DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re: LCD Complaint: Glucose Monitors (L11530),
Glucose Monitors (Local Coverage Article A33614 January 2014),

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

Docket No. C-15-1021

Date: September 11, 2015

RULING PURSUANT TO 42 C.F.R § 426.425(c) AND ORDER FOR CASE DEVELOPMENT

I conclude, based upon the review required by 42 C.F.R. § 426.425(c)(1), that the Local Coverage Determination (LCD) record is not complete and adequate to support the constructive LCD that arises from LCD L11530 and the related Local Coverage Article (LCA) A33614, which is challenged by the Aggrieved Party. Pursuant to 42 C.F.R. § 426.425(c)(3), I am required to permit discovery and the taking of evidence (including a hearing unless the matter can be decided on the written record) in accordance with 42 C.F.R. §§ 426.432 and 426.440 prior to completing the evaluation required by 42 C.F.R. § 426.431. Accordingly, I issue the following order to permit discovery and further case development.

I. Background

The Aggrieved Party requested review of the NHIC, Corp. 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 provisions of LCD L11530 and LCA A33614, which provide that continuous glucose monitors (CGM) are not covered 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 the Medicare contractor and the Centers for Medicare and Medicaid Services (CMS). On February 24, 2015, the Aggrieved Party certified that service upon both the Medicare contractor and CMS was accomplished.

On March 4, 2015, NHIC Corp., the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for CMS Jurisdiction A, responded to my Initial Order to the contractor to file the LCD record.[1] NHIC filed a three-page response letter (NHIC Response) from its Medical Director. NHIC filed five exhibits with its response, marked CMS exhibits (CMS Ex.) 1 through 5. The NHIC Response indicated that CMS Exs. 1 through 5 "provides the complete LCD record and specifically the history of and rational for all language and criteria related to continuous glucose monitors." NHIC Response at 3 (pages are not numbered and the cover-letter is not counted as a page of the response).

On April 17, 2015, the Aggrieved Party filed her Statement of the Aggrieved Party (AP Statement) with thirteen exhibits labeled A. Ex. 29 through 41. NHIC did not file a response to the AP Statement within the time permitted in my Initial Order and under 42 C.F.R. § 426.425. On August 31, 2015, the Aggrieved Party filed A. Ex. 42.

CMS Exs. 1 through 5 and A. Exs. 1 through 42 are accepted into the record and considered as evidence for this Ruling.

II. Ruling Based Upon Application of the Reasonableness Standard.

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

> (2) LOCAL COVERAGE DETERMINATION. –
>
> (A) IN GENERAL. – Review of any local coverage determination shall be subject to the following limitations:

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[1] CMS has given DME MACs the responsibility for developing and revising LCDs, maintaining the LCD record, and responsibility for 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 operations. Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.1.4.

> (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
> >
> > (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 area covered by the contractor based on whether or not 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 Part 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 *et. seq.*).

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

The Secretary's regulations establish a review procedure consistent with that specified by Congress 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).

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 at 68 Fed. Reg. 63,692, 63,703-04 (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.

B. Issue: At this first phase of the review process, the issue is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard. The issue before me does not include consideration of whether the Aggrieved Party is entitled to Medicare coverage for the item or service her physician states that she requires.

C. Findings and Conclusions Under 42 C.F.R. § 426.425(c)(3).

1. Aggrieved Party and Equipment Required.

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 continuous glucose monitor (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 doctor 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. The unawareness 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 doctor prescribed the use of a CGM and insulin infusion pump because he determined that it is an effective way to warn the Aggrieved Party of dropping blood glucose levels and avoid harmful hypoglycemic episodes. A. Ex. 2.

The Aggrieved Party asserts, and it is not disputed by NHIC or CMS, 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 that was denied. Complaint at 2; A. Ex. 29 at 2. More specifically, on October 31, 2014, the Aggrieved Party was notified that her claim for Medicare coverage of the CGM transmitter (A9277GX[2]) and the disposable sensors (A9276GX) were denied as convenience items. The decision cited LCD L11530. A. Ex. 29 at 1-2. However, the determination that a continuous glucose monitoring system, parts for which are subject to codes A9276, A9277,

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[2] 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 accurately describe 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 as "Transmitter: External, For Use With Interstitial Continuous Glucose Monitoring System. A9276 is listed in LCD L11530 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.

and A9278[3] is not covered by Medicare is actually set forth in LCA A33614, the "Glucose Monitors – Policy Article – Effective January 2014," which is incorporated by reference in LCD L11530.[4] CMS Ex. 4 at 9; A Ex. 1 at 15. LCA A33614 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 [durable medical equipment] benefit." CMS Ex. 1 at 21; A. Ex. 1 at 17. NHIC argues before me that CGM systems are not DME and not covered by Medicare because they are considered precautionary. 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 they 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. Ex. 2.

NHIC argues that coverage for the 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 Response at 2. NHIC argues that LCA A33614 (CMS Ex. 1 at 20-26), 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.

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[3] 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.

[4] NHIC submitted as evidence prior versions of LCD L11530 and LCA A33614 that were effective January 2007. CMS Ex. 4 at 1-12. There appears to be no substantive difference between the 2007 version submitted by NHIC and the 2014 revision submitted by the Aggrieved Party.

426. NHIC Response at 2-3. For reasons discussed hereafter, I conclude that LCA A33614 contains a provision that amounts to a constructive LCD that is subject to my review. Because the Aggrieved Party was denied coverage based upon the constructive LCD she meets the requirements to be an aggrieved party.

On August 17, 2015, the Aggrieved Party notified me as required by 42 C.F.R. § 426.310(b), that an ALJ with the Office of Medicare Hearings and Appeals (OMHA) approved Medicare coverage of CGM supplies for her related to her previously disapproved claims. The decision of the OMHA ALJ related to the Aggrieved Party's prior claims for coverage has no impact upon this LCD review. 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 Aggrieved Party in this case entitled to benefits and has need of the item subject to the constructive LCD. Her status as an aggrieved party is unchanged by the fact that an OMHA ALJ has granted coverage on a past claim.

3. LCD L11530, "Glucose Monitors," and LCA A33614, "Glucose Monitors – Policy Article."

The Aggrieved Party submitted A. Ex. 1 that includes a copy of LCD L11530, issued by NHIC, with an original effective date of October 1, 1993, and a revision effective date of January 1, 2014. A. Ex. 1 at 1-15; CMS Ex. 1 at 1-19. The Aggrieved Party also submitted 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. 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 and that they remain in effect. 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. A. Ex. 29 at 2.

The Aggrieved Party does not challenge a specific provision of LCD L11530. Complaint at 3-4. Instead, the Aggrieved Party challenges as a constructive LCD, the provision of Policy Article A33614, 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.

NHIC argues before me that CMS has determined that CGM and related accessories and supplies are not covered by Medicare because CMS has determined that CGM is not DME. The gist of NHIC's position is that LCA A33614 merely reflects a CMS determination that CGM is not DME and not covered by Medicare. 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 Response at 2-3. NHIC is in error because the evidence does not show that CMS has determined that all CGM and related accessories and supplies are not DME or not covered as DME under Medicare. NHIC is also in error because LCA A33614 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.

4. The Challenged Provisions of LCD L11530 and LCA A33614 Are Subject to Review and Do Not Meet the Reasonableness Standard.

First it is necessary to examine the allegation of NHIC that CMS has determined that CGM and related accessories and supplies are not DME. After explaining why that allegation is in error, I turn to the issue of whether the constructive LCD meets the reasonableness standard.

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

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. Ex. 29 at 2. LCD L11530 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. LCD L11530 does not specifically state that CGM and related accessories and supplies are not reasonable and necessary. LCD L11530 lists CPT/HCPCS Codes A9276, A9277, and A9278 for CGM accessories and supplies. LCD L11530 lists LCA A33614 as the only "Related Local Coverage Document." CMS Ex. 1 at 19. LCA A33614 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. CMS Ex. 1 at 20-21. However, LCA A33614 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. LCA A33614 does not state that CGM is not reasonable and necessary.

NHIC's position is that LCD L11530 and LCA A33614 contain no contractor determination that CGM and related accessories and supplies are not reasonable and

necessary. NHIC argues that CMS has determined that CGM is not DME and CGM is not covered for that reason. NHIC argues that no reasonable and necessary determination is required by section 1862(a)(1)(A) of the Act because CGM is not DME. NHIC argues that no LCD, actual or constructive, exists declaring on a contractor-wide basis that CGM is not reasonable and necessary as no LCD is required to declare that CGM is not covered. NHIC Response at 2-3.

NHIC cites two documents as evidence that CMS has determined that CGM is not DME and not covered by Medicare. CMS Ex. 2 is a 2002 memorandum from the CMS Director of the Center for Medicare Management to the Office of Financial Management, in which it is concluded that the "Glucowatch" is not DME. NHIC asserts that the Glucowatch is "one of the earliest FDA approved devices for continuous glucose monitoring (every 20 minutes up to 12 hours at a time)." NHIC Response at 2. 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 also 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®). NHIC Response at 2-3; CMS Ex. 5. 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 of the letter 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.

The NHIC 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. National Coverage Determination (NCD) 40.2 "Home Blood Glucose Monitors"[5] provides that home blood glucose monitors are coved by Medicare as DME, if they meet the reasonable and necessary requirements.[6] I have received no evidence that shows that CMS has determined that CGM devices and related accessories and supplies 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 the individual determinations from 2002 and 2013 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;

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[5] NCDs are available at www.cms.gov/medicare-coverage-database/.

[6] 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.

> (3) Generally is not useful to an individual in the absence of an illness or injury; and
>
> (4) Is appropriate for use in the home.

42 C.F.R. § 414.202.

CMS provides specific policy guidance to Medicare contractors through it publications. The MBPM, chapter 15, § 110.1 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. CMS provides further guidance to its contractors regarding durability, which is not an issue in this case, and how to identify whether an item is medical equipment. 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.

CMS Pub. 100-02, MBPM, chap. 15, §110.1B.2 (emphasis added). The policy guidance stated 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 whether an item of equipment is DME. Indeed, any home blood glucose monitor could be considered precautionary to the extent it alerts the user to a blood sugar level that may require medical intervention with another device. 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 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.

Based upon the evidence presented to me, a CGM and related accessories and supplies otherwise appears to meet the statutory definition of DME as interpreted by the Secretary: (1) it appears to be capable of withstanding repeated use; (2) it appears to have primarily and customarily a medical use for "brittle" diabetics in need of frequent blood glucose monitoring, which consists of monitoring a diabetic's blood glucose level for the purpose of detecting a sustainable blood glucose level and providing a warning if that level reaches a dangerously-low level that the beneficiary may be incapable of detecting without a continuous glucose monitor; (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. Exs. 5-23. The fact that a CGM facially meets the four criteria to be DME supports my conclusion that the determination not to cover CGM and related accessories and supplies under HCPCS Codes A9276, A9277, and A9278, could only 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.

Accordingly, I conclude it is necessary to consider whether or not the implicit determination reflected by LCD L11530 and LCA A33614 that CGM and related

accessories and supplies are not reasonable and necessary must be tested under the reasonableness standard as a constructive LCD.

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

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 the area of responsibility for that contractor, 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. CMS Pub. 100-08, Medicare Program Integrity Manual (MPIM), 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 such a monitor was "reasonable and necessary" under section 1862(a)(1)(A) of the Act. NHIC effectively 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 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 and there is no evidence that NHIC ever determined that CGM and related accessories and supplies are 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 a CGM is never reasonable and necessary irrespective of the beneficiary's condition. CMS Ex. 1. Therefore, there are no findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS that are required to be given deference or that may be found reasonable. Accordingly, the record is insufficient to support the constructive LCD established by LCD L11530 and LCA A33614 under the reasonableness standard.

II. Order for Case Development

I have concluded and ruled based upon the review required by 42 C.F.R. § 426.425(c), that the record for the challenged LCD is not complete and adequate to support the validity of the LCD. I am thus required to permit discovery and the taking of evidence in accordance with 42 C.F.R. §§ 426.432 and 426.440 and then evaluate the LCD in accordance with 42 C.F.R. § 426.431. 42 C.F.R. § 426.425(c)(3). If the contractor does not retire or revise, within the meaning of 42 C.F.R. § 426.420, the LCD subject to review the case will be developed on the following schedule.

A. Discovery: Discovery is ordered in accordance with 42 C.F.R. § 426.432. The period for discovery begins **October 1, 2015**. All requests for discovery must be submitted to the party opponent no later **November 2, 2015**. All responses to discover requests must be served not later than **December 1, 2015.** Discovery requests and responses will not be filed with my office unless there is a dispute, in which case disputed requests or responses will be submitted with an appropriate motion for relief.

B. Exchanges of Exhibit Lists, Documentary Evidence, Witness Lists, and Summaries of Expected Expert Testimony: Not later **January 15, 2016**, each party must file its prehearing exchange. The prehearing exchange will include the following:

- Proposed exhibits, marked and identified in accordance with the requirements set forth in this Order. Exhibits considered in my Ruling on Phase I review above must be reoffered at hearing if the party desires that they be considered in the decision on the merits.

- A list of proposed exhibits reflecting exhibit numbers and a description of the exhibit.

- A list of any witnesses that a party proposes to call at an oral hearing if oral hearing is not waived or summary judgment is not appropriate. The list of witnesses must include the witnesses' last known address, an indication of how the witness has relevant knowledge, and a short summary of the witness' testimony.

- Any subpoena requests. 42 C.F.R. § 426.435.

- Copies of affidavits, declarations, or certified transcripts of prior testimony that are offered for my consideration in lieu of oral testimony, with the declarant's last known address. Declarations submitted in support of a motion must be executed in accordance with 28 U.S.C. §1746, affidavits must be signed and sworn before a notary, and transcripts must include the court-reporter or transcriptionist's certification.

- Copies of all prior statements that in anyway relate to this case or the underlying facts, that were written, dictated, recorded, or otherwise made or caused to be made by those persons (including experts) who the party intends to use either by introducing their testimony at hearing or by submitting their affidavit, declaration, report, or other writings as evidence. The term "prior" refers to the entire period preceding the time the person testifies at hearing in this case or executes the affidavit, declaration, report, or other writing to be offered by the party as evidence in this case.

- Summaries of expert witness qualifications and opinions with the expert's name and address.

- A brief addressing all issues of law and fact. If a party deems appropriate, the party should request and discuss summary judgment in this brief. If summary judgment is denied, this brief will be treated as the party's prehearing brief or brief on the merits if oral hearing is

waived. If the parties agree to waive oral hearing and receive a decision based upon the documentary evidence and briefs, they should so advise in their respective briefs. The parties will state at the end of their respective briefs, the dates on which they will be unavailable for a five-day hearing during the 180-day period following filing the brief.

C. Filing Requirements for Documents: Parties must file all documents electronically through the DAB E-File system, accessible at https://dab.efile.hhs.gov. Service of documents on all parties will be effectuated through DAB E-File. A document is "filed" on the date is submitted into the electronic record.

D. Preparation of Proposed Exhibits: Each proposed exhibit must be:

1. Identified with the docket number of the case.

2. Marked with an abbreviated designation for the party offering the proposed exhibit ("AP" for Aggrieved Party, "CMS" for CMS) followed by the abbreviation "Ex." for "exhibit."

3. Designated with a separate, unique, and whole identifying number (i.e., "1").

All identifying markings must be placed on the proposed exhibit itself and not on a tab separator or a divider. The identifying markings must not obscure any relevant part of the proposed exhibit.

Each page of each proposed exhibit must be numbered so that the page can be located easily when the document is being discussed in a brief, during cross-examination, or in the decision. An example of how these designations should look for the Aggrieved Party is:

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The Medicare contractor will use "CMS Ex." when marking its exhibits. I will not consider any proposed exhibit that has not been prepared in the above described-manner. I will not grant automatic extensions of time to parties to correct errors in their prehearing exchanges. I may impose sanctions, including refusing to receive an exhibit or exhibits into evidence, against any party that does not exchange exhibits that conform to the requirements of this Order.

E. Prehearing Conferences: Prehearing conferences will generally be conducted by telephone at the request of the parties or on my own motion. Prehearing conferences will generally be limited to the discussion of procedural matters, will not be recorded, and no transcript will be made, but will be memorialized by a subsequent order or on the record at hearing.

F. Hearing: If, after review of the parties' briefs, I conclude that summary judgment or a waiver of oral hearing is not acceptable because consideration of testimony is necessary, then I will advise the parties by issuing a notice of hearing. I may direct that an oral hearing be by telephone, video-teleconference, or similar means within my authority to regulate these proceedings. The parties will be permitted an oral closing statement at the conclusion of the hearing. No post-hearing brief will be submitted unless I direct at the close of hearing.

Attorney Advisor W. Adam Malizio has been assigned to assist me and may be reached by telephone at (202) 565-0197, or by e-mail at adam.malizio@hhs.gov. *Ex parte* communication with me is prohibited, but procedural matters may be raised with Mr. Malizio.

This is an interlocutory order and not subject to immediate appeal. If CMS files a written waiver of further record development, I will reissue the Ruling set forth above as my Decision in order to permit immediate appeal.

IT IS SO ORDERED.

Keith W. Sickendick

Keith W. Sickendick
Administrative Law Judge

***Service of this Ruling is by DAB E-File*:**

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