Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re: Local Coverage Determination Complaint:
Glucose Monitors (L11530/L33822 and Local Coverage Articles A33614/A52464),

Contractor: NHIC Corp., Durable Medical Equipment Medicare Administrative Contractor, Jurisdiction A.

Docket No. C-15-1021

Decision No. CR4596

Date: April 29, 2016

DECISION

The constructive Local Coverage Determination (LCD), which arises from LCD L11530/L33822 and the related Local Coverage Article (LCA) A33614/A52464,[1] that

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[1] On September 30, 2015, during the pendency of this case, NHIC Corp. (NHIC) the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) for Jurisdiction A, retired LCD L11530 and LCA A33614 but reissued substantively similar documents designated LCD L33822 and LCA A52464, both effective October 1, 2015. Order dated October 14, 2015 (Departmental Appeals Board Electronic Filing System (DAB E-File) # 12. I do not consider the renumbering of the LCD and LCA a retirement of the LCD that terminates LCD review under 42 C.F.R. § 426.420, and NHIC has not argued the contrary. On October 14, 2015, I ordered NHIC to file LCD 33822 and LCA A52464 and any supplemental LCD record not later than October 21, 2015. NHIC did not file the newly number LCD and LCA until December 1, 2015. DAB E-File # 15, which is treated as if marked Court Exhibit (Ct. Ex.) 1. LCD L11530/L33822 and LCA A33614/A52464 are used in this decision to refer to the source of the constructive LCD subject to my review, both the original LCD and LCA and the renumbered version of each. The specific language that denies coverage and constitutes a constructive LCD is found in LCA A33614/A52464, specifically, "[c]ontinuous glucose monitors (A9276-A9278) are
(*Footnote continued next page.)*

denies coverage for continuous glucose monitors and related supplies (CGM) on a contractor-wide basis without a determination of whether or not CGM is reasonable and necessary, is not valid under the reasonableness standard. If neither party appeals this decision, then Medicare coverage for the Aggrieved Party's subsequent claims for CGM must be determined by NHIC based upon whether or not CGM is reasonable and necessary and without application of the invalid constructive LCD provision. 42 C.F.R. § 426.460(b)(1)(iv). NHIC must implement this decision and comply with 42 C.F.R. § 426.460 within 30 days of the date of this decision. Social Security Act (the Act) § 1869(f)(2)(A)(iii) (42 U.S.C. § 1395ff(f)(2)(A)(iii)); 42 C.F.R. § 426.460(b)(2).

I. Background

The Aggrieved Party requested review of the NHIC LCD for Glucose Monitors (L11530), and a related LCA for Glucose Monitors (A33614), by letter dated December 26, 2014 (Complaint). The Aggrieved Party filed 28 exhibits with her Complaint, labeled A. Ex. 1 through 28. Specifically, the Aggrieved Party challenged the constructive LCD that arises from the language in LCA A33614, which provides that continuous glucose monitors (CGM) are not covered by the Medicare DME benefit because CGM are "precautionary." The Aggrieved Party's argument is that NHIC uses the language of LCA A33614 and LCD L11530 to deny coverage for CGM and related supplies without considering whether CGM is reasonable and necessary and subject to coverage by Medicare. The Complaint was received at the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB) on December 29, 2014, and assigned to me for hearing and decision on February 3, 2015. On February 18, 2015, I issued an Acknowledgment of Receipt of Acceptable Complaint; Order to File LCD Record; and Schedule for Responses (Initial Order). I required Petitioner to serve copies of the Complaint upon NHIC and the Centers for Medicare & Medicaid Services (CMS). On February 24, 2015, the Aggrieved Party certified that service upon both NHIC and CMS was accomplished.

On March 4, 2015, NHIC responded to the Initial Order to file the LCD record.[2] NHIC filed a three-page response letter (NHIC Response) from its Medical Director. NHIC also

(*Footnote continued.*)

considered precautionary and therefore not covered under the DME [Durable Medical Equipment] benefit." Ct. Ex. 1 at 24; Aggrieved Party Exhibit (AP Ex.) 1 at 17.

[2] CMS has given DME MACs, such as NHIC, the responsibility for developing and revising LCDs, maintaining the LCD record, and responsibility for defending LCD challenges. However, CMS requires that LCDs developed and revised by the DME MACs be identical for each jurisdiction to ensure uniformity for suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) with national

(*Footnote continued next page.)*

filed five exhibits with its response, marked as CMS exhibits (CMS Exs.) 1 through 5. The NHIC Medical Director stated in the NHIC Response that CMS Exs. 1 through 5 constitute the complete LCD record, "specifically the history of and rationale for all language and criteria related to continuous glucose monitors." NHIC Response at 3 (pages are unnumbered). On April 17, 2015, the Aggrieved Party filed her Statement of the Aggrieved Party with thirteen exhibits labeled A. Exs. 29 through 41. NHIC did not file a response to the Aggrieved Party's Statement within the time permitted in my Initial Order and pursuant to 42 C.F.R. § 426.425. On August 31, 2015, the Aggrieved Party filed A. Ex. 42.

Pursuant to 42 C.F.R. § 426.425(c), after the time for NHIC to file a response had expired, the reasonableness standard was applied to determine whether the submitted LCD record was complete and adequate to support the validity of the LCD and related LCA and the constructive LCD related to CGM that arises from those documents. On September 11, 2015, I issued a Ruling that found the LCD record NHIC had submitted was not complete and adequate to support the validity of the constructive LCD under the reasonableness standard. 42 C.F.R. § 426.425(c)(1). Included in my Ruling was a schedule for the parties to engage in discovery and for the submission of prehearing exchanges consisting of written argument and evidence. 42 C.F.R. § 426.425(c)(3).

On September 30, 2015, NHIC retired LCD L11530 and LCA 33614 and reissued substantively the same documents designated LCD L33822 and LCA A52464. Ct. Ex. 1. By regulation, the contractor was required to notify me of the retirement of the LCD under review within 48 hours of the LCD being retired. 42 C.F.R. § 426.420(c)(1). NHIC failed to do so, and on October 14, 2015, I ordered NHIC to file a copy of the LCD record for LCD L33822 and the related LCA A52464, no later than October 21, 2015. NHIC failed to comply with my order. On November 25, 2015, I notified the parties that I would convene a prehearing conference by telephone to clarify the status of the case and try to determine the participation of NHIC, which had not filed a notice of LCD retirement as required or responded to my October 14, 2015 order to produce the LCD record for L33822. DAB E-File # 13. Two days prior to the prehearing conference, on December 1, 2015, NHIC filed copies of LCD L33822 and LCA A52464, both of which are substantially the same as the retired LCD and LCA. NHIC filed no additional documents reflecting the development of the LCD and LCA. DAB E-File # 15. On December 2, 2015, one day prior to the scheduled prehearing conference, the Aggrieved Party filed a motion for summary judgment, to strike the LCD/LCA, and a motion for a subpoena.

(*Footnote continued.*)

operations. Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, chap. 13, § 13.1.4.

On December 3, 2015, I convened a prehearing conference by telephone. In attendance were: Debra Parrish on behalf of the Aggrieved Party; Alfred Mamuya, M.D., Medical Director for NHIC; and Robin Schneckloth, an employee of NHIC who had previously filed documents electronically on behalf of NHIC. Medical Director Mamuya stated that he was going to consult with corporate counsel as well as CMS to determine how NHIC would proceed in this case.[3] The parties agreed to a revised schedule for NHIC to respond to the Aggrieved Party's motion for summary judgment and motion for a subpoena, as well as for the parties to submit prehearing exchanges of evidence and written argument. Prehearing Conference Order and Schedule for Filing Responses, Briefs, and Documentary Evidence, at 2 (Dec. 4, 2015) (DAB E-File # 17).

On December 18, 2015, NHIC filed a response to the Aggrieved Party's first set of interrogatories as well as several documents including a redacted email from the medical director of a separate DME MAC, and 20 prior decisions from administrative law judges (ALJs) in the Office of Medicare Hearings and Appeals (OMHA), labeled as Ex. 6 through Ex. 25. On December 23, 2015, the Aggrieved Party renewed her motion for a subpoena directing NHIC to respond to the Aggrieved Party's document request. In a ruling dated December 31, 2015, I denied the Aggrieved Party's motion for a subpoena because the requested documents, including prior ALJ decisions, were not shown to be relevant to my review of the challenged LCD and the request for a subpoena did not comply with the requirements in 42 C.F.R. § 426.435.

On January 12, 2016, NHIC filed a brief (NHIC Br.) in response to the Aggrieved Party's motion for summary judgment. NHIC did not file a separate prehearing exchange, list of offered exhibits, and proposed witnesses by the January 15, 2016 deadline established by my September 11, 2015 Order. On January 29, 2016, the Aggrieved Party filed her prehearing exchange, which included a renewed motion for summary judgment and 74

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[3] NHIC never shared any information in this proceeding regarding CMS guidance on how NHIC was to proceed. No information about why CMS did not enter an appearance and participate in this case was provided by either NHIC or CMS. If CMS desires uniform national policies related to DME, it would seem appropriate for CMS to engage and participate in cases such as this with qualified counsel from the Office of General Counsel. NHIC was ill-prepared to participate and defend this case. My discussion of the background of this case shows numerous violations of orders and procedures and failure to address issues timely, which unnecessarily interfered with and delayed development and decision in this case. Sanctions were contemplated but not imposed to avoid the additional cost in time and resources necessary to impose sanctions.

proposed exhibits, labeled A.P. Exs. 1 through 74, but not A.P. Exs. 52, 67, and 68, which are listed on the Aggrieved Party's exhibit list as reserved. The Aggrieved Party filed A.P. Ex. 75 on February 16, 2016, and A.P. Ex. 76 on March 11, 2016.

A.P. Exs. 1 through 27, 29 through 41, 61 through 66, and 69 through 76 are admitted into the record because they have some relevance to my review of the challenged constructive LCD. 42 C.F.R. §§ 426.431, 426.440(a), 426.450. A.P. Exs. 28, 42 through 51, and 53 through 60 consist of prior ALJ decisions from OMHA. The OMHA ALJ decisions are not relevant. The decisions of OMHA ALJs who are not medical experts have no precedential value, but are simply adjudications in individual benefit appeals with only retrospective application in those cases. Further, the OMHA ALJs determined whether or not CGM was reasonable and necessary in the individual cases adjudicated (AP Exs. 28, 42-51, 53-60), which is not the standard to be applied in the case before me. I am required to exclude any evidence that is clearly irrelevant, immaterial, or unduly repetitive. 42 C.F.R. § 426.440(b). I also do not consider the ALJ decisions that NHIC filed on December 18, 2015, labeled as Ex. 6 through Ex. 25 on the same rationale. CMS Exs. 1 through 5, which consists of copies of LCD L11530 and LCA A33614, a memorandum from the Director of CMS's Center for Medicare Management, a product classification printout, a prior edition of LCD L11530, and a letter from the Director of the CMS Division of DMEPOS Policy, are admitted. DAB E-File # 6. The copies of LCD L33822 and LCA A52464 filed by NHIC (DAB E-File # 15), which I treat as if marked Ct. Ex. 1, are also admitted and considered as evidence. Therefore, the evidence admitted is marked A.P. Exs. 1-27, 29-41, 61-66, and 69-76; CMS Exs. 1-5; and Ct. Ex. 1.

II. Discussion

A. Legal Authority: The Act provides at section 1869(f)(2) (42 U.S.C. §1395ff(f)(2)) as follows:

> (2) LOCAL COVERAGE DETERMINATION. –
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> (A) IN GENERAL. – Review of any local coverage determination shall be subject to the following limitations:
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> (i) Upon the filing of a complaint by an aggrieved party, such determination shall be reviewed by an administrative law judge. The administrative law judge. –
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> (I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the administrative law judge

> determines that the record is incomplete or lacks adequate information to support the validity of the determination;
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> (II) may, as appropriate, consult with appropriate scientific and clinical experts; and
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> (III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

A LCD, as defined by the Act, is "a determination by a fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered" within the contractor's jurisdiction based on whether the items or services are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Act § 1869(f)(2)(B) (42 U.S.C. §1395ff(f)(2)(B)) (citing Act § 1862(a)(1)(A) (42 U.S.C. § 1395y)). Pursuant to section 1862(a) of the Act, no payment may be made by Medicare Parts A or B for any expenses incurred for items or services that are not "reasonable and necessary," except as otherwise provided in that section of the Act – exceptions that are not applicable in this case. The Secretary of the Department of Health and Human Services (the Secretary) has promulgated the regulations in 42 C.F.R. pt. 426, pursuant to sections 1102 and 1871 of the Act (42 U.S.C. §§ 1302 and 1395hh), implementing subsections 1869(f)(1) and (f)(2) of the Act. 42 C.F.R. § 426.100. The procedures for LCD review are in 42 C.F.R. pt. 426, subpt. D (42 C.F.R. §§ 426.400-490).

The Act provides for a two-level review process by the ALJ. The ALJ reviews the record, and, if he or she determines that the record is complete with adequate information to support the validity of the LCD, then review is complete. If the ALJ reviews the record and determines that the record is incomplete or lacks adequate information to support the validity of the determination, then further process is required, although that process is not specified by the statute. Act § 1869(f)(2)(A).

The Secretary's regulations establish a review procedure consistent with that specified in the Act. The regulations provide that after the aggrieved party files a statement as to why the LCD is not valid and the contractor responds, "the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD." 42 C.F.R. § 426.425(c)(1). "Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process." 42 C.F.R. § 426.425(c)(2). If the ALJ does not determine that the LCD record is complete and adequate to support the validity of the LCD, then the regulation provides for discovery

and the taking of additional evidence. No hearing was intended by the drafters or required by the language of the regulation for the first phase of review. 68 Fed. Reg. 63,692, 63,700 (Nov. 7, 2003).

If the ALJ determines that the LCD record is not complete and adequate to support the LCD, then the ALJ must allow for an opportunity for the parties to complete discovery and submit additional evidence. 42 C.F.R. § 426.425(c)(3). After an opportunity for the parties to complete discovery and the taking of additional evidence, the ALJ must conduct a hearing "unless the matter can be decided on the written record." 42 C.F.R. § 426.431(a)(2). Following a hearing or a determination that no hearing is required because the case can be decided on the written record, the ALJ must close the LCD record and issue a written decision that complies with the requirements in 42 C.F.R. §§ 426.447 and 426.450. The ALJ applies the reasonableness standard when making a final decision. 42 C.F.R. § 426.450(a).

The reasonableness standard is defined at 42 C.F.R. § 426.110 as:

> [T]he standard that an ALJ or the Board must apply when conducting an LCD or an NCD [national coverage determination] review. In determining whether LCDs or NCDs 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 applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Further definition of the reasonableness standard is provided by the notice of final rulemaking. 68 Fed. Reg. 63,692 (2003). The drafters of the regulation discussed the reasonableness standard adopted as follows:

> We are using the statutory language from sections 1869(f)(1)(A)(iii) and (f)(2)(A)(I) of the Act, which instructs adjudicators to defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary. The logical corollary is that the ALJs and the Board must accord deference if the contractor's or CMS's findings of fact, interpretations of law, and application of fact to law are reasonable. The concept of deference is one that is generally applied by courts to administrative decisionmaking, in recognition of the expertise of a program agency. Thus, we view the statute as setting out a reasonableness standard that recognizes the expertise of the

> contractors and CMS in the Medicare program--specifically, in the area of coverage requiring the exercise of clinical or scientific judgment. So long as the outcome is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld. This is not simply based on the quantity of the evidence submitted, but also includes an evaluation of the persuasiveness of the material. If the contractor or CMS has a logical reason as to why some evidence is given more weight than other evidence, the ALJs and the Board may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage. In some situations, different judgments by different contractors may be supportable, especially if explained by differences such as the ready availability of qualified medical professionals in one contractor's area, but not in another. Moreover, an ALJ or the Board may not determine that an LCD is unreasonable solely on the basis that another Medicare contractor has issued an LCD that permits coverage of the service at issue, under the clinical circumstances presented by the complaint. For legal interpretations, the reasonableness standard would not be met if an interpretation is in direct conflict with the plain language of the statute or regulation being interpreted. Moreover, an interpretation in an LCD would not meet the reasonableness standard if it directly conflicts with an NCD or with a CMS Ruling. So long as an interpretation is one of the readings permitted by the plain language of the law and can be reconciled with relevant policy, however, it must be upheld, even if the ALJ or the Board might have reached a different result if interpreting the statute or regulation in the first instance.

68 Fed. Reg. at 63,703-04. Pursuant to 42 C.F.R. § 426.330, the Aggrieved Party bears the burden of persuasion, which is judged by a preponderance of the evidence.

B. Issue: The issue in this case is whether or not the challenged constructive LCD, which arises from LCD L11530/L33822 and the related LCA A33614/A52464, is valid under the reasonableness standard.

Whether the Aggrieved Party is actually entitled to Medicare coverage for the items or services her physician states that she requires is not an issue before me. This decision may not be construed to be a determination that the Aggrieved Party is entitled to Medicare reimbursement for CGM and related supplies as that issue is not within my authority to decide.

C. Closing the LCD Record: An ALJ must close the LCD record to the taking of evidence. 42 C.F.R. § 426.431(a)(3). The LCD record for this case is considered closed effective March 11, 2016, the date of the last submission by either the Aggrieved Party or NHIC.

D. Decision on the Written Record: The regulations require an ALJ to conduct a hearing, unless the case can be decided on the written record. 42 C.F.R. § 426.431(a)(2). The facts of this case are not disputed; NHIC has identified no witnesses to testify at an oral hearing; the Aggrieved Party has identified witnesses but because the case is resolved in her favor and no material issues of fact are in dispute there is no prejudice to the Aggrieved Party if I do not hear the witness testimony; and, I conclude that I need not assess the credibility of any witnesses to decide whether the challenged constructive LCD provision is valid under the reasonableness standard. Therefore, upon complete review of the LCD record and the parties' written submissions, I have determined that this matter may be decided on the written record without the need for an in-person hearing.

The Aggrieved Party also filed a motion for summary judgment in this case. Summary judgment is appropriate in this case and, for that reason also, no oral hearing is required. There is no genuine dispute as to any material fact and this decision is based upon an application of the law to the undisputed facts. NHIC argues that denial of Medicare coverage for CGM and related supplies is required because CMS has determined that CGM is not DME. NHIC points to two instances where upon review of specific devices, CMS issued informal advice that CGM equipment or supplies are not DME because they are precautionary. NHIC points to no National Coverage Determination (NCD) or other statement of CMS that CGM and related supplies is never DME or that it can never be reasonable and necessary within the meaning of the Act and covered by Medicare. NHIC advances multiple legal arguments to attempt to prevent review of its action denying Medicare coverage of CGM, a system for monitoring glucose levels in diabetics. NHIC never acknowledges that it effectively established a LCD, a rule to be applied in its jurisdiction, which directs that CGM and related supplies are never covered by Medicare without any consideration of whether or not CGM may be reasonable and necessary for some Medicare beneficiaries.

The regulations that establish the procedures for LCD and NCD review specifically authorize a decision on summary judgment when there is no disputed issue of material fact. 42 C.F.R. § 426.405(c)(18). Summary judgment is appropriate and no hearing is required

where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. When confronted with a properly supported motion for summary judgment, the nonmoving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986) (quoting *First Nat'l Bank of Ariz. v. Cities Serv. Co.*, 391 U.S. 253, 249 (1968)); *see also* Fed. R. Civ. P. 56; *Garden City Med. Clinic*, DAB No. 1763 (2001), *Everett Rehab. & Med. Ctr.*, DAB No. 1628 at 3 (1977) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony); *Big Bend Hosp. Corp., d/b/a Big Bend Hosp. Ctr.*, DAB No. 1814 at 13 (2002) (in some cases, any factual issue is resolved on the face of the written record because the proffered testimony, even if accepted as true, would not make a difference). It is insufficient for the non-movant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. A party opposing summary judgment must, by affidavits or other evidence which set forth specific facts, show that there is a genuine issue for trial. If a party opposing summary judgment does not show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *See Liberty Lobby, Inc*., 477 U.S. at 247. A test for whether an issue is regarded as genuine is if "the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *See Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3rd Cir. 1986). NHIC identifies no genuine dispute as to any material fact but, rather, relies upon arguments that this matter is not within my jurisdiction. I conclude, for reasons discussed hereafter, that NHIC's legal arguments are without merit and that the Aggrieved Party is entitled to judgment based on an application of the law to the undisputed facts.

E. Findings and Conclusions Under 42 C.F.R. § 426.450.

1. My jurisdiction is not affected by the fact the Aggrieved Party filed a claim for coverage of CGM and related supplies that was initially denied but subsequently approved by an OMHA ALJ as reasonable and necessary.

According to the Complaint, the Aggrieved Party was 69 at the time she filed her Complaint. The Aggrieved Party asserts that the equipment she needs is a CGM system. Complaint at 2. A declaration from the Aggrieved Party's physician, Richard Beaser, M.D., dated November 11, 2014, indicates that the Aggrieved Party suffers from Type I diabetes mellitus, which, despite repeated attempts to control glucose levels, has resulted in the Aggrieved Party having uncontrolled glucose levels and "brittle" diabetes. The

physician stated that the Aggrieved Party has hypoglycemic unawareness, which occurs when a person is not aware of an impending drop in blood glucose levels, resulting in change in mental status or complete loss of consciousness. According to the physician the lack of awareness of dropping blood glucose levels is caused by the loss of a person's ability to secrete epinephrine, which normally occurs in a person with dropping blood glucose levels and triggers a response in that individual. The physician prescribed the use of a CGM and an insulin infusion pump because he determined that it is an effective way to warn the Aggrieved Party of dropping glucose levels and avoid harmful hypoglycemic episodes. A.P. Ex. 2.

The Aggrieved Party asserts, and it is not disputed by NHIC, that her Medicare benefits are administered through Blue Cross and Blue Shield of Massachusetts, a Medicare Managed Care Program; she requested approval for the CGM system she was provided on April 22, 2014, and that claim was denied. Complaint at 2; A.P. Ex. 29 at 1-2. More specifically, on October 31, 2014, the Aggrieved Party was notified that her claim for Medicare coverage of the CGM transmitter (A9277GX[4]) and the disposable sensors (A9276GX) were denied as convenience items. The decision cited LCD L11530. A.P. Ex. 29 at 2. However, the determination that a CGM system, parts for which are subject to codes A9276, A9277, and A9278[5] is not covered by Medicare is actually set forth in LCA A33614/A52464, "Glucose Monitors – Policy Article," which is incorporated by reference in LCD L11530/L33822. CMS Ex. 4 at 9; A.P. Ex. 1 at 15; Ct. Ex. 1 at 22. LCA A33614/A52464 does not state that CGM systems are not covered because they are convenience items, but rather, that they are not covered because they are "precautionary" and therefore not covered "under the DME benefit." CMS Ex. 1 at 21; A.P. Ex. 1 at 17; Ct. Ex. 1 at 24. NHIC argues before me that CGM systems are not DME and not covered

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[4] This is a Current Procedural Terminology (CPT) code. The CPT code set is maintained by the American Medical Association and is used by CMS as part of the Healthcare Common Procedure Coding System (HCPCS). The purpose is to describe accurately and communicate information about medical services and procedures by the use of the code. See www.cms.hhs.gov/MedHCPCSGenInfo. A9277 is listed in LCD L11530/L33822 as "Transmitter; External, For Use With Interstitial Continuous Glucose Monitoring System." A9276 is listed as "Sensor; Invasive (e.g. Subcutaneous), Disposable, For Use with Interstitial Continuous Glucose Monitoring System, One Unit = 1 Day Supply." CMS Ex. 1 at 5; A Ex. 1 at 4. The fact that an item or service is covered by a CPT does not mean that the item or service is also covered by Medicare.

[5] CPT A9278 is a "Receiver (Monitor); External, For Use With Interstitial Continuous Glucose Monitoring System." CMS Ex. 1 at 5; A Ex. 1 at 4.

by Medicare because they have been considered precautionary in a CMS interpretative policy determination. NHIC Resp. at 4. NHIC does not argue that CGM systems are a convenience item. NHIC also does not argue that a determination has been made that CGM, including related accessories and supplies, are not covered by Medicare because a determination has been made by NHIC or CMS that CGM are not reasonable and necessary.

2. The Aggrieved Party is an "aggrieved party" within the meaning of 42 C.F.R. § 426.110.

In my Initial Order dated February 18, 2015, I found the Complaint was acceptable and, by implication, that the complainant met the requirements to be an aggrieved party within the meaning of 42 C.F.R. § 426.110. Pursuant to 42 C.F.R. § 426.320(a) only an aggrieved party may obtain review of a LCD by filing an acceptable complaint. An aggrieved party is a Medicare beneficiary or the estate of such beneficiary, who is entitled to benefits; who is in need of coverage for a service that is denied based on an applicable LCD in the relevant jurisdiction, whether or not the service was received; and who has documentation of the need from his or her treating physician. 42 C.F.R. § 426.110. There is no question that the Aggrieved Party is a Medicare beneficiary and entitled to benefits. The Aggrieved Party also provided the required statement of need from her treating physician, dated within 180 days of the day the Complaint was filed. A.P. Ex. 2.

NHIC argues that coverage for CGM and related supplies was denied because it is not DME and not based on a reasonable and necessary determination, and therefore it was not covered by Medicare. NHIC Resp. at 1, 4-5. NHIC also argues that LCA A33614/ A52464 (CMS Ex. 1 at 20-26; Ct. Ex. 1 at 23), which states that CGM and related accessories and supplies are "precautionary" and not covered under the DME benefit, is not a LCD subject to review under 42 C.F.R. pt. 426. NHIC Resp. at 5-6. For reasons discussed hereafter, I conclude that LCA A33614/A52464 contains a provision that amounts to a constructive LCD that is subject to ALJ and Board review. Because the Aggrieved Party is entitled to Medicare coverage and has a need for CGM and related supplies which are the subject of the constructive LCD, she is an aggrieved party within the meaning of the Act and regulations.

On August 17, 2015, the Aggrieved Party advised my office that an OMHA ALJ on August 12, 2015, found reasonable and necessary and approved reimbursement for a CGM transmitter (A9277) and disposable sensors (A9276) that she obtained April 22, 2014. DAB E-File # 9. An aggrieved party is required to notify the ALJ or the Board "regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint" and the reporting obligation continues through the entire review process. 42 C.F.R. § 426.310. The regulations do not provide that the payment of one or all claims related to the LCD under review deprives the aggrieved party of his or her status or standing as an aggrieved party. 42 C.F.R. § 426.110. An aggrieved

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

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

The foregoing provision of the Act only requires entitlement to benefits and a need for the items or services subject to the coverage determination. The Act specifically does not require that an aggrieved party be denied benefits in order to have standing. Neither the Act nor the regulations require termination of the LCD review, or dismissal of the pending compliant on grounds that the underlying claims were paid. 42 C.F.R. § 426.405. The Aggrieved Party in this case continues to be entitled to Medicare benefits and has need of the items subject to the constructive LCD, which is all that is required for standing. Petitioner was an aggrieved party when the complaint was filed, and she continues to be an aggrieved party, despite the payment of her underlying claim.

3. The challenged provisions of LCD L11530/L33822 and related LCA A33614/A52464 constitute a determination that CGM and related supplies are not covered in the geographic area served by NHIC and are a constructive LCD.

4. The constructive LCD does not meet the reasonableness standard.

a. *LCD L11530/L33822, "Glucose Monitors," and LCA A33614/A52464, "Glucose Monitors – Policy Article."*

The Aggrieved Party filed a copy of LCD L11530, issued by NHIC, with an original effective date of October 1, 1993, and a revision date of January 1, 2014. A.P. Ex. 1 at 1-15; CMS Ex. 1 at 1-19. The Aggrieved Party also filed a copy of the Policy Article A33614, issued by NHIC, with an original effective date of July 1, 2005, and a revision date of January 1, 2014. A.P. Ex. 1 at 16-21; CMS Ex. 1 at 20-26. There is no dispute that these are versions of the LCD and Policy Article in effect when the Aggrieved Party was denied coverage by NHIC. The October 31, 2014 decision of NHIC denying coverage of CGM supplies specifically stated that LCD "L11530 was used" by NHIC when it made the decision to deny coverage. A.P. Ex. 29 at 2.

On September 30, 2015, NHIC retired LCD L11530 and LCA A33614, but issued substantially the same LCD and LCA designated LCD L33822 and LCA A52464, with the effective date October 1, 2015. NHIC renumbered many of its LCDs for the transition from the International Classification of Diseases (ICD)-9 to the ICD-10. NHIC Corp., *ICD-10 Updates to Local Coverage Determinations (LCD) and Policy Articles (PAs)*, at 1

(rev. Sept. 2014), available at https://www.medicarenhic.com/viewdoc.aspx?id=2658. Retiring a LCD under review normally ends the review process. 42 C.F.R. § 426.420. However, review of LCD L33822 and LCA A52464 shows that there is no substantive difference between the retired and current versions of the LCD and related LCA. Terminating the review of an LCD based simply on the contractor's renumbering of that LCD would frustrate the LCD review process that Congress and the Secretary have established, and could allow the contractor to avoid any meaningful review of its LCDs by simply issuing renumbered LCDs without any substantive changes when a complaint is filed. Accordingly, I conclude that because the retirement of LCD L11530 and LCA A33614 appears to be nothing more than a renumbering of the LCD and LCA, it does not trigger dismissal pursuant to 42 C.F.R. § 426.420(e)(1) nor end my review of the challenged provision of the LCD and related LCA.

The Aggrieved Party does not challenge a specific provision of LCD L11530/L33822. Complaint at 3-4. Instead, the Aggrieved Party challenges as a constructive LCD, the provision of Policy Article A33614/A52464, under the section entitled "Non-Medical Necessity Coverage and Payment Rules" that states: "[c]ontinuous glucose monitors (A9276, A9277, A9278) are considered precautionary and therefore non-covered under the DME benefit." CMS Ex. 1 at 21; Ct. Ex. 1 at 23

NHIC's position is that there is no LCD, constructive or otherwise, that addresses non-coverage of CGM. NHIC argues that CMS has previously determined that CGM and its related accessories and supplies are not covered because they are not DME and, therefore, are not subject to coverage under the Medicare DME benefit. NHIC's position is that LCA A33614/A52464 merely reflects a CMS determination that CGM is not DME and not covered by Medicare as DME. NHIC Br. at 5-6. NHIC denies that it has made a determination that CGM is not reasonable and necessary and, therefore, there is no requirement for a LCD and there is no LCD for me to review. NHIC Br. at 5. NHIC's denial is also an admission that NHIC made no determination as to whether or not CGM and related supplies are reasonable and necessary.

I conclude that NHIC is in error because the evidence before me does not support NHIC'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. NHIC is also in error because LCA A33614/A52464 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)(1)(A) of the Act.

It is first necessary to examine NHIC's allegation that CMS has determined that CGM and related accessories and supplies are not DME. After explaining why that allegation is in error, I next turn to the issue of whether the constructive LCD in LCA A33614/A52464 meets the reasonableness standard.

b. *The record does not support a conclusion that CMS determined that all CGM and related accessories and supplies are not DME and not subject to Medicare coverage for that reason*.

NHIC argues that the Medicare program is a defined benefit program and that no CGMs are DME for purposes of Medicare coverage and reimbursement, and thus do not fall under the DME benefit. NHIC argues that only CMS can determine whether or not CGM is DME, and that decision is not reviewable, at least not by me. NHIC Br. at 1-2, 3-4. NHIC is correct that I have no jurisdiction to review a CMS determination that a particular item is or is not DME. NHIC is incorrect, however, in asserting that CMS has determined that CGM and related supplies are not DME or otherwise not covered by Medicare. NHIC argues that CGM measures interstitial (tissue) fluid glucose not blood glucose and therefore CGM is not covered by NCD 40.2 titled "Home Blood Glucose Monitors."[6] NHIC Br. at 3. I agree that CGM is not specifically covered by NCD 40.2. NCD 40.2 approves coverage for blood glucose testing and related supplies. However, NCD 40.2 does not address whether or not CGM may be covered as DME or otherwise.

The October 31, 2014 decision of NHIC denying coverage specifically stated that LCD "L11530 was used" by NHIC when it made the decision to deny coverage for CGM. A.P. Ex. 29 at 2. LCD L11530/L33822, which must be consistent with NCD 40.2, provides that some glucose monitors and related accessories and supplies may be reasonable and necessary and covered by Medicare while others are not. CMS Ex. 1 at 1-4; Ct. Ex. 1 at 2-4. LCD L11530/L33822 does not specifically state that CGM and related accessories and supplies are not reasonable and necessary. LCD L11530/L33822 lists CPT/HCPCS Codes A9276, A9277, and A9278 for CGM accessories and supplies. LCD L11530/L33822 lists LCA A33614/A52464 as the only "Related Local Coverage Document." CMS Ex. 1 at 19; Ct. Ex. 1 at 24. LCA A33614/A52464 states under a section entitled "Non-Medical Necessity Coverage and Payment Rules" that home blood glucose monitors are covered under the DME benefit citing section 1861(s)(6) of the Act, so long as they meet the reasonable and necessary requirements of LCD L11530/L33822. CMS Ex. 1 at 20-21; Ct. Ex. 1 at 24. However, LCA A33614/A52464 declares that a class of home glucose monitors known as CGM (CPT/HCPCS Codes A9276 through A9278) is not covered because they "are considered precautionary and therefore non-covered under the DME benefit." CMS Ex. 1 at 21; Ct. Ex. 1 at 24. LCA A33614/A52464 does not state that CGM is not reasonable and necessary.

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[6] CMS Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, § 40.2. NCDs are available at www.cms.gov/medicare-coverage-database/.

NHIC has presented two documents as evidence supporting its position that CMS determined CGM is not DME and not covered by Medicare. CMS Ex. 2 is a September 2002 memorandum from the CMS Director of the Center for Medicare Management to the Office of Financial Management, in which the Director concludes that the "Glucowatch" is not DME. 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. The writer of the 2002 memorandum notes that product materials warn that the Glucowatch system is not accurate enough to replace the user's home blood glucose monitor which must be used to verify Glucowatch readings. CMS Ex. 2 at 1-2. The writer concluded that the Glucowatch only alerts the user to conduct a blood glucose monitor test. Therefore, the writer concluded, the Glucowatch is not DME because it is only an alert/precautionary system like a home blood pressure monitor, a medical alert bracelet or pendent, or an emergency communications system. CMS Ex. 2 at 2.

NHIC primarily relies on an April 9, 2013 letter from the CMS Director of the Division of DMEPOS Policy, Chronic Care Policy Group, to a representative of Medtronics Diabetes, a business that produced and/or sold the "Minimed Paradigm® REAL-time Insulin Pump and Continuous Glucose Monitoring (CGM) System" (Minimed Paradigm®). CMS Ex. 5; NHIC Br. at 4. The letter indicates that Medtronics Diabetes requested an informal benefit category determination that the Minimed Paradigm® is DME. CMS Ex. 5 at 1. The April 9, 2013 letter states that CMS determined that the insulin pump is considered DME but the CGM is not because it "does not fall under the DME benefit category because it is not covered under the Medicare national coverage policy for home blood glucose monitors and is a precautionary device." CMS Ex. 5 at 2. The writer explained that the CGM device is not covered under the DME benefit because "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." CMS Ex. 5 at 2. The writer states that the CGM device is nonmedical in nature and not DME under section 110.1, chapter 15, of the Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02. The writer states that the radio transmitter feature that delivers the CGM reading to the insulin pump is a convenience feature and not covered because the user could simply manually enter the reading. CMS Ex. 5 at 2.

Thus, the entirety of NHIC's evidence shows that in 2002, a CMS official determined that a Glucowatch was not DME, and, in 2013, a CMS official determined that the CGM part of the Minimed Paradigm® is not DME because it is nonmedical and the radio transmitter is not DME but a convenience item. CMS Exs. 2, 5. NCD 40.2 provides that home blood

glucose monitors are covered by Medicare as DME, if they meet the reasonable and necessary requirements.[7] There is no evidence before me that shows CMS determined that CGM devices and related accessories and supplies under CPT/HCPCS Codes A9276, A9277, and A9278 are *never* DME and *never* subject to coverage on that basis. If CMS had issued such a blanket determination then the individual determinations from 2002 and 2013, upon which NHIC relies, would have been unnecessary.

Although I have no jurisdictional authority to review a determination by CMS that an item is not DME, in the absence of such a determination it is appropriate to consider whether CGM and related accessories and supplies are clearly not DME under the Act, the regulations, or CMS policy.

Pursuant to section 1861(n) of the Act, DME: (1) "includes iron lungs, oxygen tents, hospital beds, and wheelchairs" (including powered vehicles that may be used like a wheelchair); (2) "used in the patient's home" (or institution if that is his home); (3) whether the equipment is purchased or rented; and (4) includes blood-testing strips for those with diabetes whether or not they use insulin; but (5) does not include equipment furnished by a supplier "who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment." An additional caveat in the section that has no application in the case before me is that in case of a seat-lift chair, the seat lift mechanism is DME but not the chair itself. The Secretary has provided by regulation that:

> *Durable medical equipment* means equipment, furnished by a supplier or a home health agency 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

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[7] There is no evidence and NHIC does not argue that the Aggrieved Party's claim was denied because a CGM device does not meet the definition of a home blood glucose monitor under NCD 40.2.

> (4) Is appropriate for use in the home.

42 C.F.R. § 414.202.

CMS provides specific policy guidance to Medicare contractors through it publications. The MBPM sets forth the definition of DME from the regulation and adds that all requirements of the definition must be met before an item may be considered DME. MBPM, CMS Pub. 100-02, chap. 15, § 110.1. CMS provides further guidance to its contractors regarding durability, which it equates to the type of equipment that could be rented. In section 110.1B, CMS explains that in most instances the contractor will have to do no development (research or investigation) to determine whether an item of equipment is medical in nature but other cases do require development. Development can include receiving advice of hospitals, medical schools, medical societies and specialists in the field in which the equipment is to be applied. CMS suggests that contractors seek professional advice and obtain supplier and manufacturer information for new devices. CMS also lists presumptively medical and presumptively non-medical equipment. CMS states:

> Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, 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.

MBPM, CMS Pub. 100-02, chap. 15, § 110.1B.2 (emphasis added). The policy guidance in section 110.1B.2 that "precautionary-type equipment" is presumptively non-medical is inaccurate and misleading. There is no such criterion established or recognized under either the regulation or the Act definitions of DME. Rather, under the Act and regulation the issue is whether or not an item of equipment and related accessories and supplies meet the definition of DME.

The Health Care Financing Administration (HCFA), the precursor for CMS, recognized that section 1861(n) of the Act and the Secretary's regulation, 42 C.F.R. § 414.202, use an open ended definition for DME by stating that it includes certain things rather than providing a specific and exhaustive list or very precise definition. HCFA Ruling 96-1 at 3. HCFA also commented that its long-standing policy of broadly construing the DME benefits category is consistent with Congressional intent. *Id.* at 6; *see also NCD Complaint – Durable Medical Equipment Reference List (Air Cleaners) 280.1*, DAB No. 1999 at 3 (2005). My review of the statutory definition of DME as interpreted by the Secretary in her regulations reveals that there is no element or criteria related to or

requiring consideration of whether an item may be considered "precautionary" when determining if an item of equipment is DME. Because the definition of DME is broad and HCFA/CMS has a long-standing policy of broadly construing the DME benefits category, adding an element of whether an item is "precautionary" is inconsistent with the broad construction of DME intended by Congress and overly restrictive. CMS created unnecessary confusion in its choice of words in CMS Pub. 100-02, MBPM, Chap. 15, §110.1B.2, by stating that "precautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature." In addressing equipment such as preset portable oxygen units in CMS Pub. 100-02, CMS may have been correct in stating that they are not "primarily and customarily used to serve a medical purpose" and, therefore, they are not within the DME category. CMS could also conclude that such equipment may have utility to an individual even in the absence of illness or injury, and are thus not DME on that basis. However, construing the definition of DME to include an element or criteria related to whether an item is precautionary is in direct conflict with section 1861(n) of the Act and 42 C.F.R. § 414.202, and is not permissible. The 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 effective for the beneficiary to use.

NHIC asserts that HCPCS A9276 defines subcutaneous sensors as "disposable," and therefore not able to withstand repeated use. NHIC argues that HCPCS definitions are not reviewable by me. NHIC Br. at 2. Indeed, the descriptions of CGM in clinical studies explain that the sensors used in CGM last only for several days. However, the fact that the sensors can be used for several days shows that they are, in fact, subject to repeated use to the extent that they are used for multiple testing events over the course of the several days the device is in place. A.P. Ex. 5 at 1; A.P. Ex. 6 at 2; NHIC Br. at 2. The definition of durability states "[a]n item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented." MBPM, chap. 15, § 110.1A. Read literally, the sentence could mean that all DME must be rental equipment. However, such literal reading flies in the face of the fact that much DME, including glucose monitors, are often purchased for and used by only a single individual. MBPM, chap. 15, § 110.4. Blood glucose monitors that read color changes caused on a disposable reagent strip when a small drop of blood, drawn with a disposable lancet, is placed on the disposable strip, are clearly covered as DME under NCD 40.2. But the disposable lancets, disposable reagents, and other supplies necessary for the proper testing of glucose with the glucose monitor are also covered as DME for the beneficiary for whom the device and supplies are properly ordered. NCD 40.2. CMS policy set forth in MBPM, chap. 15, § 110.3 specifically provides that supplies necessary for the effective use of DME are subject to payment under the DME benefit. The fact that subcutaneous sensors are disposable after repeated use over several days is not inconsistent with their treatment as covered under the DME benefit simply because they are disposable.

HCPCS A9277, a CGM transmitter, and A9278, a CGM receiver, do not include "disposable" in their HCPCS definition. Therefore, they may be characterized as being durable.

Based upon the evidence presented to me, CGM and at least some of its related accessories and supplies otherwise appear to meet the statutory definition of DME as interpreted by the Secretary: (1) most of its elements appear to be capable of withstanding repeated use; (2) they appear to have primarily and customarily a medical use for "brittle" diabetics in need of frequent glucose monitoring, which consists of monitoring a diabetic's glucose level for the purpose of detecting a sustainable glucose level and providing a warning if that level reaches a dangerously-low level that the beneficiary may be incapable of detecting without a CGM warning; (3) the monitor appears to have no utility absent Type I diabetes which is an illness; and (4) the CGM is designed for use in a home setting. A.P. Exs. 5-23.

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 HCPCS Codes A9276, A9277, and A9278, 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.

I conclude that it is not clear that CGM is not DME, and CMS has not determined that no CGM may be DME or otherwise covered by Medicare because it is reasonable and necessary. Therefore, NHIC's reliance upon the two informal determinations and NCD 40.2 is unreasonable. Accordingly, I conclude it is necessary to consider whether the implicit determination reflected in LCD L11530/L33822 and LCA A33614/A52464 that CGM and its related accessories and supplies are not reasonable and necessary must be tested under the reasonableness standard as a constructive LCD.

c. *The constructive LCD in this case establishes a contractor-wide policy that CGM and related accessories and supplies are not reasonable and necessary, which does not meet the reasonableness standard.*

NHIC argues that its determination announced in the LCA not to cover CGM and related supplies is not subject to my review because its determination is not a LCD. NHIC Br. at 5. NHIC is in error. The determination not to cover CGM on a contractor-wide basis, without a determination of whether CGM and related supplies may be reasonable and necessary is a constructive LCD, even though NHIC placed the non-coverage determination in the LCA.

A LCD is:

> [A] determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary – or carrier – wide basis under such parts, in accordance with section 1862(a)(1)(A).

Act § 1869(f)(2)(B). Section 1862(a)(1)(A) provides that no payment will be made under Medicare Parts A or B for any expenses for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." Thus, a LCD is a determination by a Medicare contractor that is applied to claims filed within that contractor's jurisdiction, that a particular item or service is or is not covered by Medicare based upon whether or not the item or service is considered reasonable and necessary for the diagnosis or treatment of illness or injury or improvement of functioning. MPIM, CMS Pub. 100-08, Chap. 13, § 13.1.3. CMS has specified that a LCD may not restrict or conflict with NCDs (MPIM § 13.5); and only reasonable and necessary provisions are considered part of a LCD (MPIM § 13.5.1).

An appellate panel of the Board has determined that neither the form nor the characterization by a Medicare contractor or CMS controls in deciding whether a policy is a LCD and subject to review pursuant to section 1869(f)(2) of the Act. *In re: LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050 at 9-11 (2006). The Board suggests that whether a policy is a LCD is a legal issue to be decided based upon the substance and content of the policy, *i.e.*, a policy to deny coverage for a particular item or service on a contractor-wide basis. *Id.* NHIC argues that the determination in this case was not a LCD because the determination was that CGM and related accessories and supplies subject to HCPCS Codes A9276, A9277, and A9278 were precautionary and not included under the DME benefit, and the determination was not whether CGM was "reasonable and necessary" under section 1862(a)(1)(A) of the Act. NHIC concedes by its argument that it made no determination as to whether or not CGM and related accessories and supplies are reasonable and necessary, having relied instead on the misconception, based on the two informal CMS memoranda, that CGM is simply not DME.

The reasonableness standard is defined at 42 C.F.R. § 426.110 as:

> [T]he standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs 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 applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

The contractor's constructive LCD in this case excludes CGM and related accessories and supplies from coverage across NHIC's jurisdiction, yet there is no evidence that NHIC ever determined that CGM and related accessories and supplies are never reasonable and necessary. The contractor 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. CMS Ex. 1. There is simply no evidence before me that explains how CGM does not meet DME requirements or why CGM cannot ever be reasonable and necessary under section 1862(a)(1)(A) of the Act. Therefore, I find that there are no findings of fact, interpretations of law, and applications of law to fact by the contractor or CMS that are required to be given deference or that may be found reasonable. When applying the reasonableness standard, the LCD record does not support the challenged provision of the constructive LCD established by LCD L11530/L33822 and LCA A33614/52464.

NHIC argues that OMHA ALJ and Medicare Appeals Council decisions stating that CGM is not covered by the Medicare DME benefit are precedential and binding. NHIC Br. at 6. NHIC is again in error. Decisions of the OMHA ALJs and the Medicare Appeals Council are only precedential to the extent that they have been decided in the past. They clearly are not binding precedent in the legal sense beyond the parties to the particular case subject to the decision. The fact that some OMHA ALJs have applied the constructive LCD and found CGM not covered and the Medicare Appeals Panel has upheld such determinations is not binding upon either me or the Departmental Appeals Board. In fact, the regulations clearly provide that LCDs and other policies of CMS are not binding upon ALJs or the Medicare Appeals Council. 42 C.F.R. § 405.1062. The OMHA ALJ and Medicare Appeals Council decisions offered by both parties for my consideration contain no indication that the ALJs involved or the Medicare Appeals Council conducted an actual review of the LCD provision. But that is not surprising in that it is clearly beyond their jurisdiction under 42 C.F.R. § 405.1062(c). Therefore, those decisions are not relevant and have no impact upon my decision making.

III. Conclusion

The provision of the constructive LCD contained in LCD L11530/L33822 and LCA A33614/A52464 that states "[c]ontinuous glucose monitors (A9276-A9278) are considered precautionary and therefore not covered under the DME [durable medical equipment] benefit," is not valid under the reasonableness standard.

Neither party submitted any evidence or other data under seal in this proceeding. Therefore, I have not considered any evidence that would require a separate discussion to be issued under seal. 42 C.F.R. § 426.450(b)(5).

IV. Appeal Rights

The parties are notified pursuant to 42 C.F.R. §§ 426.450 and 426.465 of their right to appeal this Decision to the Board for review. Unless there is good cause shown, an appeal must be filed within 30 days of the date of this Decision. 42 C.F.R. § 426.465(e). An appeal must include the full names and addresses of the parties, including the name of the LCD at issue, the date this Decision is issued, the docket number for this case (C-15-1021), a statement identifying the parts of this Decision that are being appealed, and a statement explaining why this Decision should be reversed. 42 C.F.R. § 426.465(f)(1)-(3).

The Aggrieved Party may appeal to the Board any part of this Decision that states a provision of an LCD is valid under the reasonableness standard or dismisses a complaint regarding an LCD. 42 C.F.R. § 426.465(a)(1)-(2).

NHIC or CMS may appeal to the Board any part of this Decision that states a provision (or provisions) of an LCD is (are) unreasonable. 42 C.F.R. § 426.465(b).

/s/
Keith W. Sickendick
Administrative Law Judge