Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

In re CMS LCD COMPLAINT: Wheelchair Options/Accessories (L11451)
Docket No. A-10-99
Decision No. 2370
March 29, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

An Aggrieved Party (AP) appeals the August 20, 2010 decision of Administrative Law Judge Steven T. Kessel upholding as reasonable a purported local coverage determination (LCD) denying coverage for a power seat elevator for a power wheelchair. *CMS LCD Complaint: Wheelchair Options/Accessories (L11451)*, DAB CR2205 (2010) (ALJ Decision). We reverse the ALJ Decision and dismiss the appeal because the contractor's policy not to cover the requested item did not meet the definition of an LCD so ALJ and Board review is not available.

Legal Background

An LCD is defined as a Medicare contractor's determination whether or not to cover a particular Medicare item or service on a contractor-wide basis "in accordance with section 1862(a)(1)(A)" of the Social Security Act (Act).[1] Act § 1869(f)(2)(B) (42 U.S.C. § 1395ff(f)(2)(B)); 42 C.F.R. § 400.202. Section 1862(a)(1)(A) of the Act bars Medicare payment for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury," with exceptions not relevant here. That provision is referred to as the "medical necessity" standard. *See, e.g., CMS LCD Complaint: Homeopathic Medicine and Transfer Factor,* DAB No. 2315, at 2 (2010); *LCD Appeal of Non-coverage of Intravenous Immunoglobulin*, DAB No. 2059, at 2 (2007), *aff'd sub nom. S.A., R.A.S., R.S., and M.W. v. Leavitt,* Civ. No. 07-0200-CV-W-GAF (D. Mo. June 30, 2008), *aff'd sub nom. S.A.; R.A.S.; R.S.; M.W. v. Sebelius,* 352 F. App'x 134 (8th Cir. 2009). An LCD is issued by a Medicare contractor in a particular region and applies the medical necessity standard for that region but is not binding beyond the issuing contractor. *LCD Appeal of Non-coverage of Intravenous Immunoglobulin* at 2.

[1] The current version of the Act can be found at http://www.socialsecurity.gov/OP_ Home/ssact/ssact.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

Section 1869(f)(2) of the Act permits Medicare beneficiaries denied coverage for items or services on the basis of an LCD to challenge the validity of the LCD before an ALJ and then the Board. The regulations provide for the beneficiary challenging an LCD (the AP) to file an "LCD complaint" explaining why the LCD is not valid and to submit supporting clinical or scientific evidence, and for the contractor or CMS to file the "LCD record" ("any document or material that the contractor considered during the development of the LCD") and to respond to the AP's arguments. 42 C.F.R. §§ 426.110; 426.418(a); *see generally* 42 C.F.R. Part 426, subparts C, D. The ALJ "applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD" and "must uphold a challenged [LCD] if the findings of fact, interpretations of law, and applications of fact to law by the contractor . . . are reasonable based on the LCD . . . record and the relevant record developed before the ALJ[.]"[2] 42 C.F.R. §§ 426.110, 426.425(c)(1). The ALJ's review authority is limited to contractor policies that meet the definition of LCDs, and does not extend to any policy that is not an LCD as defined in the Act and regulations. 42 C.F.R. §§ 426.325(a), (b)(5), (12), 426.405(d)(5).

APs may appeal to the Board "any part of an ALJ's decision that . . . [s]tates that a provision of an LCD is valid under the reasonableness standard." 42 C.F.R. § 426.465(a)(1). The standard of review before the Board is "whether the ALJ decision contains any material error, including any failure to properly apply the reasonableness standard." 42 C.F.R. § 426.476(b).

The requested item was claimed as durable medical equipment, or DME. DME is among the "medical and other health services" for which sections 1832(a) and 1861(s)(6) of the Act authorize Medicare payment. Section 1861(n) of the Act contains a non-exclusive list of DME items including "a power-operated vehicle that may be appropriately used as a wheelchair . . . used in the patient's home . . . ." The regulations define DME as "equipment that— (1) Can withstand repeated use; (2) Is primarily and customarily used to serve a medical purpose; (3) Generally is not useful to an individual in the absence of an illness or injury; and (4) Is appropriate for use in the home." 42 C.F.R. § 414.202 (emphasis added).

Case Background

The AP is a 24-year-old man with muscular dystrophy. AP LCD App. at 2. The CMS contractor, CIGNA Government Services (CIGNA), granted his request for coverage for a power wheelchair but denied coverage for a power "seat elevator" accessory on the

[2] This process for challenging an LCD is distinct from the process by which a beneficiary may appeal an individual decision by a contractor to deny Medicare coverage for an item or service, in which an ALJ at the Office of Medicare Hearings and Appeals may decide whether to apply the LCD in the particular circumstances at issue, but cannot make a determination as to its validity that is binding on the contractor. *See* 42 C.F.R. Part 405, subpart I.

ground that it "is considered not primarily medical in nature and is a non-covered option on a power wheelchair." P. Ex. D at 2 (emphasis added).[3] Among the documents CIGNA stated that it utilized in its decision were LCD 11451, "LCD for Wheelchair Options/Accessories," and a "policy article" referenced therein ("A20284 - Policy Article for Wheelchair Options/Accessories"). *Id*.; ALJ Decision at 3.

LCD 11451 itself does not address power seat elevators, and states that "[a] power seating system – tilt only, recline only, or combination tilt and recline – with or without power elevating leg rests will be covered" if certain criteria are met relating to the individual patient, the wheelchair, and the seating system. P. Ex. B at 2-3. LCD 11451, however, identifies as a "related document" the policy article, which states, as relevant here, that "[a] power seat elevation feature (E2300) and power standing feature (E2301) are noncovered because they are not primarily medical in nature." *Id*. at 21; P. Ex. C at 2. The AP timely requested ALJ review through his representative, the wheelchair supplier.[4]

Before the ALJ, CIGNA moved that the complaint be dismissed for lack of jurisdiction. CIGNA argued, as does CMS on appeal, that the denial of coverage was based not on an LCD subject to ALJ review, but on "CMS' long-standing policy," reflected in CIGNA's policy article, "that wheelchair seat elevators are not primarily medical in nature and therefore do not fall within the definition of 'durable medical equipment'" at 42 C.F.R. § 414.202 (equipment that, among other requirements, "[i]s primarily and customarily used to serve a medical purpose") for which Medicare payment is available. CIGNA Motion to Dismiss (MD) at 4; s*ee* CMS Resp. to AP Br. at 2 ("seat elevators on power wheelchairs do not constitute durable medical equipment (DME) for purposes of coverage under section 1861(n) of the Act, as well as CMS's regulations"). CIGNA argued that the policy article provision denying coverage for a power seat elevator thus does not meet the definition of an LCD as a determination that an item is not medically necessary. MD at 2-4, citing Act § 1869(f)(2)(B) and 42 C.F.R. § 400.202 (LCD is a contractor's determination whether or not to cover a particular Medicare item or service on a contractor-wide basis "in accordance with section 1862(a)(1)(A)" of the Act, i.e., the medical necessity standard). CIGNA argued that the regulations limit ALJ review to

[3] We retain the ALJ's designation of the AP's exhibits to his appeal as Petitioner's Exhibits (P. Exs.) A through G and his subsequent exhibits as Petitioner's Exhibits 1 – 13, and the ALJ's designation of the materials CIGNA submitted in response to the ALJ's order to submit the LCD record as LCD File Exhibits 1 – 3.

[4] For the purposes of the appeal the ALJ accepted the AP's undisputed contention that he could use the seat elevator 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 exit his home expediently in the case of an emergency. ALJ Decision at 3. Additionally, the AP submitted medical records and physician statements supporting his request for the power wheelchair and seat elevator, in fulfillment of the requirement to provide "a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD." P Ex. E; 42 C.F.R. § 426.400(c)(3). Neither CMS nor CIGNA have argued that the AP has not met this threshold requirement for challenging an LCD.

policies that are LCDs within that definition. MD; s*ee also* CMS Resp. at 4, 6, citing 42 C.F.R. §§ 426.405(d)(5), 42 C.F.R § 426.325(b)(5).

The ALJ denied CIGNA's motion to dismiss, on the ground that CIGNA had not provided "any documentation of the alleged CMS interpretation of the Act and regulation" that "a seat lift device installed on a power wheelchair" is not DME as defined in the Act and regulations and thus not "a covered item or service." ALJ Ruling Denying MD at 2 (June 1, 2010). The ALJ found that CIGNA's reliance on the policy article and the LCD "leaves open the question of whether the LCD meets the standard of reasonableness" and that dismissal of the hearing request "would be premature at this point." *Id*. at 2-3.

The ALJ then directed CIGNA to produce the LCD record. *Id*. In response, CIGNA repeated its request that the appeal be dismissed and submitted the following three documents that it said "demonstrate[] that the challenged article is based on [Act] § 1861(n) and not 1862(a)(1)(A)" (CIGNA Letter to ALJ at 2 (June 14, 2010)):

- An email dated October 14, 2003 from Walter Rutemueller, Technical Advisor with CMS's Division of DME, to the DME Regional Carrier (DMERC) medical directors, in response to the question whether "[p]ower seat elevation features and power standing features" for power wheelchairs "are eligible for coverage under the DME benefit, and if not, how they should be denied." LCD File Ex. 1. The directors noted that DMERCs had "historically denied these accessories," either "as statutorily noncovered" as a "convenience item" that was "not primarily medical in nature" under section 1861(n) of the Act, or "as not medically necessary." Mr. Rutemueller replied that "[w]e would consider all of the features you mentioned . . . i.e., power elevation, power standing . . . to be noncovered by reason of 1861(n)." *Id*.
- A National Coverage Determination (NCD)[5] identified as NCD 280.15 (LCD File Ex. 3), and
- A decision memorandum (LCD File Ex. 2) supporting NCD 280.15, both of which relate to the "iBOT 4000," a specific motorized wheelchair other than the one for which the AP was granted coverage, that "relies on a computerized system of sensors, gyroscopes, and electric motors" to travel on uneven surfaces, climb stairs, and balance on two wheels. ALJ Decision at 5, citing LCD File Ex. 3, at 1-2. The NCD and the decision memorandum state that coverage for the iBOT 4000 was limited to its "Standard Function" in which it travels on smooth surfaces and inclines like a standard powered wheelchair, and not available for other functions including the "Balance Function" in which it elevates by standing on two wheels,

[5] NCDs are issued by CMS, apply nationally, are binding at all levels of administrative review, and may be challenged before the Board. 42 C.F.R. § 405.1060; 68 Fed. Reg. 63,692, at 63,693 (Nov. 7, 2003); 42 C.F.R. Part 426, subpart E.

> as not presumptively medical in nature. The ALJ relied on this NCD and memorandum in his decision.

The ALJ Decision

The ALJ held that the LCD "satisfies the reasonableness standard defined by 42 C.F.R. § 426.110." ALJ Decision at 2. The ALJ relied on CMS's analysis in the decision memorandum supporting NCD 280.15, which found that only the "Standard Function" on the iBOT 4000 "was customarily used for a medical purpose and not for environmental control and/or enhancement." *Id*. at 6. He also cited CMS's finding in the decision memorandum that the "Balance Function" that includes seat elevation serves "'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.'" *Id*. The ALJ found that "the principles" of NCD 280.15 and the decision memorandum explaining noncoverage for the balance/elevation function of the iBOT 4000 –

> 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.

Id. The ALJ found, based on CIGNA's submissions, that "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," that "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," and that CMS "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." *Id*. at 6, 9, 10. The ALJ noted that CIGNA had denied the AP's request on the ground that a power seat elevator is "not primarily medical in nature" and pointed out that CIGNA's submissions reflected a CMS determination "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." *Id*. at 3, 6, 9 (emphasis in original). He rejected the AP's claim that the assignment of a Medicare "code" to power seat elevators meant that they were covered, finding that "the fact that a code exists for a power seat elevator does not establish that it is durable medical equipment." *Id*. at 9. Finally, he concluded that the undisputed fact that the requested item might improve the AP's quality of life did not qualify it as DME. *Id*. at 10. Although the ALJ agreed with CIGNA that CMS had long considered seat elevators not to be DME, a determination he found reasonable, he did not address CIGNA's argument that its policy denying coverage on that basis was not an LCD subject to review.

The AP timely appealed the ALJ Decision, and CMS, in response, moved that the appeal be dismissed on the same grounds that CIGNA asserted before the ALJ. CMS argues in the alternative that the ALJ Decision contains no material error and should be affirmed. The AP opposed the motion to dismiss on the ground that CMS had failed to appeal the ALJ Decision within the 30 day time period provided in 42 C.F.R. § 426.465(e) (absent "good cause shown, an appeal . . . must be filed with the Board within 30 days of the date the ALJ's decision was issued."). The AP also argues that CIGNA's policy article is a reviewable LCD.

Analysis

We reverse the ALJ Decision because the ALJ exceeded the permissible scope of his authority by reviewing a policy determination that is not an LCD as defined in the Act and regulations subject to review, and that is expressly excluded from his review by the governing regulations.

The ALJ correctly found that the basis for CIGNA's denial of the AP's request for coverage was the determination in the policy article that power seat elevators are not DME for which Medicare reimbursement is available. He recognized that CIGNA's denial of the AP's request on the ground that a power seat elevator is "not primarily medical in nature" means that the item had been determined not to satisfy one of the standards in the definition of DME at 42 C.F.R. § 414.202, that DME is equipment . . . that is "primarily and customarily" used for "a medical purpose . . . ." ALJ Decision at 3, 6, *citing* LCD File Ex. 2, at 7 (NCD 280.15 decision memorandum citing regulatory definition of DME as incorporated in CMS's Medicare Benefit Policy Manual). As noted above, he found that CMS had determined that power seat elevators that raised and lowered their occupants but which did not tilt as an assist to standing were not DME. *Id*. at 9. The materials he cited in support of that finding included the opinion of Mr. Rutemueller, which shows that CMS had considered a "power elevation" feature on a power wheelchair "to be noncovered by reason of 1861(n)," which extends Medicare coverage to qualifying items of DME. *Id*. at 5, citing LCD File Ex. 1.

The ALJ's finding that CIGNA denied coverage based on the determination in the policy article that a power seat elevator has been determined not to qualify as DME under section 1861(n) of the Act is supported by the materials he cited, which show that CIGNA consistently relied on the cited language in the policy article as the basis for the denial of coverage. Having found that the determination in the policy article that a power seat elevator is not DME was the basis of the denial, however, the ALJ erred by proceeding to consider whether that determination was reasonable, an issue outside his review authority.

An ALJ's authority in hearing LCD complaints is limited to review of contractor policies that are LCDs, and does not extend to other contractor determinations that do not qualify as LCDs, notwithstanding that they may result in denials of coverage. The regulations

governing LCD review state that "[o]nly LCDs" that are currently effective may be challenged, and forbid review of "[c]ontractor decisions that are not based on section 1862(a)(1)(A) of the Act," i.e., the medical necessity standard. 42 C.F.R. § 426.325(a), (b)(5). They also forbid review of "[a]ny other policy that is not an LCD . . . as set forth in § 400.202 of this chapter," which defines LCD as a determination based on the medical necessity standard. 42 C.F.R. § 426.325(b)(12). The regulations also state that "[t]he ALJ does not have authority to . . . [c]onduct a review of any policy that is not an LCD, as defined in § 400.202 of this chapter." 42 C.F.R. § 426.405(d)(5).

CMS in implementing the LCD appeal process emphasized the limited nature of the available review, stating that "[p]rovisions of contractor policies that are based on things ***other than the reasonable and necessary provision*** of section 1862(a)(1)(A) of the Act, such as benefit category determinations, ***statutory exclusion determinations***, and HCPCS/Revenue Code coding determinations, would not be subject to review under this part [Part 426]." 68 Fed. Reg. at 63,707 (emphasis added).

The determination that power seat elevators are excluded from coverage for not meeting the definition of DME for which coverage is available under section 1861(n) of the Act, which the ALJ found was the basis of the denial of coverage, was a statutory exclusion determination. CIGNA's coverage determination was not an LCD as defined in the Act and regulations, and the ALJ nowhere concluded that this determination met the definition of an LCD. In determining whether the provision which barred coverage here is reviewable as an LCD, it is irrelevant whether it was titled as an LCD or was referred to in a document so titled. *See LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050, at 10 (2006) ("whether a policy is an LCD is a legal issue based on the substance and content of the policy, not on the label or characterization of the policy by the contractor").

Additionally, the policy article statement that power seat elevators are not primarily medical in nature does not, as the AP contends, amount to a determination "that, in CIGNA's view, power seat elevators do not meet the medical necessity standard," making the policy article an LCD. AP Resp. at 3. There is no dispute that the definition of DME encompasses equipment that can be medically necessary for the treatment of an illness or injury. *See* 42 C.F.R. § 414.202 (DME defined in part as "not useful to an individual in the absence of illness or injury"). However, the fact that such equipment may be medically beneficial to a particular individual does not necessarily mean that it meets the additional requirement in the DME definition that it be "primarily" medical in nature. *See, e.g., NCD Complaint - Durable Medical Equipment Reference List (Air Cleaners) § 280.1*, DAB No. 1999 (2005) (air purification system was not "primarily medical" in nature and thus not DME despite being "particularly beneficial to persons with certain medical conditions"). A determination that an item is not "primarily

medical" in nature is not a determination that the item cannot also serve a medical purpose in the treatment of an illness or injury.[6]

As the CIGNA policy article was not an LCD as defined in the Act and regulations, and was instead a statutory exclusion determination, the limited review process applicable only to LCDs was not available here. *See LCD Appeal of Non-Coverage of Transfer Factor* at 10, citing 68 Fed. Reg. 63,707 ("As the preamble to the regulations makes clear, the purpose of excluding certain documents and actions from LCD review was to limit challenges only to LCDs as defined in the Act and regulations by excluding those that do 'not meet the definition of an LCD.'"). Accordingly, the ALJ should have dismissed the appeal.

The AP argues that the ALJ failed to follow NCDs 280.1 (Durable Medical Equipment Reference List) and 280.3 (Mobility Assistive Equipment). NCD 280.1 contains a list of DME that does not include power seat elevators on power wheelchairs, as the AP recognized, and advises contractors to make individual determinations of medical need for any item "which does not appear to fall logically into any of the generic categories listed[.]" P. Ex. F; P. Br. at 10. NCD 280.3 permits "mobility assistive equipment" to be found medically necessary on a case by case basis "for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home." P. Ex. 12, at 2-3. The ALJ concluded that the "general finding" in these NCDs does not apply to specific items of equipment and was controlled by the "specific finding" in NCD 280.15 for the iBOT 4000 that seat elevators that raise or lower their occupants do not have a medical purpose. ALJ Decision at 11. We need not resolve these arguments here, because we conclude that the ALJ exceeded the scope of his permissible review authority by reaching the validity of CIGNA's policy. For this reason, the AP's contention on the merits that "the ALJ's conclusion that seat elevators do not meet the definition of DME was a material error" relates to an issue that was beyond the ALJ's, and our, review authority. AP Br. at 2.

Finally, that CMS did not appeal the ALJ Decision does not preclude us from considering the argument in its motion to dismiss. In reaching its conclusions, the Board "is bound by applicable laws, regulations, and NCDs," which include the regulations defining LCD and limiting the scope of available review. 42 C.F.R. § 426.476(c). CMS's failure to

[6] While the ALJ did comment that power seat elevators are not medically necessary, he did so in the context of concluding that power seat elevators are not DME. *See* ALJ Decision at 4, 10, *citing* Act § 1861(n) (stating that a "power-operated vehicle . . . used as a wheelchair" is DME if "determined to be necessary on the basis of the individual's medical and physical condition"); ALJ Decision at 6, *citing* LCD File Ex. 2, at 7 (requirement in definition of DME as incorporated in CMS's Medicare Benefit Policy Manual that item "must be useful for treatment of an illness or injury"). The ALJ did not cite section 1862 of the Act or conclude that the policy article language on power seat elevators met the definition of an LCD in the Act and regulations. CMS before us does not contend that power seat elevators are never medically necessary but rather that they are not primarily medical. CMS Br. at 8-12.

appeal the ALJ Decision does not empower us to ignore those regulations or to consider an issue the regulations exclude from our and the ALJ's review. Moreover, it is also not clear that CMS could have appealed the ALJ decision in its favor, as the regulations permit a contractor or CMS to "appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable." 42 C.F.R. § 426.465(b).

Conclusion

For the reasons explained above, we reverse the ALJ Decision and dismiss the appeal on the ground that it seeks review of a matter that is outside the scope of review granted to the ALJ and the Board.

_____/s/_____
Sheila Ann Hegy

_____/s/_____
Constance B. Tobias

_____/s/_____
Leslie A. Sussan
Presiding Board Member