Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD Complaint:	)	
	)	Date: July 24, 2007
End-Diastolic Pneumatic Compression Therapy (Circulator Boot), LCD Policy # L99199 (Draft).	)	Docket No. C-07-310
	)	Decision No. CR1628
Contractor: First Coast Service Options, Inc.	)	

DECISION

The complaint is dismissed pursuant to 42 C.F.R. § 426.444(b)(3) because Complainant is not an aggrieved party within the meaning of 42 C.F.R. §§ 426.110 and 426.320.

An appeal of this decision, as provided for by 42 C.F.R. § 426.465(a), must be filed within 30 days of the date of this decision (42 C.F.R. § 426.465(e)) and satisfy the other requirements of 42 C.F.R. § 426.465(f). Absent a showing of good cause, failure to timely appeal waives the right to challenge any part of this decision and it becomes final and not subject to further review. 42 C.F.R. § 426.468.

Pursuant to 42 C.F.R. § 426.410(c)(3), Complainant is precluded from filing again regarding the same subject for six months from the date of this decision.

I. Background

Complainant submitted an undated request for administrative law judge (ALJ) review of a local coverage determination (LCD) that was assigned to me on March 21, 2007. I advised Complainant by letter dated April 4, 2007, that his complaint was not acceptable because it appeared to challenge a draft LCD and because it did not appear that he was an aggrieved party. I advised Complainant that he had one opportunity to file an amended complaint that met the requirements of 42 C.F.R. § 426.400, and if he did not, I would be compelled to dismiss the complaint. On May 7, 2007, I received Complainant's response.

II. Discussion

A LCD, as defined by the Social Security Act (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. Act, section 1869(f)(2)(B) (42 U.S.C. §1395ff(f)(2)(B)).

The Secretary promulgated regulations pursuant to sections 1102 and 1871 of the Act (42 U.S.C. §§ 1302 and 1395hh), implementing sections 1869(f)(1) and (f)(2) of the Act. 42 C.F.R. § 426.100. The regulations are found at 42 C.F.R. Part 426. An aggrieved party is a Medicare beneficiary or the estate of a beneficiary who is (1) entitled to benefits under Part A or B of Medicare; (2) is in need of coverage for a service that was denied based on an LCD whether or not the service was actually received; and (3) has documentation from a treating physician that shows the services are required. 42 C.F.R. § 426.110. Only an aggrieved party may initiate review of an LCD by filing an acceptable complaint. 42 C.F.R. § 426.320(a). If an acceptable complaint is filed, the procedures for review of an LCD are in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et. seq.*). The Act and regulations provide for a two-level review process by the ALJ.

Before any review of an LCD may be undertaken by an ALJ, the ALJ must determine as a threshold matter whether the complaint is adequate. 42 C.F.R. §§ 426.400; 426.410. If the ALJ finds the compliant is not adequate, a Complainant is permitted one opportunity to correct the complaint. 42 C.F.R. § 426.410(c).

In this case, Complainant indicates that he wants to challenge the failure of the contractor, First Coast Service Options, Inc., and the Centers for Medicare and Medicaid Services (CMS) to implement a draft LCD Number 99199, End-Diastolic Pneumatic Compression Therapy (Circulator Boot). This draft LCD would have been applicable in the State of Florida where Complainant resides. The draft would have permitted Medicare coverage for the use of a circulator boot for chronic venous insufficiency (CVI) with venous stasis ulcer of the lower extremities; diabetic ulcer of the lower extremities; or arterial ischemic ulcers of the lower extremity in certain cases.[1]

---

[1] An LCD providing for such coverage is currently in effect for the State of Pennsylvania. LCD Number L10034, End-Diastolic Pneumatic Compression Therapy, Contractor: Highmark Medicare Services Pennsylvania Carrier, effective January 11, 2003, revised April 15, 2005.

According to the statement of his treating physician, Complainant suffered from diabetic foot ulcers for many years with an amputation in 2003. Complainant's physician indicted that another partial amputation was being considered but it was avoided by the use of circulator boot therapy. According to an October 12, 2006 decision of an ALJ with the Office of Medicare Hearings and Appeals[2] submitted with the complaint, a claim for coverage of 160 circulator boot system treatments was initially denied and then denied on reconsideration, leaving the provider of the services responsible for payment.

The ALJ decided that the 160 circulator boot treatments were covered services that should be paid by Medicare to the provider.[3] Petitioner does not state in either his original complaint or his amendment that he has received another initial denial based upon an LCD subsequent to the ALJ decision granting him benefits. Complainant must wait six months from the date of this decision to file an acceptable complaint to challenge an LCD that is cited as the basis for denying him coverage for circulator boot treatments.

The facts alleged by Complainant and reflected by the documents submitted in support of his complaint do not show that he is an aggrieved party within meaning of 42 C.F.R. § 426.110. Although Complainant was denied coverage initially and on reconsideration, the ALJ declared coverage was appropriate. Thus, Complainant does not currently meet

---

[2] Appeals of denial of coverage for services are heard and decided by ALJ's from the Department of Health and Human Services, Office of Medicare Hearings and Appeals. Benefits or coverage appeals are separate from LCD reviews. 42 C.F.R. § 426.310(a).

[3] The ALJ noted that there is a National Coverage Determination (NCD), Publication Number 100-3, Manual Section Number 280.6, that specifies that pneumatic devices are covered for treatment of lyphedema or for CVI with venous stasis ulcers if certain coverage criteria are met. The NCD does not specifically preclude coverage for treatment of other conditions such as diabetic ulcers. I note that in at least two regions there are LCDs that specifically limit the use of pneumatic compression devices to only lyphedema or CVI with venous stasis ulcers. LCD Number L11492, Pneumatic Compression Devices, DME PSC: Electronic Data Systems Corp. and DME MAC: Noridian Administrative Services; LCD Number L11503, Pneumatic Compression Devices, DME PSC: TriCenturion and DME MAC: National Government Services. According to the ALJ decision, Complainant's claim was initially denied based on LCD Number L5780, List of Medicare Non-covered Services, which the ALJ found inapplicable. The ALJ decided coverage was appropriate based on NCD Number 100-3 and LCD Number L5780, Pneumatic Compression Devices, First Coast Service Options, Inc.

the requirement that coverage for a service was denied based on an applicable LCD. I am required to dismiss a complaint if it is not filed by an aggrieved party. 42 C.F.R. § 426.444(b)(3). Furthermore, the draft LCD Number 99199, End-Diastolic Pneumatic Compression Therapy (Circulator Boot) is not subject to my review as only LCD's that are currently effective may be challenged. 42 C.F.R. § 426.325(a).

III. Conclusion

For the foregoing reasons, the complaint is dismissed as it is not acceptable.

/s/

Keith W. Sickendick
Administrative Law Judge