Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD Complaint:
Posterior Tibial Nerve Stimulation PTNS (L28457),

Docket No. C-11-610

Decision No. CR2656

Date: October 31, 2012

DECISION DISMISSING LCD COMPLAINT

In this case, an aggrieved Medicare beneficiary (Aggrieved Party) challenges Local Coverage Determination (LCD) L28457, issued by the Medicare Contractor, Wisconsin Physicians Service Insurance Corporation (Contractor). LCD 28457 precludes Medicare reimbursement for a procedure called Posterior Tibial Nerve Stimulation (PTNS), which is prescribed to treat urinary dysfunction.

For the reasons discussed below, I dismiss the Aggrieved Party's complaint as unacceptable.

Discussion

> ***The Aggrieved Party's complaint must be dismissed because it does not include a written statement from his treating physician declaring that he needs the service that is the subject of the LCD.***[1]

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program (Social Security Act (Act) §§ 1102, 1871, 1874) with the assistance of Medicare contractors, who act on its behalf in determining and making payments to providers and suppliers of Medicare items and services. Act §§ 1816, 1842. To this end, Medicare contractors issue written determinations, called LCDs, addressing whether, on a

[1] I make this one finding of fact/conclusion of law.

contractor-wide basis, a particular item or service is covered. Act § 1869(f)(2)(B); *see also* 42 C.F.R. § 400.202.

A Medicare beneficiary who, based on an LCD, has been denied coverage for an item or service may challenge that LCD before an administrative law judge (ALJ). He initiates the review by filing a written complaint that meets the criteria specified in the governing regulations. 42 C.F.R. §§ 426.400; 426.410(b)(2). I have no authority to review the merits of an unacceptable complaint. 42 C.F.R. §§ 426.405(d)(7); 426.410(c)(2).

To be acceptable, the complaint must include a written statement from the aggrieved party's *treating physician* declaring that the beneficiary needs the service that is the subject of the LCD. The statement may be in the form of a written order. 42 C.F.R. § 426.400(c)(3). The beneficiary's treating physician is defined as "the physician who is the beneficiary's *primary clinician* with responsibility for over-seeing the beneficiary's care and either approving or providing the service at issue in the challenge." 42 C.F.R. § 426.110 (emphasis added). Responding to comments, the drafters of the regulation explained that the "treating physician" must be the Medicare beneficiary's "primary caregiver," who is "responsible for the beneficiary's overall care" because that physician – as opposed to "any treating practitioner" – is "best situated to determine 'in need' status." 68 Fed. Reg. 63,692, 63,696 (Nov. 7, 2003) (Final Rule).

Although I initially determined that the complaint filed in this case was acceptable, after careful review, I realized that the complaint was not acceptable because it did not include a statement from the Aggrieved Party's treating physician. The complaint included a treatment order signed by a physician, Willard P. DeBraber, D.O., but the Aggrieved Party did not establish that Dr. DeBraber was his treating physician. 42 C.F.R. § 426.400(c)(3). Pursuant to 42 C.F.R. § 426.410(c)(1), in an order dated September 17, 2012, I granted the Aggrieved Party thirty days in which to amend his unacceptable complaint. Order (Sept. 17, 2012). In a submission dated October 15, 2012, the Aggrieved Party submitted a second affidavit from Dr. DeBraber. P. Ex. 2.1.

To meet the requirement for a treating physician written statement, the Aggrieved Party has now submitted two affidavits from Dr. DeBraber and one from a general nurse practitioner, Leslie Wooldridge. P. Ex. 2. The Aggrieved Party has not established that either of these individuals qualifies as his "primary clinician."

First, Nurse Wooldridge cannot qualify as the Aggrieved Party's treating physician because she is not a physician. The drafters of the regulation explicitly rejected suggestions that non-physician practitioners be allowed to document the beneficiary's need. 68 Fed. Reg. at 63,696, *supra*. Moreover, even if a nurse practitioner could provide the written statement, Nurse Wooldridge does not claim to be the Aggrieved Party's primary clinician and claims no responsibility for overseeing his care. She is a

clinician who merely reviewed his medical records and examined him once. P. Ex. 2 (Wooldridge Aff. ¶ 18).

Nor has the Aggrieved Party established that Dr. DeBraber qualifies as his treating physician, because he has not shown that Dr. DeBraber is his primary clinician responsible for his overall care. As I pointed out in my September 17 order, in his initial affidavit, dated June 16, 2011, Dr. DeBraber did not claim that he even examined the Aggrieved Party; he simply reviewed medical records and signed a treatment order. P. Ex. 2 at 2, (DeBraber Aff. ¶ ¶ 15, 20) ("I have reviewed the medical records for [the Aggrieved Party] and believe PTNS was and is reasonable and medically necessary for [the Aggrieved Party]."); P. Ex. 5. Thus, Dr. DeBraber's first affidavit establishes that he is a strong proponent of PTNS, but he has virtually no treating relationship with the Aggrieved Party; he based his opinions on his review of medical records. P. Ex. 2 at 2 (DeBraber Aff. ¶ 15).

In his second affidavit, Dr. DeBraber adds some ambiguous language about "coordinating," "collaborating," and "overseeing" the Aggrieved Party's incontinence care and says that he has "supervised . . . several treatments" that were provided by others. P. Ex. 2.1 at 2, 3 (DeBraber Aff. ¶ ¶ 21, 22, 23). Again, he does not claim to be the Aggrieved Party's primary clinician. In fact, he examined the Aggrieved Party, for the first and only time, on October 4, 2012, about three weeks after I gave the Aggrieved Party time to amend his complaint. *Id*. at 3 (DeBraber Aff. ¶ 25).

Thus, on February 17, 2011, Dr. DeBraber wrote an order for a patient he had never examined. More than a year and a half later – apparently in response to my suggestion that he does not meet the regulatory definition for "treating physician" – he finally examined the Aggrieved Party. His relationship to the Aggrieved Party is far too peripheral to meet the regulatory requirements.[2] His affidavits establish that he is not the Aggrieved Party's primary caregiver, responsible for the beneficiary's overall care.

---

[2] It is noteworthy that Congress twice considered, but explicitly rejected, a broader standing provision that would have enabled other interested parties, including suppliers and providers, to file complaints about LCDs. *See* H.R. Rep. No. 108-391 (2003), *reprinted in* 2003 U.S.C.C.A.N. 1808, 2003 WL 26075426; H.R. 2356, 106th Cong. (1999). The effect of Congress's narrowing of the language in the final bill was to prohibit persons and entities that directly profit from expanded Medicare coverage to challenge LCDs. Thus, to permit Dr. DeBraber to qualify as the Aggrieved Party's treating physician, where the relationship between Dr. DeBraber and the supplier is not explained, would be inconsistent with the history to narrow the scope of individuals who have a legal right to initiate a challenge to an LCD.

I therefore dismiss the Aggrieved Party's complaint pursuant to 42 C.F.R. § 426.410(c)(2).

/s/
Carolyn Cozad Hughes
Administrative Law Judge