Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

LCD Complaint: Glucose Monitors
(L11530/L33822 and Local Coverage Articles A33614/A52464)
Docket No. A-16-96
Decision No. 2782
April 10, 2017

DECISION

This case concerns a Medicare coverage policy, issued by a Medicare program contractor, which states that continuous glucose monitors (CGMs) "are considered precautionary and non-covered under the DME [durable medical equipment] benefit." A Medicare beneficiary, to whom we refer as the Complainant, challenged the policy under 42 C.F.R. Part 426, which authorizes the Departmental Appeals Board (Board) and its administrative law judges (ALJs) to review the "validity" of "local coverage determinations" (LCDs) issued by Medicare contractors. After receiving evidence from both the Complainant and the contractor that authored the policy, an ALJ granted summary judgment to the Complainant, holding: (1) that the policy is a "constructive LCD" subject to review under 42 C.F.R. Part 426; and (2) that the policy is not valid under the applicable "reasonableness" standard of review. *See Local Coverage Determination Complaint: Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB CR4596 (2016) (ALJ Decision). The Centers for Medicare & Medicaid Services (CMS) has appealed the ALJ's decision, contending that the ALJ had no authority to review the policy's validity.

We hold that the challenged coverage policy is not an LCD as defined in the Medicare statute and regulations and is therefore not subject to review under 42 C.F.R. Part 426. Accordingly, we reverse the ALJ's contrary holding, vacate his conclusion that the challenged policy is invalid under the reasonableness standard, and dismiss the complaint.

Legal Background

The Medicare program, authorized under Title 18 (sections 1801 *et seq.*) of the Social Security Act (Act), provides federally funded health insurance for the aged and disabled.

42 U.S.C. § 1395 *et seq.*[1] Title 18's provisions are implemented in part through regulations issued by the Secretary of Health & Human Services. *See* Act § 1871(a)(1) (authorizing the Secretary to issue regulations to implement and effectuate the Medicare statute). CMS administers Medicare on behalf of the Secretary and contracts with private entities (insurance companies) to process Medicare coverage claims and perform a variety of other program functions. *See id.* §§ 1816(a), 1842(a), 1874(a).

Title 18 does not comprehensively specify each health care item or service covered (or excluded from coverage) by Medicare. 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003). "Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered . . . ." *Id.*; *see also* Act § 1869(a) (authorizing the Secretary to determine what claims are covered); *State of N.Y. on Behalf of Stein v. Sec'y of HHS*, 924 F.2d 431, 433 (2nd Cir. 1991) (discussing the Secretary's authority to make coverage decisions).

The scope of Medicare coverage is defined mainly in Parts A and B of Title 18. This case involves Part B, which authorizes coverage for several categories of outpatient "benefits" described in section 1832 (and other sections) of the Act. Part B's benefits include DME.[2] Act §§ 1832(a)(1) (defining the benefits under Part B to include "medical and other health services") and 1861(s)(6) (defining "medical and other health services" to include DME). The Medicare statute defines DME, mostly with illustrative examples, in section 1861(n). Medicare program regulations further define DME as equipment having certain general characteristics. *See* 42 C.F.R. § 414.202 (defining DME to mean an item that: (1) can withstand repeated use; (2) has an expected life of at least three years; (3) is primarily and customarily used to serve a medical purpose; (4) generally is not useful to persons in the absence of an illness or injury; and (5) is appropriate for use in the home).

At least two preliminary conditions must be met in order to obtain Part B coverage of a health care item or service. *See* 68 Fed. Reg. at 55,635. First, the item or service must fall within a statutory benefit category (*e.g.*, physicians' services, diagnostic tests, or DME). *See id.* Second, the item or service is not covered if it is excluded from coverage by section 1862(a) or other provisions of the Act. *Id.*; *see also*

[1] The current version of the Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

[2] The regulations in 42 C.F.R. Part 410 also specify the categories of "benefits" available under Medicare Part B, including DME. 42 C.F.R. §§ 410.1(b), 410.3(a), 410.10(h).

42 C.F.R. §§ 410.3(a)(1) (stating that Part B pays for "[m]edical and other health services"), 410.10 (specifying categories of covered "medical and other health services," such as DME), and 410.12(a) (stating that the medical and other health services listed in section 410.10 "are covered by Medicare Part B *only if they are not excluded*" (italics added)).

Moreover, section 1862(a)(1)(A) of the Act generally prohibits Medicare payment for any item or service that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also* 42 C.F.R. § 411.15(k). This provision establishes what is known as the "medical necessity" requirement. *CMS LCD Complaint: Wheelchair Options/Accessories (L11451)*, DAB No. 2370, at 1 (2011).

The Medicare program makes coverage decisions with respect to specific items or services in two ways: first, by issuing generally applicable policies with prospective effect; and second, by adjudicating individual coverage claims.[3] Generally applicable coverage policies include "national coverage determinations" (NCDs), issued by CMS, that apply uniformly nationwide and are binding on (among others) the Medicare program's contractors. *See* Act § 1869(f)(1); 68 Fed. Reg. at 55,635.

In the absence of a governing NCD (or other binding legal authority that resolves the specific coverage question), a Medicare contractor may develop and issue "local" coverage policies applicable to claims arising within its geographic (or other) jurisdiction. 68 Fed. Reg. at 63,693. Local coverage policies address various subjects, including proper procedure coding, whether particular items or services fall within a statutory benefit category, and whether (or under what circumstances) an item or service is excluded from coverage under section 1862(a)(1)(A) as not "reasonable and necessary."[4] *Id.*; *LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050, at 8 n.10 (2006).

As relevant here, the Medicare statute recognizes one specific type of local coverage policy – namely, an LCD. An LCD is defined in the Medicare statute, and in 42 C.F.R. § 400.202, as a determination, issued by a Medicare contractor, about whether to cover an item or service "in accordance with section 1862(a)(1)(A)" of the Act. *See* Act § 1869(f)(2)(B) (stating that an LCD is a determination "respecting whether or not a

[3] *See generally* Act §§ 1862(l), 1869; *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); CMS, Proposed Rule, *Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations*, 67 Fed. Reg. 54,534, 54,535-36 (Aug. 22, 2002); CMS, Final Rule, *Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations*, 68 Fed. Reg. 63,692, 63,692-93 (Nov. 7, 2003).

[4] If no NCD, LCD, or other coverage policy is in place for an item or service, a contractor may make coverage decisions regarding that item or service on a case-by-case basis, as part of the claims adjudication process. *See* 68 Fed. Reg. at 63,693.

particular item or service is covered . . . in accordance with section 1862(a)(1)(A)"); 42 C.F.R. § 400.202 (defining an LCD as a contractor's "decision . . . whether to cover a particular service . . . in accordance with section 1862(a)(1)(A)"). Thus, an LCD addresses whether a particular item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act.

As authorized by section 1869(f) of the Act, the regulations in 42 C.F.R. Part 426 create an administrative review process through which a Medicare beneficiary may, in certain circumstances, challenge the "validity" of an LCD. *See* 68 Fed. Reg. at 63,694; *CMS LCD Complaint: Pneumatic Compression Devices*, DAB No. 2082, at 2-3 (2007). The review process is available only to an "aggrieved party" – defined in Part 426 to mean a Medicare beneficiary with a documented need for Medicare coverage that has been denied on the basis of an LCD.[5] 42 C.F.R. § 426.110.

The Part 426 review process provides for evidence-taking and a first-level review of the challenged LCD by an ALJ, followed by an opportunity for any party to appeal the ALJ's decision to the Board. *See* 42 C.F.R. Part 426, subpart D. In reviewing an LCD's validity, an ALJ and the Board must apply what the regulations call the "reasonableness standard." *Id.* §§ 426.300(a), 426.425(c)(1), 426.476(b)(1). That standard requires the reviewer to find an LCD valid "if the findings of fact, interpretations of law, and applications of fact to law by the contractor . . . are reasonable" based on the record developed in the Part 426 proceeding. *Id.* § 426.110.

An aggrieved party initiates the LCD review process by filing a "complaint" with the Board's Civil Remedies Division. *Id.* § 426.400(a). After the complaint is docketed, the ALJ determines if the complaint is "acceptable" (that is, meets certain threshold requirements not at issue here). *Id.* § 426.410(b). If the complaint is deemed acceptable, the ALJ forwards a copy to CMS and to the authoring contractor and directs the contractor to produce the "LCD record," which "consists of any document or material that the contractor considered during the development of the LCD[.]" *Id.* §§ 426.410(d), 426.418(a). The ALJ then allows the parties an opportunity to proffer statements of their positions about whether the LCD record is "complete and adequate to support the validity of the LCD" under the reasonableness standard. *Id.* § 426.425(a)-(b). If the ALJ decides at that point that the LCD is not complete and adequate to support the LCD's validity, he

[5] The LCD appeal process is distinct from the Medicare claims appeal process. 42 C.F.R. § 426.310(a). The Medicare claims appeal process (under 42 C.F.R. Part 405, subparts H and I) resolves disputes about the merits of individual coverage and payment claims, whereas the LCD appeal process hears challenges to the validity of coverage policies apart from the merits of any particular Medicare claim. *See* 42 C.F.R. § 426.310(a); *CMS LCD Complaint: Homeopathic Med. & Transfer Factor*, DAB No. 2315, at 3 (2010); *CMS LCD Complaint: Pneumatic Compression Devices*, DAB No. 2082, at 6 n.4 (2007).

or she "permits discovery and the taking of evidence," which may involve a hearing unless the matter can be decided "on the written record." *Id.* §§ 426.425(c)(3), 426.431(a)(1)-(2). After evidence-taking is complete, the ALJ closes the record and issues a final written decision. *Id.* §§ 426.431(a)(3), (a)(5), 426.447.

Case Background

The facts recounted in this section are undisputed unless otherwise indicated.

The Complainant (the Medicare beneficiary who brought this case) has diabetes. Because she is unaware of when her blood sugar drops to unsafe levels, her doctor determined that she needs a continuous glucose monitor (CGM) to warn her of that occurrence and thereby prevent the potentially serious complications of hypoglycemia.

A CGM does not measure *blood* glucose; rather, it estimates, on a continuous basis, the level of glucose in "interstitial" fluid. A CGM has three basic components: a disposable sensor, placed under the skin, that generates an electrical signal in response to the amount of interstitial glucose present and converts that signal into a glucose measurement; a transmitter to which the sensor's information is relayed; and a receiver (or monitor) that is wirelessly connected to the transmitter and receives the interstitial glucose measurement from the transmitter and displays it to the user. (A different device, a blood glucose monitor or meter, is used to measure glucose levels in the blood.)

On May 21, 2014, National Health Insurance Corporation (NHIC), a Medicare contractor, denied the Complainant's request for Medicare Part B coverage of a CGM transmitter and sensors. The Complainant asked for reconsideration, and NHIC sustained its initial determination, stating that the transmitter and sensors were "convenience items" and that "local coverage determination (LCD) L11530 was used" to make its decision. *See* Complainant's Ex. 26.

LCD L11530 (which, as we explain later, is no longer in force) spelled out coverage criteria for *blood* glucose monitors, not for CGMs.[6] *See* CMS Ex. 1, at 1-19. However, L11530 cited a relevant "Local Coverage Article" (LCA) – number A33614. *Id.* at 19, 20. In a section titled "Non-Medical Necessity Coverage and Payment Rules," LCA A33614 (also no longer in force) stated that "[c]ontinuous glucose monitors . . . are considered precautionary and therefore noncovered under the DME benefit."[7] *Id.* at 19, 20, 21.

[6] The only place that CGMs were mentioned in LCD L11530 was in its listing of procedure codes for CGM components. *See* CMS Ex. 1, at 5 (A9276-9278). L11530 stated that the mere "appearance of a code" in that document "does not necessarily indicate coverage." *Id.* at 4.

[7] In its March 4, 2015 submission to the ALJ, NHIC stated that local coverage articles, as distinct from LCDs, "detail specific statutory and regulatory payment policy requirements that must be met, and relate to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. other than 'reasonable

In December 2014, the Complainant filed a complaint under 42 C.F.R. Part 426, seeking review of LCD L11530 and LCA A33614. The complaint generally alleged that LCD L11530, "as modified by" LCA A33614, impermissibly denied Medicare coverage of CGMs, contrary to "evidence-based medicine," "scientific and medical literature," NCD 40.2, "the LCD development process," and "Medicare policy concerning reasonableness and medical necessity." *See* Dec. 26, 2014 Complaint ¶¶ 1, 3, 5, 38, 40, 44, 46-47, 58.

The ALJ determined that the complaint was "acceptable," directed that it be served on both NHIC and CMS, and ordered NHIC to produce the pertinent "LCD record." Acknowledgment of Receipt of Acceptable Complaint; Order to File LCD Record; and Briefing Schedule, CRD Docket No. C-15-1021, at 1-2 (Feb. 18, 2015). Only NHIC responded to the complaint; CMS did not enter an appearance or otherwise participate in the proceeding before the ALJ.

On March 4, 2015, NHIC produced the LCD record and filed its initial response to the complaint. NHIC's Response to Docket No. C-15-1021 (NHIC Resp.). NHIC explained that "[n]one of the policy statements contained in LCD L11530 apply to continuous glucose monitoring." *Id.* at 2. In addition, NHIC asserted that LCA A33614 reflected CMS's position that CGMs are not covered by Medicare Part B because they are not DME. *Id.* at 3. As evidence of that position, NHIC cited two documents:

- A September 9, 2002 internal CMS memorandum whose author concluded that the Glucowatch continuous glucose monitoring system[8] "[did] not fall within the durable medical equipment (DME) benefit category" because it "function[ed] more as an alert/precautionary system by prompting the patient to perform a blood glucose monitor test and/or to notify his physician when the glucose level falls within a dangerous level"; and

- An April 9, 2013 letter from CMS to the Medtronic Corporation in which CMS provided an "informal benefit category determination" that Medtronic's continuous glucose monitoring system (called Minimed Paradigm) "does not fall under the DME benefit category because it is not covered under the Medicare

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and necessary')." NHIC's Response to Docket No. C-15-1021, at 2; *see also* CMS, "Medicare Coverage Determination Process: Local Coverage Determinations," available at https://www.cms.gov/medicare/coverage/determinationprocess/LCDs.html (explaining that contractors' "articles" are intended to provide information about Medicare coverage requirements "not related to section 1862(a)(1)(A)" (last visited April 10, 2017)).

[8] The ALJ commented that the "2002 memorandum does not specifically refer to the Glucowatch as a CGM device but contains a description of the device and its operation that is strongly suggestive that it is a type of CGM." ALJ Decision at 16. The memorandum does, in fact, indicate that the Glucowatch performs the essential function of a CGM: "measur[ing] glucose in interstitial fluid collected through the skin . . . ." CMS Ex. 2, at 2.

> national coverage policy for home blood glucose monitors" and because it is a "precautionary device" in the sense that "it is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick and use of a blood glucose monitor may be required."

See id. at 3-4; CMS Ex. 2, at 2; CMS Ex. 5, at 1, 2. NHIC asserted that because its noncoverage policy regarding CGMs was based on an adverse "benefit category determination" (as evidenced by the documentation just described), and not a medical necessity determination under section 1862(a)(1)(A), the policy was not, in fact, a reviewable LCD. NHIC Resp. at 4.

On September 11, 2015, the ALJ issued an interim ruling that LCA A33614 "contains a provision that amounts to a *constructive LCD* that is subject to my review" (italics added) because it "effectively denies coverage of CGM and related accessories and supplies without a proper determination that CGM and related accessories and supplies are not reasonable and necessary within the meaning of the Act." Ruling Pursuant to 42 C.F.R § 426.425(c) and Order for Case Development, CRD Dkt. No. C-15-1021, at 8. The ALJ also held that the Complainant met the regulatory definition of an "aggrieved party" because her coverage claim for CGM had been denied by Medicare on the basis of the constructive LCD. *Id.* at 7-8. In addition, the ALJ held that the record before him was not "complete and adequate to support the validity" of the constructive LCD under the reasonableness standard of review. *Id.* at 15. Hence, in accordance with section 426.425(c)(3), the ALJ permitted the parties to conduct discovery and to supplement the record on the issue of whether the presumed LCD (as stated in LCA A33614) was valid. *Id.* at 15-17.

During the ensuing phase of record development, NHIC "retired" LCD L11530, replacing it with LCD L33822; in addition, NHIC retired LCA A33614 (the article cited by L11530) and issued LCA A52464 in its place.[9] *See* ALJ Decision at 1 n.1, 13-14. L33822, like its predecessor, sets out coverage policies regarding blood glucose monitors (not CGMs). And A52464, like its predecessor, states that "[c]ontinuous glucose monitors . . . are considered precautionary and therefore non-covered under the DME benefit." The ALJ found (and neither party disagrees) that the issuance of L33822 and A52464 was nothing more than a "renumbering" of L11530 and A33614 and thus did not require him to dismiss the complaint. ALJ Decision at 14. (Because L33822 and A52464 are, in fact, identical in relevant respects to their predecessors, we use those numerical designations from here on to identify the relevant contractor policies.)

[9] The contractor submitted copies of L33822 and A52464 for the record on December 1, 2015. *See* CRD Docket No C-15-1021, entry number 15.

After the parties completed discovery and made their supplemental submissions, which included cross-motions for summary judgment, the ALJ closed the record and issued the decision now before us. Finding summary judgment appropriate, the ALJ re-affirmed his earlier holding that the Complainant was an "aggrieved party" within the meaning of the Part 426 regulations.[10] ALJ Decision at 12. He also re-affirmed that L33822 and A52464 had established a "constructive LCD" regarding CGMs based on the following reasoning:

> I conclude that [L33822 and A52464 establish a constructive LCD subject to Part 426 review] because the evidence before me does not support NHIC's position that CMS determined [that] all CGM and related accessories and supplies are not DME and not covered as DME under the Medicare DME benefit. NHIC is also in error because [the Local Coverage Article] effectively denies coverage of CGM and related accessories and supplies without, as NHIC freely admits, the required determination that CGM and related accessories and supplies are not reasonable and necessary within the meaning of section 1862(a)(l)(A) of the Act.
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> The fact that the main components of CGM facially meet the four criteria to be DME supports a conclusion that the [contractor's] determination not to cover CGM and related accessories and supplies . . . must be based on a "reasonable and necessary" determination by CMS or its contractor, absent a specific determination by CMS that no CGM and related accessories and supplies can be DME.

Id. at 14, 20.

Having held that NHIC's policies contained an "implicit" determination that CGMs are not reasonable and necessary, the ALJ proceeded to decide whether that determination was valid under the reasonableness standard. *Id.* at 20. He concluded that it was not valid, stating that NHIC and CMS "have not produced any record in the form of peer-reviewed literature, medical opinions, or even any analysis from an individual with a medical background that supports a conclusion that CGM is never reasonable and necessary irrespective of the beneficiary's condition." *Id.* at 20-22.

CMS then timely filed this appeal.

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[10] The ALJ noted that that the Complainant had successfully appealed NHIC's October 31, 2014 coverage determination through the Medicare claims appeal process in 42 C.F.R. Part 405 (subpart I), but held that that circumstance did not deprive him of "jurisdiction" to rule on the merits of the Complainant's LCD challenge under 42 C.F.R. Part 426.

Discussion

CMS's appeal raises multiple issues. We need address only one: whether the ALJ erred in holding that the challenged contractor policy, as set out in LCA A52464, is an LCD and, therefore, subject to ALJ review.[11] CMS submits that the policy is not an LCD – and is therefore unreviewable under 42 C.F.R. Part 426 – because it is "based on the contractor's determination that CGMs do not fall within a defined Medicare benefit category (DME), without making a determination as to whether CGMs are considered medically reasonable or necessary." *See* CMS' Statement in Support of Notice of Appeal (dated June 27, 2016) at 16-19. The Complainant defends the ALJ's contrary holding and supporting analysis. *See* Complainant's Response Brief (Response) at 11-16.

1. *CMS is entitled to appeal any part of the ALJ's decision.*

Before discussing the reviewability issue, we reject the Complainant's contention that CMS has no right to raise it before the Board. *See* Response at 2, 9, 11; Sur-Reply to CMS's Reply (Sur-Reply) at 4-5. Title 42 C.F.R. § 426.465(b) states that "[a] contractor or CMS may appeal to the Board any part of an ALJ's decision that states that a provision (or provisions) of an LCD is (are) unreasonable." In this case, the ALJ issued a decision which states that a presumed LCD is "unreasonable" (that is, not valid under the reasonableness standard). *See* ALJ Decision at 23. Section 426.465(b) plainly gives CMS the right to contest "any part" of the ALJ's decision, including the threshold holding that LCA A52464's noncoverage policy regarding CGMs is a constructive LCD reviewable under 42 C.F.R. Part 426.

The Complainant submits that section 426.465(b) allows CMS to appeal only the discrete "part" (or parts) of the ALJ decision which assess the validity of the challenged contractor policy. Response at 9 (stating that CMS "may only appeal the part of an ALJ's decision that states a provision of an LCD is unreasonable"). The Complainant cites no authority for its cramped construction of the regulation, and we reject it. That construction ignores the fact that a threshold issue in any appeal challenging an ALJ's determination regarding the validity of an LCD is whether the ALJ had authority to review the challenge, including whether the challenged statement before the ALJ is an LCD. The Board decision in *CMS LCD Complaint: Wheelchair Options/Accessories (L11451)* involved just such a jurisdictional inquiry. There the Board reversed an ALJ's decision which held that a purported LCD was reasonable because the Board concluded

[11] Because we hold that the challenged policy is not reviewable, we need not address CMS's contention that the Complainant is not an "aggrieved party" or its contention that the policy, even if reviewable, is valid under the reasonableness standard. *See* CMS Appeal Statement at 14, 19. For the same reason, we do not address the Complainant's contention (Response at 2, 16) that CMS improperly introduced new evidence and new arguments on appeal to support the ALJ's conclusion regarding the policy's validity.

that the ALJ had no authority to review the contractor policy at issue since it did not meet the definition of an LCD. The Board did so, we note, even though CMS had not raised the jurisdictional issue on appeal, stating that "CMS's failure to appeal [an ALJ's decision] does not empower [it] to ignore [the Part 426] regulations or to consider an issue the regulations exclude from our and the ALJ's review." DAB No. 2370, at 8-9. The Board clearly has authority, indeed a duty, to review jurisdictional issues, and section 426.465(b) may not reasonably be read as undercutting that authority.

The Complainant's proposed interpretation of section 426.465(b) also directly conflicts with other provisions of Part 426. For example, in describing the Board's "standard of review," section 426.476(b)(1) states that the Board "determines whether the ALJ decision contains *any material error*, including any failure to properly apply the reasonableness standard" (italics added). That provision clearly states that the Board may review the ALJ's decision for any error affecting the decision's legality, while making no exception for CMS-filed appeals.[12] Irrespective of which party requests Board review, the Board has an affirmative legal duty to decide the appeal in a manner respecting the statutory and regulatory limits on an ALJ's authority. *Cf.* 42 C.F.R. § 426.476(c) (stating that the Board "is bound by applicable laws [and] regulations" in "reaching its conclusions"). For these reasons, we hold that CMS may challenge any part of the ALJ Decision, including his holding that the challenged coverage policy is an LCD subject to review under 42 C.F.R. Part 426.

2. *The challenged coverage policy regarding CGMs was not an LCD and was therefore not subject to review under 42 C.F.R. Part 426.*

The Part 426 regulations create a review process of narrow scope. Section 426.405(d)(5) states that an ALJ may not review "any [contractor] policy that is not an LCD, as defined in § 400.202[.]" And section 426.441(b)(1) states that an ALJ "must dismiss" a complaint if it seeks review of a provision that the ALJ "does not have the authority to rule on . . . under § 426.405(d)." Similarly, section 426.325(b) contains a long list of "items" that are "not reviewable" under Part 426, including, as relevant here, "[c]ontractor decisions that are not based on section 1862(a)(1)(A)" of the Act and "[a]ny . . . policy that is not an LCD . . . as set forth in § 400.202 of this chapter." Consistent with these provisions, the Board has held that an ALJ's "review authority" concerning coverage policies issued by Medicare contractors "is limited to . . . 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." *CMS LCD Complaint: Wheelchair Options/Accessories (L11451)* at 2.

[12] In addition, section 426.476(b)(3) permits any party to appeal allegedly prejudicial procedural rulings, undercutting the proposition that CMS may appeal only the ultimate legal conclusion regarding an LCD's validity.

As noted, the Medicare statute and regulations define an LCD to mean a determination "in accordance with section 1862(a)(1)(A)" of the Act. *See* Act § 1869(f)(2)(B); 42 C.F.R. § 400.202. Hence, a contractor's coverage policy constitutes an LCD, and is thus reviewable under Part 426, only to the extent that it specifies whether (or under what circumstances) a health care item or service is (or is not), in section 1862(a)(1)(A)'s words, "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *CMS LCD Complaint: Wheelchair Options/Accessories (L11462)* at 1 (stating that an LCD "applies the medical necessity standard" in section 1862(a)(1)(A)). "LCD review" under Part 426 review does not extend to "[p]rovisions of contractor polices that are based on things other than the reasonable and necessary provision of section 1862(a)(1)(A), such as *benefit category determinations*, statutory exclusion determinations, and HCPCS/Revenue coding determinations . . . ." 68 Fed. Reg. at 63,707 (italics added).

In this case the challenged coverage policy states that CGMs are "precautionary and therefore non-covered under the DME benefit." On its face the policy is not an LCD because it does not deny Medicare coverage based on a determination that CGMs are not reasonable and necessary under section 1862(a)(1)(A) of the Act. Instead, the policy reflects a benefit category determination, which is that CGMs do not meet the legal definition of DME and thus cannot be covered by Medicare under that benefit category. The contractor so informed the ALJ, telling him that the CGM policy contained in LCA A52464 is based on informal benefit category determinations made by CMS in 2002 and 2013 regarding two continuous glucose monitoring systems. We see no evidence that the policy is based on anything other than a benefit category determination.

The ALJ found that the contractor's policy relies on a "misconception . . . that CGM[s] [are] simply not DME," and that this misconception was founded on the application of a criterion – that an item must not be "precautionary" – not found in the statutory and regulatory definitions of DME. *See* ALJ Decision at 18-19, 21 (taking the position that CMS's view, as expressed in manual guidance, that "'precautionary-type equipment' is presumptively non-medical is inaccurate and misleading").[13] At the outset, we note that

[13] In order to be classified as DME under Medicare's regulations, an item must be "primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202. In program guidance, CMS lists certain items that "do not constitute medical equipment" because they "are considered nonmedical in nature." The listed items include "precautionary-type equipment" such as "portable oxygen systems," "preset portable oxygen units," "spare tanks of oxygen," and "spare [water] deionization tanks." *See* Medicare National Coverage Determinations Manual, CMS Pub. 100-03, Ch. 1, Part 4, § 230.7(A), 280.1 (Durable Medical Equipment Reference list); Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, § 110.1(B)(2) (stating that "physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature").

whether or not the contractor made an incorrect or poorly conceived benefit category determination is irrelevant. A contractor policy that does not meet Medicare's definition of an LCD does not become reviewable by virtue of it being misguided, unfounded, or erroneous. If a contractor coverage policy is based on something other than a medical necessity determination – as the CGM policy in LCA A52464 indicates – then it is not an LCD, and an ALJ may not review it under 42 C.F.R. Part 426, irrespective of how the ALJ views the merits of the policy.

We also find no support for the ALJ's conclusion that by determining that "precautionary-type equipment" is "nonmedical in nature" and, thus, not DME, the CMS guidance was somehow adding a new criterion to the statutory and regulatory definition of DME. The regulatory definition, as we stated earlier, already requires that to qualify as DME, a device must, among other criteria, be "primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202. Thus, a determination that equipment is "nonmedical in nature" appears to speak to an existing criterion rather than adding a criterion.

We also find no support for the additional reasons the ALJ gave for his conclusion that although the challenged policy on its face does not satisfy the statutory and regulatory definition of an LCD, the policy should nonetheless be presumed to be an LCD. The ALJ gave as one reason that CMS had not made a determination that CGMs (and their accessories) are "*never* DME and *never* subject to coverage on that basis." ALJ Decision at 17 (italics in original); *see also id.* at 14 (stating that the contractor's position on the reviewability of the challenged policy was "in error because the evidence before me does not support [the contractor's] position that CMS determined all CGM and related accessories and supplies are not DME and not covered as DME under the Medicare DME benefit"). The ALJ also observed that the contractor's policy "effectively denies coverage of CGM and related accessories and supplies without, as [the contractor] freely admits, the *required determination that CGM and related accessories and supplies are not reasonable and necessary* within the meaning of section 1862(a)(1)(A) of the Act." *Id.* at 14 (italics added). Based on these premises, and upon his independent judgment that the "main components of CGM facially meet" regulatory criteria to be classified as DME, the ALJ concluded that the contractor's noncoverage determination in LCA A52464 *must have been* based on a medical necessity determination. *Id.* at 17-20.[14]

[14] The ALJ stated that conclusion as follows: "The fact that the main components of CGM facially meet the four criteria to be DME supports a conclusion that the determination not to cover CGM and related accessories and supplies under [the procedure codes specified in LCA A52464] must be based on a 'reasonable and necessary' determination by CMS or its contractor, absent a specific determination by CMS that no CGM and related accessories and supplies can be DME." ALJ Decision at 20.

There is an internal inconsistency in the ALJ's reasoning. His assertion that the contractor's policy effectively denies coverage of CGMs and related accessories and supplies "without . . . the required determination that CGM and the related accessories and supplies are not reasonable and necessary" (ALJ Decision at 14) expressly acknowledges that the policy is not based upon a determination that those items are not reasonable and necessary. It follows that the policy is not an LCD because LCDs are policy statements about whether particular items or services are reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. Yet, the ALJ concluded that the policy was an LCD, a conclusion essential to establishing the ALJ's authority to review the policy.

Apart from that internal inconsistency, the ALJ's conclusion that the contractor's policy must have been based on section 1862(a)(1)(A) is wholly speculative, and both of the conclusion's premises are faulty. It is irrelevant that CMS has not issued a coverage determination that CGMs are categorically not (or "never") DME. Absent binding guidance from CMS about whether, or under what circumstances, CGMs may be covered as DME, the Medicare program's contractors[15] may lawfully adopt their own "local" coverage policy regarding those items (as NHIC did here) or address the coverage question on a case-by-case basis through adjudication of individual claims. *See* 68 Fed. Reg. at 63,693. Furthermore, there is nothing significant about the fact that NHIC issued a noncoverage policy regarding CGMs without making a medical necessity determination. No such determination was "required" in this circumstance. As discussed in the background section, a threshold requirement for Medicare Part B coverage is that the item or service at issue fall within a benefit category specified in Title 18 of the Act. *Cf.* 68 Fed. Reg. at 63,693 (stating that Medicare will pay a coverage claim if it "is for an item that falls within a Medicare benefit category, is reasonable and necessary for [the] individual, and is not otherwise statutorily excluded"). Hence, Medicare may lawfully deny Part B coverage for an item or service *without a medical necessity determination* if the item or service does not fall within one of Part B's benefit categories.

On page 19 of his decision, the ALJ stated that "[t]he determination of CMS and its contractor that an item of equipment is a precautionary item is ***actually*** a determination that the item of equipment is not 'reasonable and necessary' because other equipment that is covered by Medicare is available, even though it may be less convenient or medically

[15] There are four program contractors which administer the Medicare DME benefit. These entities are known as Durable Medical Equipment Medicare Administrative Contractors, or DME MACs.

effective for the beneficiary to use" (italics and emphasis added). We do not fully understand this statement (which the Complainant seized upon in her appeal brief[16]). If the statement is simply a reiteration of the ALJ's conclusion that the challenged coverage policy is a misconceived benefit category determination, then we reject the statement for the same reasons we rejected that conclusion. So far as the statement applies to the noncoverage policy at issue here, the statement directly conflicts with the ALJ's earlier statement, on page 14 of his decision, that the contractor had ***not*** made a "required" medical necessity determination regarding CGMs and related supplies. And, in fact, there is nothing in the record indicating that the contractor developed the challenged policy by applying the medical necessity criteria that contractors consider in developing an LCD. *See Medicare Program Integrity Manual*, CMS Pub. 100-08, Chapter 13 ("Local Coverage Determinations"), ¶ 13.5.1 (instructing contractors to "consider a service to be reasonable and necessary" if it is, among other things, "safe and effective," "not experimental or investigational," and "appropriate").[17] If the intended meaning of the ALJ's statement (on page 19) is that any policy which denies Medicare coverage of equipment on the ground that it is "precautionary" should be regarded as a *de facto* medical necessity determination (irrespective of the policy issuer's contrary intent or stated purpose), he did not cite or explain the authority supporting that proposition. The ALJ did not, for example, explain why the term "precautionary" must be understood in this context to be synonymous or coextensive with the condition of being not "reasonable and necessary," as that latter term is understood by the Medicare program. *See Medicare Benefit Policy Manual*, CMS Pub. 100-02, Chapter 15, § 110.1 (separately defining the criteria for an item to be classified as DME, and for a piece of DME to be considered "reasonable and necessary," noting that that "[a]lthough an item may be classified as DME, it may not be covered in every instance" if it is not otherwise "necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member"). In sum, we see nothing in the Medicare statute or regulations or CMS policy which persuades us to disregard what is plainly established on this case's record: that the challenged noncoverage policy is, by its terms and intent, an adverse benefit category determination and not a determination that CGMs and related supplies are not reasonable and necessary under section 1862(a)(1)(A) of the Act.

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[16] The Complainant asserts that the ALJ "appropriately found the statement that CGM was precautionary was a determination that CGM is not reasonable and necessary, and thus the LCA constituted a 'constructive LCD.'" Response at 14.

[17] According to CMS's Medicare Benefit Policy Manual, an item of DME is "necessary" if it is "expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member." CMS Pub. 100-02, Chapter 15, § 110.1(C)(1). Whether an item is "reasonable," says that guidance, depends on several considerations, such as whether the item "serve[s] essentially the same purpose as equipment already available to the beneficiary[.]" *Id.* § 110.1(C)(2). CMS's Medicare Program Manuals are publicly available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/manuals (last visited April 10, 2017).

The Complainant asserts that *LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050, supports the ALJ's conclusion that NHIC's CGM policy is a "constructive LCD" and thus reviewable, Response at 15, but provides no explanation to support this assertion. We see nothing in *Transfer Factor* that supports this assertion. In *Transfer Factor*, the ALJ dismissed a complaint involving an online article published by the contractor (explaining coverage and coding policies) on two grounds: (1) that the article was not an LCD because statements by CMS and the contractor established that the coverage determinations were made on a claim-by-claim basis rather than carrier-wide; and (2) that even assuming the article was an LCD, the contractor had withdrawn the non-coverage provisions to which the aggrieved party objected. The Board disagreed with the ALJ on the first ground but upheld the dismissal on the second ground; thus, its disagreement on the issue of whether the policy was an LCD did not overturn the ALJ's dismissal and was not essential to the Board's decision to uphold it. Moreover, the Board's disagreement with the ALJ on the first ground was not based on any finding that the policy at issue was a "constructive LCD." The Board merely agreed with the ALJ and both parties in that case that "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[,]" and concluded based on what the Board found to be "unequivocal" language in the article at issue that it was an LCD. DAB No. 2050, at 10-11. We find no such "unequivocal" language here. Finally, and importantly, the Board's basis in *Transfer Factor* for disagreeing with the ALJ on the issue of whether the policy constituted an LCD did not involve the issue presented here of whether the contractor's noncoverage policy was based on section 1862(a)(1)(A) of the Act. Complainant addresses none of these distinctions between *Transfer Factor* and the instant case, and we conclude that those distinctions make *Transfer Factor* inapplicable here.

This case has more in common with *LCD Complaint: Wheelchair Options/Accessories (L11451)*. *Wheelchair Options* concerned a powered wheelchair accessory called a power seat elevator. A Medicare contractor denied a beneficiary's coverage claim for that item, citing an LCD that contained no relevant coverage policy but which cross-referenced a policy article stating that a power seat elevator was "noncovered because [it] [is] not primarily medical in nature." DAB No. 2370, at 3. The beneficiary filed a Part 426 complaint to challenge that policy. The contractor moved to dismiss the complaint, arguing that the denial of coverage was based, not on an LCD (a determination about whether an item is reasonable and necessary), but instead on a longstanding CMS policy, enunciated in the contractor'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." DAB No. 2370, at 3. The ALJ denied the motion to dismiss and ultimately issued a decision in which he sustained, as valid under

the reasonableness standard, the contractor's policy that power seat elevators were not DME. *Id.* at 5. The beneficiary appealed the decision, and CMS, in response, argued that the ALJ lacked the authority to review the policy because it did not meet the legal definition of an LCD. *Id.* at 6. Agreeing with CMS, the Board held that the contractor's policy regarding power seat elevators was not an LCD (as defined by the Medicare statute and regulations) because it was based on a determination that those items were not DME, rather than on a medical necessity determination under section 1862(a)(1)(A) of the Act. DAB No. 2370, at 6-7. The Board therefore concluded that the ALJ had "exceeded the permissible scope of his authority" in deciding that the contractor's policy was valid under the reasonableness standard. *Id.* at 6, 8.

As did the ALJ in *Wheelchair Options*, the ALJ here reviewed the substantive validity of a contractor policy which denies coverage based solely on the ground that the items in question (CGMs) are not DME, rather than for lack of medical necessity. We therefore conclude, as the Board in *Wheelchair Options* did, that the challenged policy is not an LCD and that the ALJ should have dismissed the complaint pursuant to 42 C.F.R. §§ 426.444(b)(1) and 426.405(d)(5) instead of proceeding to review the policy's validity under the reasonableness standard.[18]

[18] After the briefing period closed, CMS informed us of a recent change in CMS coverage policy regarding CGMs. On January 17, 2017, the Administrator of CMS issued Ruling 1682-R. "CMS Rulings" are "published under the authority of the Administrator [of] CMS," 42 C.F.R. § 405.1063(b), and "provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters." CMS Ruling No. 1682-R (Ruling) at 1; *see also* Index of Downloadable CMS Rulings, available at https://www.cms.gov/regulations-and-guidance/guidance/rulings/cms-rulings.html (last visited April 10, 2017). CMS Ruling 1682-R classifies, as "within the scope of [the] Medicare Part B benefit category for DME," continuous glucose monitoring systems that are "used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions." Ruling at 13-14. Nothing in CMS Ruling 1682-R (whose effective date is January 12, 2017) alters our decision holding that the CGM policy issued by NHIC in LCA A52464 is not an LCD, and neither party contends that the ruling is otherwise material to the outcome of this appeal.

Conclusion

The complaint in this case should have been dismissed because it sought review of a matter that is outside the scope of review granted to an ALJ under section 1869(f)(2) of the Act and 42 C.F.R. Part 426. Accordingly, we reverse the ALJ's contrary holding, vacate his conclusion that the challenged policy is invalid under the reasonableness standard, and dismiss the complaint.

/s/
Leslie A. Sussan

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member