Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re LCD Complaint:

Wheelchair Options/Accessories (LCD ID No. L11462),
Wheelchair Options/Accessories (Policy Article ID No. A19846, January 2010)

Contractor: Noridian Administrative Services (DME MAC)

Region X, Jurisdiction D

Docket No. C-10-678

Decision No.: CR2314

Date: January 24, 2011

DECISION

This Local Coverage Determination (LCD) complaint must be dismissed pursuant to 42 C.F.R. § 426.444(b)(1). Pursuant to 42 C.F.R. § 426.405(d)(5), I have no authority or jurisdiction to conduct a review of any policy that is not a LCD within the meaning of 42 C.F.R. § 400.202.

I. Background

On April 30, 2010, Permobil Inc., through its General Counsel, filed this LCD complaint on behalf of one Medicare beneficiary, the Aggrieved Party (AP).[1] The case was assigned to me on May 5, 2010. On May 24, 2010, I issued an "Acknowledgement of Receipt of Acceptable Complaint; Order to File LCD Record; and Briefing Schedule."

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[1] The names of Medicare beneficiaries are not listed in published decisions to protect their privacy. 68 Fed. Reg. 63,691, 63,709 (Nov. 7, 2003). Permobile, Inc. manufactures powered wheelchairs.

On June 4, 2010, the AP filed an Amended LCD Complaint, with an exhibit list and exhibits (A Exs.) 1 through 8. On July 7, 2010, I received from Noridian, a copy of LCD L11462, a copy of Policy Article A41127, "Article for Power Mobility Devices," effective January 2009, and a copy of Policy Article A19826, "Article for Cold Therapy," effective July 2009, attached to a hand-written note that advised me that I should let a particular individual know if anything else is needed.[2] Richard W. Whitten, MD, Noridian's Medical Director, sent me a letter dated July 13, 2010, as a further reply to my May 24, 2010 Order (Whitten Letter), with an email from Walter Rutemueller dated October 14, 2003 attached and which I have marked Contractor exhibit (C. Ex.) 1.

On July 12, 2010, the AP filed a motion for a decision that Noridian's LCD record is not valid under the reasonableness standard for the non-coverage of a power standing feature on wheelchairs. Counsel for CMS entered an appearance in this case on July 14, 2010. On July 15, 2010, I ordered that Noridian and/or CMS respond to the AP's motion. On August 12, 2010, the AP filed another motion for a determination that Noridian's LCD record was inadequate under the reasonableness standard with A. Exs. 9 through 25. I treat the AP's filing on August 12, 2010, as the AP's statement pursuant to 42 C.F.R. § 426.425(a), as that document was due on August 13, 2010 and no other pleading was received from the AP by that date.

On September 10, 2010, CMS filed a response to the AP's pleadings and CMS requested that the complaint be dismissed (CMS Br.). CMS filed CMS exhibits (CMS Exs.) 1 and 2. On September 23, 2010, the AP requested leave to respond with its response (AP Response) to the CMS motion to dismiss and that request is granted.

No objections have been made to the admissibility of C. Ex. 1, CMS Exs. 1 and 2, or A. Exs. 1 through 25 and all are admitted and considered as evidence. The copies of LCD L11462, Policy Article A41127, and Policy Article A19826 submitted by Noridian are not admitted. Article A19826 is related to "cold therapy" and is not relevant to the matter before me. The copy of Article A41127 provided by Noridian was the version effective January 2009, which has been superseded by a version effective January 2011. The copy of the LCD L11462 provided by the contractor is the revision effective April 1, 2010, which is currently in effect.[3] However, the April 1, 2010 revision of LCD L11462 is in evidence as A. Ex. 2, and it is not necessary to admit cumulative evidence.

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[2] I can determine from the face of the documents that the LCD was printed from the Centers for Medicare and Medicaid Services (CMS) website and that the two articles were printed from the Noridian Medicare website.

[3] A new revision of LCD L11462 with an effective date of February 4, 2011, is available at www.CMS.gov/mcd. However, the new revision is not in effect and not subject to my review. 42 C.F.R. § 426.405(d)(4).

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act (the Act) (42 U.S.C. § 1395j), establishes the supplementary medical insurance benefits program for the aged and the disabled known as Medicare Part B. Qualified individuals must elect to participate in the Medicare Part B program, which is funded by enrollees' premiums and appropriations from the federal government. The coverage or benefits of Medicare Part B are described in sections 1832, 1833, and 1834 of the Act (42 U.S.C. §§ 1395k, 1395l, and 1395m). However, section 1862 of the Act (42 U.S.C. § 1395y), which is applicable to both Medicare Part A and Part B, provides that no payment may be made for items or services "which . . . are not reasonable and necessary for the diagnosis or treatment of illnesses or injury or to improve the function of a malformed body member. . . ." The Secretary of the Department of Health and Human Services (the Secretary) has provided by regulation that any services not reasonable and necessary for one of the purposes listed in the regulations are excluded from coverage under Medicare. 42 C.F.R. § 411.15(k). The Medicare Benefit Policy Manual, CMS Publication 100-02, Chapter 16, §§ 10 and 20 provides that no payment may be made for 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 administration of Medicare Part B is through contractors. Act §§ 1842, 1874A (42 U.S.C. §§ 1395u, 1395kk-1). The Act provides for both National Coverage Determinations (NCD) and LCDs. Act § 1869(f)(1)(B) and (2)(B) (42 U.S.C. §1395ff(f)(1)(B) and (2)(B)). A LCD is a determination by a Medicare contractor, either a fiscal intermediary or a carrier, applicable to the area served by the contractor "respecting whether or not a particular item or service is covered," i.e., whether or not the item or service is reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Act. Act § 1869(f)(2)(B). In the absence of a NCD or a LCD, individual claims determinations are made based upon an individual beneficiary's particular factual situation. 68 Fed. Reg. at 63,693 (citing *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)) (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication).

Review of a LCD is distinct from review of an individual claim determination. 68 Fed. Reg. at 63,692-94. The right to administrative and judicial review of individual claims determinations is established by sections 1869(a) through (d) of the Act and the regulations of the Secretary governing review are at 42 C.F.R. §§ 405.1000 through 405.1140. Individual claim determinations are not subject to review under the LCD process. 68 Fed. Reg. at 63,707. Pursuant to the Act and the Secretary's implementing regulations, the Departmental Appeals Board (the Board) has the authority to review NCDs, Administrative Law Judges (ALJs) assigned to the Civil Remedies Division of the

Board have the authority to review LCDs subject to further review by the Board, and individual claims determinations are reviewed by ALJs assigned to the Office of Medicare Hearings and Appeals subject to further review by the Medicare Appeals Counsel.[4]

Section 1869(f)(2)(A) of the Act (42 U.S.C. §1395ff(f)(2))[5] provides for the review of a LCD by an ALJ subject to the limitations that (1) a complaint must be filed by an AP; (2) the ALJ must review the record of the LCD; (3) only if the record is determined by the ALJ to be incomplete or to lack adequate information to support the validity of the LCD, the ALJ will permit discovery and the taking of evidence to evaluate the reasonableness of the LCD; (4) the ALJ may consult appropriate scientific and clinical experts; and (5) the ALJ will "defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(2)(A)(i)(III). An AP may request that the Board review an adverse ALJ determination. Act § 1869(f)(2)(A)(ii).

An AP is one who has standing within the meaning of section 1869(f)(5):

> An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under Part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.

The Secretary promulgated regulations implementing sections 1869(f)(1) and (f)(2) of the Act for the review of NCDs and LCDs. 68 Fed. Reg. at 63,691. The regulations are found at 42 C.F.R. Part 426. The procedures for review of a LCD are in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et. seq.*). The regulatory history for the new regulations states that the regulations expanded the definition of an aggrieved party "to

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[4] Benefit appeals under Parts A, B, and C were previously adjudicated by ALJs assigned to the Social Security Administration (SSA). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173, § 931(a) and (b), required that the Secretary and the Commissioner of Social Security transfer the responsibility for adjudicating such appeals from SSA to the Department of Health and Human Services. OMHA was the result. 70 Fed. Reg. 36,386 (June 23, 2005) (Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority).

[5] Provisions for the review of NCDs and LCDs were added to section 1869 of the Act by the Benefit Improvement and Protections Act of 2000 (BIPA), Pub. L. 106-554, § 522.

include a beneficiary who received a service, but whose claim for the service was denied extending an opportunity to that beneficiary" to file a complaint for a NCD or LCD review. 68 Fed. Reg. at 63,693-95.

Section 1869(f)(2) of the Act establishes a two-phase LCD review process by the ALJ. The ALJ reviews the record and, if he or she determines that the record is complete with adequate information to support the validity of the LCD, review is complete. If the ALJ reviews the record and determines that the record is incomplete or lacks adequate information to support the validity of the determination, than further process is required, although that process is not specified by the statute. The Secretary's regulations establish a review procedure consistent with that specified by Congress. The regulations provide that after an AP files a statement as to why the LCD is not valid[6] and the contractor responds, "the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD." 42 C.F.R. § 426.425(c)(1). "Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process." 42 C.F.R. § 426.425(c)(2). If the ALJ does not determine that the LCD record is complete and adequate to support the validity of the LCD, then the regulation provides for discovery and the taking of additional evidence. No hearing was intended by the drafters or required by the language of the regulation for the first phase review. 68 Fed. Reg. at 63,700, 63,710. Pursuant to 42 C.F.R. § 426.330, the AP bears the burden of proof and persuasion, which is judged by a preponderance of the evidence.

B. Issue

Whether the LCD complaint must be dismissed for lack of jurisdiction?

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold followed by the pertinent facts and analysis.

1. The AP was not denied coverage based on a LCD.

2. I have no jurisdiction to review the denial of coverage based on a decision or policy that is not a LCD.

3. The AP's complaint must be dismissed.

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[6] The aggrieved party may file copies of clinical or scientific evidence in support of its complaint that a LCD is not reasonable. 42 C.F.R. §§ 426.400(c)(6), 426.403.

The AP states in the Amended LCD Complaint that she suffers from Multiple Sclerosis and that she has used a power wheelchair since 1986 because she is completely non-ambulatory without the wheelchair. The AP alleges complete dependence upon the assistance of others for activities of daily living due to lack of strength in her upper extremities. Amended Complaint at 2. The AP's physician advises that the AP has permanent limitations of no functional use of her lower extremities and only limited use of her upper extremities. The physician states that the AP needs the power stand-up feature for her wheelchair as she is unable to stand or shift her weight independently and, due to her size, it is difficult for an attendant to help the AP stand or shift her weight. The physician states that it is important for the AP to stand to improve her autonomic nervous system activity, to increase her autonomic tone, prevent orthostatic hypotension, to provide a greater range of movement for her chest for breathing, to help prevent constipation, to prevent venous stasis, to reduce the risk of deep vein thrombosis and pulmonary emboli, and to prevent pressure sores. A. Ex. 6 at 7. I accept the foregoing facts as true for purposes of this decision.

The evidence shows that the AP was notified by letter dated January 5, 2010, that she was denied coverage for the power stand feature that she needs because "[p]owered accessories for wheelchair is/are not a Medicare covered benefit and is/are excluded from coverage under your Health Plan." A Ex. 4. The AP was notified by letter dated February 17, 2010, that her request for reconsideration of the coverage decision was denied because the power accessory for which the AP sought coverage was not a covered benefit. It is significant that neither notification advised Petitioner that she was denied coverage because the power accessory was determined, either by individual medical review or the application of a LCD, not to be reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Act.

My jurisdiction or authority in this case is clearly delineated at 42 C.F.R. §§ 426.405, 426.450, and 426.455. I am limited to addressing the issues of whether or not a LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard and whether the LCD is valid or invalid under the reasonableness standard. 42 C.F.R. § 426.450(a). CMS and Noridian argue that I have no jurisdiction in this case as the AP does not challenge a LCD. (Whitten Letter at 4; CMS Br. at 3-8. I agree and conclude that I must dismiss this case for want of jurisdiction.

Noridian argues that this LCD complaint should be dismissed pursuant to 42 C.F.R. §§ 426.405(c)(2) and 426.405(d)(5), as the decision or policy that the AP challenges is not a LCD because it is based upon section 1861(n) of the Act rather than section 1862(a)(1)(A). Whitten Letter at 4. The gist of the Noridian argument is that the challenged provision is not a LCD within the meaning of 42 C.F.R. § 400.202, and that I am not authorized to conduct the requested review of the policy applied to deny the AP coverage in this case.

CMS argues that I must dismiss the complaint because 42 C.F.R. § 426.325(b)(5) provides that contractor decisions or policies not based on the reasonable and necessary test of section 1862(a)(1)(A) are not subject to review pursuant to 42 C.F.R. Part 426, because such decisions are not LCDs. CMS argues that the Noridian decision in this case is based upon the determination that the equipment in question was not durable medical equipment (DME) within the meaning of section 1861(n) of the Act. CMS also argues that 42 C.F.R. § 426.325(b)(12) precludes review of any policy that is not a LCD or a NCD and in this case the offending provision is found in a Noridian Policy Article, not a LCD. CMS Br. at 1-8.

Section 1862(a)(1)(A) of the Act provides that Medicare Parts A and B may not pay for any items or services that are "not reasonable and necessary for the treatment of illness or injury or to improve the function of a malformed body member." Section 1869(f)(2)(B) of the Act provides:

> For purposes of this section, the term "local coverage determination" means a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary – or carrier – wide basis under such parts **in accordance with section 1862(a)(1)(A)**.

(Emphasis added). The Secretary defined a LCD consistently with section 1869(f)(2)(B) of the Act, as follows:

> Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with **section 1862(a)(1)(A) of the Act**. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

42 C.F.R. § 400.202 (emphasis added).

The definition of LCD under the Act and regulations is precise. A LCD is a determination of the Medicare contractor as to whether or not a particular item or service meets the reasonable and necessary requirement of section 1862(a)(1)(A) of the Act. A LCD is used by a contractor to determine Medicare coverage for an item or service without individual medical review. I am limited to reviewing a LCD. Act §

1869(f)(2)(A); 42 C.F.R. §§ 426.325(b)(4), (5), (12), and 425.405(d)(5). Section 1861(n) of the Act describes DME. CMS and Noridian are correct that I have no authority under section 1869(f)(2)(A) of the Act to review a determination by CMS that an item is not DME within the meaning of section 1861(n) and not subject to Medicare coverage on that basis.

In this case the evidence shows that the denial of coverage was based upon a CMS determination and guidance to its contractor that a power seat elevation feature or power standing feature is not DME within the meaning of section 1861(n) of the Act. C. Ex. 1; CMS Ex. 1, at 2; CMS Ex. 2, at 2, ¶ 7; A. Ex. 3, at 2. Coverage was not denied in this case based upon a LCD that a power seat elevation feature or power standing feature is not reasonable and necessary for the treatment of illness, injury, or to improve function.

The AP argues in her response to the CMS motion to dismiss that the motion to dismiss should be denied because it is untimely. The argument is without merit. I cannot decide an issue that I do not have jurisdiction or authority to decide under the Act or the Secretary's regulations. Thus, a motion to dismiss for lack of jurisdiction cannot be untimely. Indeed, in the absence of the CMS motion it would have been necessary for me to specify the issue for the parties to brief and the result would have been no different.

The AP also cites the decision of an appellate panel of the Board in *LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050 (2006), to support her position that I have jurisdiction. However, the *Transfer Factor* case is distinguishable because that case did not involve DME or a determination under section 1861(n) of the Act.

Accordingly, I conclude that there is no LCD for me to review, I have no jurisdiction, and the AP's complaint must be dismissed.

4. Appeal rights. 42 C.F.R. §§ 426.462, 426.465.

Pursuant to 42 C.F.R. § 426.465(a), an AP may request review by the Board. Except upon a showing of good cause, a request for review by the DAB must be filed within 30 days of the date of this decision (42 C.F.R. § 426.465(e)) and must comply with the requirements of 42 C.F.R. § 426.465(f).

III. Conclusion

For the foregoing reasons, the LCD complaint must be dismissed for lack of jurisdiction.

/s/
Keith W. Sickendick
Administrative Law Judge