Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD COMPLAINT: Glucose Monitors (L11530)

Contractor: NHIC, Corp.

Docket No. C-14-1196

Decision No. CR3424

Date: October 20, 2014

DECISION DISMISSING LCD COMPLAINT

A Medicare beneficiary (Aggrieved Party)¹ filed a complaint challenging a Local Coverage Determination (LCD), titled "Glucose Monitors," issued by the Medicare contractor NHIC, Corp. After providing an opportunity to amend, I must dismiss the Aggrieved Party's complaint as unacceptable because the challenge still does not meet the regulatory requirements.

Background

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program and contracts with carriers and intermediaries (Medicare contractors) to act on its behalf in determining and making payments to providers and suppliers of Medicare items and services. Social Security Act (Act) §§ 1816, 1842. Medicare contractors issue written determinations, called LCDs, addressing whether, on a contractor-wide basis, a particular item or service is covered through Medicare. Act § 1869(f)(2)(B); *see also* 42 C.F.R. § 400.202.

A Medicare beneficiary who has been denied coverage for an item or service based on a LCD may challenge that LCD before an administrative law judge (ALJ). The Medicare beneficiary initiates the review by filing a written complaint that meets the criteria

¹ The names of Medicare beneficiaries are not listed in published decisions to protect their privacy. 68 Fed. Reg. 63,691, 63,708 (Nov. 7, 2003).

specified in the governing regulations. 42 C.F.R. §§ 426.400; 426.410(b)(2). After the LCD complaint is docketed, the ALJ evaluates whether the complaint is "acceptable." 42 C.F.R. § 426.410(b). An ALJ does not have authority to review the merits of an "unacceptable complaint." *See* 42 C.F.R. §§ 426.405(d)(7); 426.410(c)(2). If the complaint is determined to be unacceptable, the ALJ must provide the beneficiary an opportunity to amend the compliant. 42 C.F.R. § 426.410(c)(1). If the ALJ also determines that the amended complaint is unacceptable, the ALJ must issue a decision dismissing the LCD complaint. 42 C.F.R. § 426.410(c)(2). If a complaint is determined unacceptable after one amendment, the beneficiary is precluded from filing again for six months after being informed that the complaint is unacceptable. 42 C.F.R. § 426.410(c)(3).

On May 15, 2014, the Aggrieved Party filed a letter in which she requested to ". . . illicit help and support and to supply pertinent, crucial information to obtain approval for coverage of my diabetic medical equipment Dexcom Continuous Glucose Monitor system . . . that includes sensors which must be replaced weekly." The letter was construed to be a complaint challenging LCD L11530, titled "Glucose Monitors," which applies in the Aggrieved Party's state of residence. The case was assigned to me on June 2, 2014.

I evaluated the complaint as required by 42 C.F.R. § 426.410(b), (c) and (d) and found that it was unacceptable. I advised the Aggrieved Party, through an order dated June 13, 2014, why her complaint was unacceptable, and I granted her an opportunity to amend it. I also advised the Aggrieved Party that if she did not submit an amended, acceptable complaint, I was required to issue a decision dismissing the complaint as unacceptable. *See* 42 C.F.R. § 426.410(c). On July 14, 2014, the Aggrieved Party filed her amended complaint.

Discussion

I find the Aggrieved Party's amended complaint is unacceptable, and I must dismiss it because the amended complaint does not meet all of the regulatory requirements for an acceptable challenge to the LCD.

In her amended complaint, the Aggrieved Party discussed her personal need for a continuous glucose monitoring system and, in support of her challenge, provided the following documents: two physician prescriptions, one for a DexCom Continuous Glucose Monitoring System and a second for sensors; an invoice from DexCom, Inc. showing she purchased the glucose monitor system and sensors on June 6, 2014; a copy of her personal daily blood glucose log for the week of July 1, 2014; a copy of a blood glucose trend graph showing her personal glucose values for the period May 28, 2014 through June 3, 2014, along with a data sheet showing her blood glucose readings for the

same time period; and a copy of page 15 from the DexCom G4 PLATINUM User's Guide, which shows pictures of the various components of the monitoring system.

Upon reviewing the Aggrieved Party's July 14, 2014 amended complaint, I find that it still does not comply with all of the regulatory requirements needed for an acceptable LCD challenge. The Aggrieved Party did not identify in her amended complaint the specific provision of an LCD that adversely affected her as required by 42 C.F.R. § 426.400(c)(4)(iii). The Aggrieved Party also did not explain why the provision(s) of the LCD are not valid under the reasonableness standard as required by 42 C.F.R. § 426.400(c)(5). Additionally, the Aggrieved Party did not provide copies of clinical or scientific evidence that support her complaint as well as an explanation as to why she thinks the evidence shows that the LCD is not reasonable as required by 42 C.F.R. § 426.400(c)(6)(i).

It is evident that the Aggrieved Party and her treating physician agree that the Aggrieved Party needs the glucose monitoring system to treat her medical conditions; however, that is not enough to support an acceptable challenge to the LCD. Accordingly, I must dismiss the Aggrieved Party's complaint as unacceptable pursuant to 42 C.F.R. § 426.410(c)(2).

_____/s/ Joseph Grow

Administrative Law Judge