring the appellant to provide adequate information to support Medicare coverage and in determining that the physician's order alone was sufficient for Medicare coverage. Exh. MAC-1 at 2.

The appellant responded to CMS' referral memorandum on April 14, 2011. Exh. MAC-2. The appellant generally contends that the dressings at issue were medically reasonable and necessary as a secondary dressing and in the quantities claimed. *Id.* at 3-6. The appellant further argues, *inter alia*:

- CMS and its contractors had a burden to refute the evidence presented by the appellant (*id.* at 1-2, 11);
- the ALJ rightfully deferred the treating physician's judgment in finding Medicare coverage for the supplies at issue (*id.* at 2, 10-11);
- the impregnated dressings at issue were approved by the Food and Drug Administration (FDA) as a secondary dressing and therefore Medicare should cover the dressings for this purpose (*id.* at 2, 6-7);
- the contractors did not correctly follow the guidance set forth in the LCD in denying the claims at issue (*id.*); and
- asks the Council to order the contractor not to deny the appellant's future claims for Medicare payment (*id.* at 12-13).

DISCUSSION

The discussion below is organized into several subsections to fully address the coverage and liability issues, as well as the appellant's responsive arguments and request for relief.

Request for Additional Relief

We first address the appellant's request for "additional" relief, specifically, that the Council "provide assurance that the [contractor] will not continue its course of improper claims denials". Exh. MAC-2 at 12. The appellant argues that the

contractor's routine denials of the appellant's claims are not only contrary to the "basic concepts of due process" under the U.S. Constitution, but have larger implications for the appellant as a participant in the Medicare program, because the denials raise the appellant's error rate and adversely affect its business operations. *Id.* at 12-13. 6

The appellant states that "this request for relief arises out of the Medicare Act and is inextricably intertwined with MP TotalCare's claims for payment, which are being heard by the Council. MP TotalCare is channeling its request for relief through the administrative appeals process." Exh. MAC-2 at 13. This explanation notwithstanding, the appellant does not cite any legal authority that would require, much less permit, the Council to afford the type of "additional" relief sought, which is, in essence, declaratory relief. The Council is aware of no such authority. That the appellant sees a need to expressly state that the request for "additional" relief is "inextricably intertwined" with the claims now under review (we do not agree) and "arises from the Medicare Act" suggests the appellant is aware it is asking for relief the Council cannot grant. The appellant wants our "assurance" that a CMS contractor, going forward, will not take coverage actions adverse to the appellant's interests where claims have not even been filed, much less undergone the administrative review process in accordance with the applicable procedures. Stated another way, there is no actual case or controversy properly before the Council. Inasmuch as the appellant is asking for relief that we are not empowered to grant, on matters over which we have no jurisdiction, and on matters for which no case or controversy is actually before us, we will take no action on the appellant's request for "additional" relief.

Moreover, to the extent the appellant's due process arguments may be considered within the context of the Medicare administrative review process, we comment that the appellant has been afforded the opportunity to challenge the contractor's unfavorable determinations on the claims that were filed, through the redetermination, reconsideration, and ALJ review processes. The appellant also was afforded an opportunity to protest CMS' request for the Council's own motion review of the ALJ's decision based on material legal error. The appellant has exercised its right to do so.

The appellant claims that the Medicare contractor denied the claims at issue, and is incorrectly denying the appellant's claims recurrently, based on what the appellant contends are "automatic denials" due to "improper" updates to the applicable LCD. Exh. MAC-2 at 8-9.

ALJs and the Council are bound by Medicare statutes, regulations, CMS rulings, and National Coverage Determinations. 42 C.F.R. § 405.1060(a)(4). ALJs and the Council are not bound by LCDs, "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a) (emphasis added). If an ALJ or the Council declines to follow an LCD, the ALJ's or the Council's decision must explain the basis for not doing so. 42 C.F.R. § 405.1062(b). A decision not to follow an LCD is confined "only to the specific claim being considered and does not have precedential effect." *Id.* ALJs and the Council may not set aside or review the validity of a local medical review policy (LMRP) or LCD for purposes of a section 1869 claim appeal. 42 C.F.R. § 405.1062(c)(1). The Departmental Appeals Board may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title. *Id.* LCD reviews are distinct from the claims appeals processes set forth in subparts G and H of part 405 of Title 42 of the Code of Federal Regulations. 42 C.F.R. §§ 426.310(a), 426.325(b)(11). Only under the regulations set forth in part 426 can an aggrieved party "state why the LCD is not valid". 42 C.F.R. § 426.425.

Accordingly, the Council has no jurisdiction to evaluate any alleged improper procedures taken by the contractor to issue or update the applicable LCD. The appellant's arguments concerning whether the claims at issue meet the conditions for coverage set forth in the LCD, in effect at the time the dressings were provided to the beneficiaries, are discussed below.

Deference to the Treating Physician

The appellant argues that CMS and its contractors should defer to the medical opinion of the treating physicians who ordered the supplies at issue. Exh. MAC-2 at 2, 10-11.

In rejecting the use of the treating physician rule in Medicare cases, the Second Circuit has stated that "[t]he Medicare statute unambiguously vests final authority in the Secretary,

and no one else, to determine whether a service is reasonable and necessary, and thus whether reimbursement should be made." ⁸ *State of New York o/b/o Bodnar v. Secretary*, 903 F.2d 122, 125 (1990). In *State of New York o/b/o/ Stein v. Secy of HHS*, 924 F.2d 431, 433-34 (2d Cir. 1991), and in *State of New York o/b/o Holland v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991), the Second Circuit reiterated that the treating physician rule should not be applied in Medicare cases without the input of the Secretary of Health and Human Services. In 1993, CMS' predecessor (Health Care Financing Administration) provided that input by developing Ruling 93-1, effective May 18, 1993, in response to litigation concerning coverage of Medicare Part A services.⁹ The U.S. Supreme Court reached the same conclusion in *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, No. 02-469 slip op. at 5 (2003). The Court held that adoption of the treating physician rule in contexts outside of the Social Security Administration's disability adjudication was best left to Congress or the supervising administrative agency. *Id.* at 9.¹⁰

CMS Ruling 93-1, in sum, 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. Rather, "[a] physician's opinion will be evaluated in the context of the evidence in the complete administrative record." Moreover, the Ruling adds parenthetically that the Ruling does not "by omission or implication" endorse the application of the "treating physician rule" to services not addressed in the Ruling, e.g., services other than Medicare Part A services, as in the instant case. CMS Ruling 93-1 provides:

It is [CMS's] Ruling that no presumptive weight should be assigned to the treating physician's medical

⁹ By regulation, CMS Rulings are binding on ALJs and the Council. 42 C.F.R. §§ 401.108, 405.1063.

¹⁰ Since Ruling 93-1, the district courts' decisions have not been fully consistent. In two decisions, the district courts have faulted the agency adjudicators for not giving sufficient consideration to the treating physician's opinion in Medicare coverage cases. See *Smith o/b/o McDonald v. Shalala*, 855 F.Supp. 658 (D.Vt. 1994) (according to the Secretary's Home Health Agency Manual, then in effect, "some extra weight" should have been given to the treating physician's opinion); *Pfalzgraf v. Shalala*, 997 F.Supp. 360 (W.D.N.Y. 1998) (failure to refer to or mention the treating physician's assessment was error). These rulings are inconsistent with both the Second Circuit's and the Supreme Court's rulings. In a third and more recent decision, the district court declined to apply the treating physician rule to Medicare cases, citing the Second Circuit's decisions. See *Arruejo v. Thompson*, 2001 WL 1563699 (E.D.N.Y. 2001).

opinion in determining the medical necessity of inpatient 9
hospital or SNF [skilled nursing facility] services
under section 1862(a)(1) of the Act. A physician's
opinion will be evaluated in the context of the
evidence in the complete administrative record. Even
though a physician's certification is required for
payment, coverage decisions are not made based solely
on this certification; they are made based on
objective medical information about the patient's
condition and the services received. This information
is available from the claims form and, when necessary,
the medical record which includes the physician's
certification.

CMS Ruling 93-1.

The treating physician rule, as addressed in CMS Ruling 93-1,
therefore, is not applicable to this Part B case involving a
supplier of surgical dressings. The appellant-supplier is not
entitled to a benefit of presumption that the physician's
ordering of the dressings in question establishes medical
necessity or otherwise meets Medicare's coverage requirements
for the dressings. Further, the appellant's argument that the
contractor's denials improperly infringe on the independent
medical judgment of the treating or prescribing physicians is
unavailing.

Burden to Establish Medicare Coverage

The appellant claims the record is devoid of evidence to refute
that the surgical dressings at issue were medically reasonable
and necessary. Exh. MAC-2 at 1-2, 11. Specifically, the
appellant claims that CMS and its contractors "offered no
testimony or evidence to refute [the appellant's] evidence of
medical necessity". *Id.* at 11. And, even though the ALJ's
decision was substantially favorable to the appellant, the
appellant now contends that the ALJ did not "fully develop the
administrative record" because "there was no evidence to refute
[the appellant's] documentation." Exh. MAC-2 at 11.

The appellant seems to be asking the Council to draw an adverse
inference against CMS and/or the Medicare contractors based on
the extent of CMS's or the contractors' participation during the
ALJ proceedings.¹¹ The regulations in Subpart I, to which the

¹¹ The CMS contractor did participate, though in limited capacity, through the
written submission of the Medical Director for DME MAC Jurisdiction D. See
Beneficiary D.R. case file (D.R.), Exh. 16.

ALJ and the Council are bound, prohibit such an action. CMS 10
may participate at the hearing level as either a "participant"
or a "party". Neither the ALJ nor the Council may require CMS
or a contractor to enter a case and participate as a participant
or party; nor may the ALJ or Council draw an adverse inference
if either decides not to enter as a participant or party. 42
C.F.R. § 405.1012(d), see also 42 C.F.R. §§ 405.1000(c),
405.1010, 405.1012, 405.1010(f).

But, more importantly, as CMS stated, in this case, as in all
Medicare appeals, the appellant has the burden to establish
entitlement to Medicare payment. Exh. MAC-1 at 2, 7-9. Section
1862(a)(1)(A) of the Act bars coverage of items and services
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. The regulations make clear that it is
the responsibility of the provider or supplier to furnish
sufficient information to determine whether payment is due and
the amount of the payment. Act at § 1833(e); 42 C.F.R.
§ 424.5(a)(6). It is the appellant's responsibility to adduce
the evidence to demonstrate that the item or service at issue is
medically reasonable and necessary, and otherwise meets
Medicare's coverage requirements. See MPIM, Ch. 13 at § 13.7.1.

The Secretary may require medical documentation, in addition to
a prescription, to support medical reasonableness and necessity.
See Maximum Comfort v. Secretary of Health & Human Services, 512
F.3d 1081 (9th Cir. 2007), *petition for cert. denied*, 129 S.Ct.
115 (U.S. Oct. 6, 2008) (No. 07-1507); *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). The patient's medical record must contain sufficient
documentation of the patient's medical condition to substantiate
the necessity for the type and quantity of items ordered. The
supplier should obtain as much medical documentation from the
patient's medical record as it determines it needs to assure
itself that the coverage requirements have been met; otherwise,
the supplier could be held financially liable for the dollar
amount involved in the absence of a valid advance beneficiary
notice. MPIM, Ch. 5 at §§ 5.7, 5.8. Accordingly, the Council
agrees with CMS that the appellant, not CMS or its contractors,
bears the burden to demonstrate that the dressings at issue were
medically reasonable and necessary when furnished to the
beneficiaries.

The appellant argues that the contractor's denials are rooted in a "mistaken belief" that the dressings at issue were ordered for the equivalent of an "off-label" use or for an experimental purpose. The appellant asserts that the Kerlix AMD dressings have been determined medically reasonable and necessary, and, even more specifically, that the use of the dressings as secondary dressings is a recognized use, because the FDA has approved Kerlix AMD for marketing for "use as a primary or secondary dressing...." Exh. MAC-2 at 6-7.

"CMS may consider for Medicare coverage" FDA approved "devices" "that have been categorized as nonexperimental/investigational." 42 C.F.R. § 405.201(a)(2) (emphasis added). The regulations further clarify that CMS uses FDA categorization "as a factor in making Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1) (emphasis added). Thus, under Medicare regulations, the fact that an item may be deemed non-experimental/investigational by virtue of its FDA classification means, as a threshold matter, only that it is eligible to be considered for Medicare coverage.

This conclusion is reinforced by statements published by CMS in the Federal Register. On September 26, 2003, the Department of Health and Human Services (HHS), under the joint signature of the Secretary of HHS and the CMS Administrator, issued a notice describing the revised decision-making process that CMS uses to make a NCD. 68 Fed. Reg. 55634 (Sept. 26, 2003). In addition to describing the new process, the notice discussed the difference between CMS review of a medical device as compared to reviews conducted by the FDA. *Id.* at 55636. In pertinent part, the notice explains that:

Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions, respectively. However, CMS and its contractors make coverage determinations and the FDA conducts pre-market review of products under different statutory standards and different delegated authority. (67 FR 66755, Nov. 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether the product is reasonable and necessary for the Medicare

population. Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA pre-market review process) for at least one indication to be eligible for coverage [discussion of Category B devices omitted] FDA approval/clearance alone does not generally entitle that device to coverage.

Id.

Moreover, FDA clearance does not preclude CMS or its contractors, in analyzing whether a particular item or service is medically reasonable and necessary, from making an independent inquiry into whether the item or service is safe and effective and not experimental or investigational. MPIM, Ch. 13, § 5.1. Nor does it preclude CMS or its contractors from inquiring whether the item or service is supported by “[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies.” *Id.* at § 7.1. If FDA clearance were dispositive of these issues, there would be no need for the MPIM provisions, or, for that matter, coverage policies to which adjudicators substantially defer.

Accordingly, the FDA marketing clearance that the impregnated dressings for secondary dressing obtained does not, by itself, establish that the dressings at issue meet Medicare coverage requirements; *i.e.*, that the dressings have been shown to be a medically reasonable and necessary treatment for use as a secondary dressing. The Council finds, as detailed further below, that the evidence does not establish that the dressings met medical necessity standards for Medicare coverage.

Coverage for Kerlix AMD (A6266) and Alginate Dressings (A6197)

As stated above, CMS’ position is that the ALJ erred in allowing Medicare coverage for the dressings simply because a physician ordered the supplies at issue and did not base his decision on the record before him. Exh. MAC-1 at 5-9; *see also* 42 C.F.R. § 405.1046(a). CMS also contends that the ALJ did not substantially defer to the LCD or explain why he chose not to do so. Exh. MAC-1 at 2; *see also* 42 C.F.R. §§ 405.1062(a) and (b). CMS states that the ALJ additionally made errors of law material to the outcome of the claims by not requiring the appellant to provide adequate information to support coverage and in determining that the physician’s order alone was sufficient for coverage. Exh. MAC-1 at 2.

In rebuttal, the appellant argues that a number of clinical studies demonstrate the effectiveness of "AMD in wound care treatment" and that "as a secondary dressing, AMD is medically appropriate". Exh. MAC-2 at 4, 5. Further, the appellant states that "AMD, when used as a secondary dressing, is properly billed as HCPCS Code A6266 and meets the requirements for coverage under LCD L11460". *Id.* at 7. The appellant argues that the plain roll gauze, the gauze to which the appellant's claims were downcoded, "cannot offer the therapeutic and protective functions because plain roll gauze does not possess the same important characteristics". *Id.*

13

LCD L11460 explains that Medicare provides coverage for rolled gauze when, *inter alia*, certain conditions are met: (1) the gauze is used as a secondary dressing to wrap a wound caused by a surgical procedure or after debridement; (2) a physician signs and dates a written order for the gauze that the supplier receives before submitting a claim for payment; and (3) the gauze is used only up to once per day and is medically reasonable and necessary for the treatment of a wound. See LCD L11460 at Exh. MAC-3. The supplied sterile impregnated gauze was used once per day as secondary or tertiary dressings to cover wounds after debridement, and a physician signed and dated written orders for the supplies in these cases. Dec. at 6; see also, e.g., D.R., Exh. 5.

For alginate dressings, the LCD states:

Alginate or other fiber gelling dressing covers are covered for moderately to highly exudative full thickness wounds (e.g., stage III or IV ulcers); and alginate or other fiber gelling dressings fillers for moderately to highly exudative full thickness wound cavities (e.g., stage III or IV ulcers). They are not medically necessary on dry wounds or wounds covered with eschar. Usual dressing change is up to once per day. One wound cover sheet of the approximate size of the wound or up to 2 units of wound filler (1 unit = 6 inches of alginate or other fiber gelling dressing rope) is usually used at each dressing change....

See LCD L11460, Exh. MAC-3.

LCD L11460 further states that the reasons supporting the medical reasonableness and necessity for the quantity of gauze provided must be documented in the record and based upon factors particular to the beneficiary's condition, such as "the current

status" of the wound, "the likelihood of change," and "recent use of dressings." LCD L11460, Exh. MAC-3. In addition, the LCD states that suppliers are expected to "have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly." *Id.* The Council also notes that the DME MAC Jurisdiction D's Medical Director wrote that the provision of excessive surgical dressings was not medically reasonable and necessary. See D.R., Exh. 16 at 2. 14

Each beneficiary's medical documentation consists of a prescription from the treating physician, a "Wound Care Physician Written Order" generated by the appellant and/or a "Review of Systems" form. See, e.g., D.R., Exh. 5. In each case, the record lacks documentation to support that the beneficiary required additional dressings, e.g., the documentation does not provide information about the beneficiaries' prior usage of dressings, expected wound changes that necessitate excess dressings and/or an explanation of why more dressings are required in the specific case. See, e.g., *id.*

For the reasons explained above, the Council finds that the records do not demonstrate that each beneficiary required the sterile impregnated dressings pursuant to the criteria set forth in the applicable LCD. The Council alternatively finds that the records demonstrate that the beneficiaries required plain gauze at a one per day, per wound frequency. The Council also concurs with CMS and finds that the appellant has not shown that it is entitled to bill for additional units of alginate dressings in quantities in excess of 30/31 yards per wound, per month. See Exh. MAC-1 at 6-7.

LIMITATION ON LIABILITY

The ALJ covered the dressings at issue and therefore did not address liability. Exh. MAC-1 at 5. However, CMS cites section 1879 of the Social Security Act (the Act) and states that only beneficiaries or providers who did not know and could not reasonably have been expected to know that the items or services would be excluded from Medicare coverage may have their liability waived. *Id.* at 7.

The appellant asserts that it "did not know, and could not have been expected to know, that coverage for these claims would have been denied". Exh. MAC-2 at 12.

The appellant states:

15

The fact remains that neither CMS nor Noridian has published any formal notice in its manuals, LCDs, bulletins, written guidance or directives, or articles informing DMEPOS suppliers that Noridian will not pay for AMD when the item is used as a secondary dressing.

Exh. MAC-2 at 12. (Emphasis in original).

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 noncoverage. Act at § 1879(a); 42 C.F.R. §§ 411.400, 411.404, 411.406; Medicare Claims Processing Manual (MCPM), Pub. 100-04, Ch. 30 at § 40. A beneficiary is deemed to have knowledge of noncoverage if the supplier provides written 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 has actual or constructive knowledge of noncoverage 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 (e)(3).

The appellant argues, specifically, that the DME MAC has not issued guidance that AMD dressings are not covered as a secondary treatment. This argument misses the point. The larger, and more relevant, question is whether the appellant provided sufficient medical documentation to support coverage for the dressings at issue, not just whether the dressings were used as secondary dressings. CMS manuals, as well as coverage policies applicable to the items at issue (LCDs L11460 and L11449) and the accompanying policy articles A23903 and A37303, detailed Medicare's applicable coverage requirements. Impregnated sterile gauze *may* be covered when the medical records contain requisite documentation to support Medicare coverage in accordance with LCD provisions and other applicable requirements, all of which the supplier is presumed to know.

Thus, the Council finds that the appellant could reasonably have been expected to know that Medicare would not pay for the items at issue. Further, there is no evidence that the appellant issued written notices to the beneficiaries that Medicare might not pay for the dressings at issue. Accordingly, the Council

finds the appellant liable for the non-covered dressings at issue in this case. The beneficiaries are not liable.

16

DECISION

The Council reverses the ALJ's decision and finds that the record does not support a finding that the quantities of sterile impregnated gauze or alginate dressings supplied to the beneficiaries in these cases were medically reasonable and necessary.

Thus, the Council denies Medicare coverage for all the claims billed using HCPCS A6266. The Council finds, alternatively, that Medicare coverage is available for the dressings allowed at a down-coded level, i.e., for "conforming bandage, non-elastic, knitted/woven, width greater than or equal to three inches and less than five inches, per yard," using HCPCS A6446.

For the claims for alginate dressings billed using HCPCS A6197, coverage will not be allowed for additional units of the dressings in quantities in excess of 30/31 yards per wound per month.

The appellant remains liable for the non-covered costs.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/Constance B. Tobias, Chair
Departmental Appeals Board

Date: June 22, 2011