Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD COMPLAINT: Wheelchair Options/ Accessories (L11451),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-542

Decision No. CR2205

Date: August 20, 2010

AMENDED DECISION

I find to be reasonable Local Coverage Determination (LCD) 11451. I therefore deny the challenge of Petitioner.

I. Background

On March 9, 2010 Petitioner filed a challenge to LCD 11451, a local coverage determination issued by CIGNA, a Medicare contractor. This challenge was assigned to me for a hearing and a decision pursuant to 42 C.F.R. Part 426. I reviewed the challenge and found it to be acceptable. I then directed CIGNA to furnish me and Petitioner with its LCD file. CIGNA moved that I dismiss the challenge and I denied the motion. CIGNA then furnished its file to Petitioner and to me. I afforded Petitioner the opportunity to review and to respond to the documents that it had been furnished by CIGNA. Petitioner filed a document that it styled "Petitioner's Motion for a Decision that CIGNA's LCD Record is Not Valid for Non-coverage of Power Seat Elevators on Wheelchairs" (Petitioner's motion for a decision) and 13 exhibits. I receive the exhibits into the record of this case as P. Ex. 1 – P. Ex. 13. I also receive into the record Petitioner's hearing request with attached exhibits "A" through "G" and CIGNA's LCD file with attached exhibits 1 – 4.

This case is now ready for decision. Neither CIGNA nor Petitioner requested to present testimony in person. I find the LCD record to be complete and adequate for me to decide this case. Moreover, I find no need for an in-person hearing based on what has been presented by the parties. This case may be decided based on the written record. 42 C.F.R. § 426.431(a)(2).

II. Issue, findings of fact and conclusions of law

A. Issue

The sole issue in this case is whether LCD 11451 satisfies the reasonableness standard defined by 42 C.F.R. § 426.110.

B. Findings of fact and conclusions of law

I make the following findings of fact and conclusions of law (Findings).

1. LCD 11451 satisfies the reasonableness standard defined by 42 C.F.R. § 426.110.

In deciding any challenge on the merits to an LCD the sole issue that I may hear and decide is whether the LCD satisfies the reasonableness standard of 42 C.F.R. § 426.110. 42 C.F.R. § 426.425(c). The reasonableness standard states that:

> In determining whether LCDs . . . are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and the applications of fact to law . . . are reasonable based on the LCD . . . record and the relevant record developed before . . . [the administrative law judge].

42 C.F.R. § 426.110. This standard requires me to uphold a challenged LCD if I find that the contractor's determination is reasonable. In deciding whether an LCD is reasonable I do not substitute my policy judgments and conclusions for that of the contractor. If I find that the LCD is reasonable based on the evidence before me I must sustain the LCD even if I could find that the evidence might support a different policy determination. I do not decide what an LCD *should cover* but rather, whether the distinctions made by an LCD are reasonable based on the objective evidence before me.

Nor may I decide the reasonableness of an LCD determination based on the unique facts of an individual beneficiary's case. The issue before me is not whether any particular Medicare beneficiary might benefit from the care that is excluded from coverage by an LCD but whether the LCD determination is reasonable when considered across the entire

spectrum of beneficiaries who might seek to have a particular item or service covered. Thus, an LCD may be determined to be reasonable even if it has the consequence of denying an individual beneficiary coverage which might benefit him or her under the unique circumstances of his or her case.

The specific issue in this case is whether the portion of LCD 11451, as applied through a subsequent CIGNA policy statement, denying Medicare coverage for seat elevators on powered wheelchairs is reasonable. I find it to be reasonable and so I deny Petitioner's challenge to the LCD.

On December 3, 2009 CIGNA issued an advanced determination of Medicare coverage to Medical Mobility, Inc., (Medical Mobility) a durable medical equipment supplier in Murfreesboro, Tennessee. Exhibit D to Petitioner's hearing request. The determination allowed coverage to Petitioner for a multiple power option power wheelchair. The determination specifically excluded coverage for a seat elevator. In denying coverage for this item, CIGNA stated:

> A seat elevator is considered not primarily medical in nature and is a non-covered option on a power wheelchair.

Id. at 2. CIGNA advised Medical Mobility that the determination was based on documents that included, among other things, LCD 11451, and document that is entitled Policy Article for Wheelchair Options/Accessories A20284.

A seat elevator on a powered wheelchair is an item that electronically raises and lowers the seat of the wheelchair thus raising and lowering the wheelchair's occupant. It may be used for, among other things, enabling the occupant to reach items – such as a shelf or a cabinet drawer – that would not otherwise be accessible to him or her. It may also be used to raise the occupant to a level so that he or she may speak face to face with another individual. Petitioner contends that, in his case, the seat elevator also may be used as a means of assisting him to transfer in and out of his wheelchair and participate in the various activities of daily living such as toileting, bathing, dressing, feeding, grooming, and to be able to exit his home expediently in the case of an emergency. Petitioner's hearing request at 2. For purposes of this decision I accept Petitioner's assertion as truthful.

To summarize my findings, I conclude that LCD 11451 is consistent with the requirements of law and with CMS's policy governing reimbursement for motorized wheelchair accessories. In declining to reimburse for powered seat elevators the LCD restates a policy that CMS has expressed in other documents. I find the LCD to be reasonable because it is consistent with CMS's policy. CMS distinguishes between reimbursable durable medical equipment that is determined to be medically necessary

and equipment which, while of benefit to the user, is not medically necessary. Powered seat elevators in motorized wheelchairs have been found by CMS to fall in that latter category and, for that reason, have been held not to be reimbursable. LCD 11451 reiterates that conclusion.

Section 1861(n) of the Social Security Act (Act) defines "durable medical equipment" as items that are reimbursable under the Medicare program. The term includes:

> a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition . . . .

Id. The Act draws a distinction between a powered wheelchair that is a necessary element of an individual's medical care and one that is issued for another purpose, such as for the convenience of the beneficiary or to improve the quality of his or her life. Only those devices that are necessary will be covered under Medicare.

The LCD at issue in this case was first effective on or after October 1, 1993 and was revised to address services performed on or after January 1, 2009. The LCD addresses options and accessories for wheelchairs. It provides, generally, that:

> Options and accessories for wheelchairs are covered if the patient has a wheelchair that meets Medicare coverage criteria and the option/accessory itself is medically necessary. . . .

Exhibit B to Petitioner's hearing request at 2. LCD 11451 does not provide coverage for powered seat elevator systems. It does cover a "power seating system", which is specified as "tilt only, recline only, or combination tilt and recline – with or without power elevating legrests", but only if certain criteria not relevant to this case are met. *Id.* at 4. Essentially, the LCD distinguishes between an elevating mechanism that is intended to mechanically assist the occupant of a wheelchair from a seated to a standing position and one which raises and lowers the seat of a wheelchair in order to assist the occupant of the chair with activities of daily living. The former device is considered to be medically necessary in the appropriate case whereas the latter, while it may improve a beneficiary's quality of life, is not considered to be medically necessary.

The LCD also contains "revenue codes" which are specific codes that providers may use to identify items for which they claim reimbursement. *Id.* at 6. I do not infer from the inclusion of any item under a revenue code that the item will be reimbursed if a provider seeks reimbursement for that item. Rather, the revenue codes are neutral in the sense that they allow a provider to describe specifically the items for which it seeks reimbursement

without suggesting that any of these items will be reimbursed if a claim is filed for it. Therefore, although revenue code item E2300 describes a "power wheelchair accessory, power seat elevation system", the presence of this item under the listed codes does not mean, necessarily, that Medicare will reimburse for it.

On October 14, 2003, Walter Rutemueller, a technical advisor to the Division of Durable Medical Equipment, Centers for Medicare Management of the Centers for Medicare and Medicaid Services (CMS), issued an opinion directed to all durable medical equipment regional carrier medical directors. Ex. 1 of the LCD file. Mr. Rutemueller addressed specifically the issue of whether certain accessories to power wheelchairs, including "power elevation", were reimbursable Medicare items. *Id.*. The opinion, which was issued in response to an inquiry from a carrier, stated that CMS would consider certain features including "power elevation" "to be noncovered by reason of 1861(n)". Although this opinion is not lengthy or detailed, it is consistent with the distinction between wheelchair accessories that are determined to be medically necessary and those that are not necessary but which may enhance the quality of life of the user. CMS concluded, consistent with section 1861(n) of the Act, that powered seat elevators were not medically necessary and, therefore, not covered.

CMS explained why powered seat elevators were not reimbursable in much greater detail in a National Coverage Determination (NCD) entitled "NCD for INDEPENDENCE iBOT Mobility System (280.15). Exhibit 3 of the LCD file. This NCD addressed a specific type of motorized wheelchair which it described as:

> a battery-powered mobility device that relies on a computerized system of sensors, gyroscopes, and electric motors to allow indoor and outdoor use on stairs as well as on level and uneven surfaces. The mobility system incorporates a number of different functions, including: a) Standard Function that provides mobility on smooth surfaces and inclines at home, work, and in other environments; b) 4-Wheel Function that provides movement across obstacles, uneven terrain, curbs, grass, gravel, and other soft surfaces; c) Balance Function that provides mobility *in a seated position at an elevated height*; d) Stair Function that allows for ascent and descent of stairs, with or without assistance; and e) Remote Function that assists in the transportation of the product while unoccupied. . . .

Id. at 1-2 (emphasis added). The NCD concluded that the Standard Function was reimbursable because it met the statutory definition of a motorized wheelchair in section 1861 of the Act as a wheelchair used in a beneficiary's home that is reasonable and necessary for beneficiaries who have a mobility deficiency sufficient to impair their participation in mobility-related activities of daily living. However, the NCD also concluded that the other functions, including the Balance Function, did not meet the statutory definition of a motorized wheelchair. Consequently, the NCD excluded these other functions from Medicare reimbursement.

The NCD was supported by extensive analysis. In a request for public comment dated January 26, 2006, CMS stated a four prong test for determining whether an item would qualify for reimbursement as durable medical equipment. Exhibit 2 of the LCD file at 7. The test contains the following elements: (1) an item is "durable" if it can withstand repeated use; (2) it is "medical equipment" if it is used primarily and customarily for a medical purpose and not for environmental control or to enhance the environment in which the beneficiary is placed; (3) it must be useful for treatment of an illness or injury or to the improvement of a malformed body member; and (4) the individual must have a medical need for the item in his or her home. *Id.* Using this test, the analysis of the iBOT 4000 system concluded that there was not clinical evidence showing that anything other than the Standard Function on the iBOT 4000 was customarily used for a medical purpose and not for environmental control and/or enhancement. *Id.* at 15. Referring specifically to the Balance Function (which includes seat elevation capability) the analysis found:

> Seat elevation serves the same purpose as other equipment that assist all persons in reaching items out of reach or having an "eye-level" conversation with a standing person. We believe that these are common needs among many persons and that a seat elevation function that assists a patient in accomplishing these activities is not presumptively medical in nature. In addition, the clinical trials did not demonstrate how the Balance Function serves a medical purpose to treat an illness or injury, or to improve the functioning of a malformed body member. . . .

Id. at 17. The analysis distinguished between a powered seat elevator such as that utilized by the iBOT 4000 and a Medicare-covered lift that effectively assists a beneficiary in standing up and sitting down without other assistance. By contrast, the Balance Function maintains the user in a seated position. *Id.*

The NCD applies to a specific mechanical device, the iBOT 4000. However, the principles of this NCD are entirely consistent with what CMS has stated over the years: seat elevator mechanisms in motorized wheelchairs are not reimbursable items under Medicare because they are intended primarily to enhance the quality of a beneficiary's life and not for a medical purpose such as treatment of an illness. Consequently, they are not durable medical equipment within the meaning of section 1861(n) of the Act.

Recently, CIGNA reiterated its policy not to cover powered seat elevators. In a document entitled Article for Wheelchair Options/Accessories – Policy Article – Effective January 2010 (A20284), CIGNA stated that a power seat elevation feature (E2300) is noncovered because it is not primarily medical in nature. Exhibit "CEE" to hearing request at 2.

CIGNA's policy not to reimburse for powered seat elevators is reasonable. It embodies a distinction that CMS has long maintained, that being a distinction between that which is medically necessary and that which may be beneficial but which is not medically necessary. Powered seat elevators have been held by CMS and by CIGNA not to be medically necessary because, although they may enhance the quality of beneficiaries' lives, they do not treat illnesses or promote cures.

LCD 11451 is not supported by extensive medical research done by CIGNA. But, there is no requirement in law that CIGNA perform such research. CIGNA is entitled to rely on research performed by other entities – in this case CMS – if that research provides reasonable support for the policy expressed in an LCD. As I have discussed, CMS performed extensive analysis in analyzing the features of the iBOT 4000. Its analysis established that the powered seat elevator function of that device is not medically necessary. CIGNA is entitled to rely on that research and analysis in implementing its LCD and in follow-up policy statements that apply to power seat elevator devices.

Where an NCD covers the same issue as is covered by an LCD the policy expressed in the NCD has the force of law and is binding on the carriers. Thus, any LCD issued by a carrier must be consistent with the policy expressed in an NCD. The NCD which I have discussed in this case addresses the power seat elevator function of a specific device, the iBOT 4000, and not *all* power seat elevators. But, the analysis that underlies the finding of the NCD concerning power seat elevators is clearly more broadly applicable. Essentially, the NCD concludes that power seat elevators that raise and lower a wheelchair's occupant – as distinguished from those that tilt the occupant into a standing position – are not medically necessary. CIGNA acted entirely reasonably in implementing that policy in its LCD.

Petitioner argues that CIGNA's LCD determination is invalid in that it does not rely on medical evidence such as scientific articles, technology assessment, or clinical guidelines to support its determination that power seat elevators are not medically necessary. Petitioner's motion for a decision at 1. However, there is no legal requirement that a carrier must independently perform an evidentiary review as a prerequisite to issuing an LCD if the policy expressed in the LCD is consistent with a broader policy expressed by CMS or with the law. I do not find the LCD in this case to be reasonable based on research performed by CIGNA. I find it to be reasonable because it is consistent with a policy determination by CMS, a policy determination that was extensively analyzed and supported.

Petitioner asserts also that CIGNA is relying only on a "two sentence email that offers a conclusory opinion that seat elevators do not meet the definition of . . . [durable medical equipment] because they are not primarily medical in nature and thus, are not covered." Petitioner's motion for a decision at 1. That is not an accurate characterization of what

CIGNA relies on. As I have discussed, CIGNA relies on a policy of CMS which denies reimbursement for power seat elevator devices. The e-mail alluded to by Petitioner is consistent with that policy. Exhibit 1 of the LCD file.

Petitioner argues that Exhibits 2 and 3 of the LCD file should be excluded from evidence as irrelevant to the issue of whether LCD 11451 is reasonable. That is so, argues Petitioner, because 42 C.F.R. § 426.418 defines an LCD record to be limited to medical evidence considered "on or before the date the LCD was issued. . . ." Petitioner asserts that LCD 11451 was issued prior to the NCD governing the iBOT 4000 and that NCD's supporting analysis. Consequently, according to Petitioner, Exhibits 2 and 3, which relate to that NCD, are irrelevant.

I disagree with this analysis. First, LCD 11451 is not a static document. It has been revised and was clarified most recently by Policy Statement A20284 issued in January 2010. Documents generated prior to the issuance of clarifications and revisions to the LCD obviously are generated on or before those clarifications and are, therefore, part of the LCD file.

Moreover, Exhibits 2 and 3 are relevant to determining CMS's policy even if they are not, strictly speaking, part of the LCD record. In hearing and deciding this case I am not limited to considering only evidence that is part of the LCD record. I may consider all evidence that is relevant and Exhibits 2 and 3 are clearly relevant as evidence of CMS's policy and as a rationale for CIGNA's clarification of its LCD to expressly exclude reimbursement for power seat elevators. 42 C.F.R. § 426.110.

Petitioner also argues that the iBOT 4000 is distinguishable from a generic power seat elevator because, allegedly, the iBOT 4000 has only two positions, down and up. Petitioner's motion for a decision at 12. Petitioner contends that the iBOT 4000 "Balance Function" cannot provide the kinds of assistance that generic power seat elevators provide due to this limited "up" or "down" positioning of the device. However, that is not what was found in the analysis of the iBOT 4000, which concluded that the seat elevator function of the iBOT 4000 could be used to help the occupant perform activities that included reaching items that are out of reach and other activities of daily living. Furthermore, Petitioner has not provided me with technical evidence proving that the iBOT 4000 is so limited in its functions as Petitioner contends.

Petitioner next argues that "other contractors of CMS and other U.S. government agencies" define power seat elevators as durable medical equipment. Petitioner's motion for a decision at 4. Thus, Petitioner contends, CIGNA's exclusion of power seat elevators from reimbursement is inconsistent with those other entities' policies and is unreasonable. *Id.* As support for this contention Petitioner asserts that, in 2003, an entity that Petitioner describes as "SADMERC (now known as PDAC)" issued a code for power seat elevators "which could only have occurred if the product meets the definition of DME." *Id.* According to Petitioner, PDAC is the entity with which CMS contracts to

develop billing codes for items for which reimbursement is claimed. *Id.* at 4-5. Logically, according to Petitioner, PDAC would not have developed a code for powered seat elevators (E2300) unless these devices are reimbursable. *Id.* at 5

I disagree. As I discuss above, the reimbursement code is a system for describing what is claimed by a provider. It is a *classification system* which enables both the provider and the reimbursing entity to know what is being claimed without requiring a detailed verbal description of the claimed item. But, the fact that a code exists for an item does not mean that a policy determination has been made that the item will be reimbursed if claimed. Consequently, the fact that a code exists for a power seat elevator does not establish that it is durable medical equipment.

As support for its argument Petitioner relies on an affidavit from a former medical director of SADMERC in which the affiant asserts that, if a power seat elevator does not meet the definition of DME, a code would not have been issued for the product. P. Ex. 2. I find this assertion not to be credible in the absence of supporting evidence explaining why the code was issued. Moreover, the argument flies in the face of that which is obvious. CMS determined that power seat elevators that raised and lowered their occupants but which did not tilt as an assist to standing were *not* durable medical equipment. The fact that a reimbursement code exists for a power seat elevator does not derogate from the policy determination that is embodied in the NCD.

Petitioner also argues that various State Medicaid agencies reimburse for seat elevators. Petitioner has not provided supporting evidence to show precisely what these entities reimburse for or under what circumstances. Moreover, the fact that reimbursing entities may come to different conclusions does not mean that any of their conclusions are, necessarily, unreasonable.

Petitioner asserts additionally, that the Food and Drug Administration classifies mobility devices as physical medicine devices. Therefore, according to Petitioner, they must logically be durable medical equipment. But, the statutory function of the Food and Drug Administration is not the same as that of Medicare. CMS and its contractors have the independent responsibility to determine what is reimbursable under Medicare. They are not bound in their determinations by the classifications that the Food and Drug Administration might make.

Petitioner argues at length that power seat elevators are, in fact, medically necessary devices. Petitioner's motion for a decision at 5 – 8. I do not find Petitioner's arguments to be persuasive for two reasons. First, Petitioner's arguments aim at proving that it may be reasonable for Medicare to cover power seat elevators under certain circumstances. Even if that is so it does not prove that CIGNA's policy determination as expressed in LCD 11451 and Policy Statement A20284 is unreasonable.

Second, many of the arguments stated by Petitioner supporting coverage for power seat elevators address quality of life as opposed to medical issues. Section 1861(n) of the Act does not define durable medical equipment and, in particular, powered wheelchairs, to include devices that improve the quality of a beneficiary's life. Devices are not covered if they are not medically necessary. Power seat elevators – even if they improve the quality of beneficiaries' lives – do not fall within the Act's definition of durable medical equipment if they are not medically necessary.

For example, Petitioner cites to the affidavit of Teresa Plummer, a consultant, as support for its argument that power seat lifts are medically necessary:

> The seat elevator has significant medical uses and is an essential component of power wheelchair for many clients. I have worked with pediatric and adolescent clients using power wheelchairs who require the use of a seat elevator in order to participate in essential activities of daily living such as brushing their teeth, reaching into the refrigerator for beverages or food, turning lights on, elevator doors open, and temperature controls in the home environment. Additionally, seat elevators are necessary for independent and caregiver assisted transfers to and from the wheelchair, toileting, bathing, grooming, eating, and dressing.

P. Ex. 5 at ¶ 2; Petitioner's motion for a decision at 6-7. Assuming the truth of these assertions, they are not a description of medically necessary functions. Rather, they describe precisely the sort of activities that CMS determined to be quality of life related and not medically necessary. I do not disagree with Petitioner that power seat elevators may dramatically improve the quality of beneficiaries' lives. But, improving the quality of life does not equate to medically necessary under section 1861(n) of the Act nor does it qualify an item as durable medical equipment.

Petitioner contends that a power seat elevator may assist a disabled individual to arise from a seated position. Petitioner's motion for a decision at 7. However, CMS addressed this issue in its policy findings about power seat elevators and concluded that seat lifts that tilt so as to facilitate standing may be medically necessary whereas those that simply raise or lower the occupant are not. Petitioner has not shown this distinction to be unreasonable.

Petitioner asserts also that "numerous Administrative Law Judges have determined in individual appeals from the denial of coverage of seat elevators, that seat elevators meet the definition of . . . [durable medical equipment] and should be covered by Medicare." Petitioner's motion for a decision at 8. However, the decisions that Petitioner refers to are not precedential and, moreover, they do not address the issue that I must decide, that being whether LCD 11451 is reasonable.

Additionally, Petitioner argues that LCD 11451 contravenes an NCD other than that which I have discussed in this decision, an NCD addressing mobility assistive equipment. Petitioner's motion for a decision at 10; P. Ex. 12. Petitioner asserts that the NCD makes a general finding that mobility assistive equipment is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home. *Id.* However, this is a *general* finding and does not apply to specific items of equipment. The NCD governing power seat elevators in the iBOT 4000 contains a *specific* finding that seat elevators that raise or lower their occupants do not have a medical purpose. That finding must control because it is specific.

2. I deny Petitioner's challenge to LCD 11451.

I must deny Petitioner's challenge to LCD 11451 because I conclude that CIGNA acted reasonably.

/s/
Steven T. Kessel
Administrative Law Judge