Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

In re CMS LCD Complaint:
Posterior Tibial Nerve Stimulation PTNS (L28457)
Docket No. A-13-18
Decision No. 2503
March 22, 2013

REMAND OF ADMINISTRATIVE LAW JUDGE DECISION

We reverse the October 31, 2012 decision of an Administrative Law Judge (ALJ) dismissing the Local Coverage Determination (LCD) complaint filed by the beneficiary. *In re CMS LCD Complaint: Posterior Tibial Nerve Stimulation PTNS (L28457)*, DAB CR2656 (2012) (ALJ Decision). The ALJ dismissed the complaint based on her determination that the physician from whom the beneficiary submitted a written statement of medical necessity does not qualify as a "treating physician" under the LCD challenge regulations. As explained below, we conclude that the physician does qualify as the beneficiary's treating physician. Accordingly, we remand the case to the ALJ for further proceedings.

Legal Background

An LCD is defined as a Medicare contractor's determination whether to cover a particular Medicare item or service on a contractor-wide basis "in accordance with section 1862(a)(1)(A)" of the Social Security Act (Act).[1] Act § 1869(f)(2)(B); 42 C.F.R. § 400.202. With certain exceptions not relevant here, section 1862(a)(1)(A) of the Act bars Medicare payment for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." That provision is referred to as the "medical necessity" standard. *See, e.g., In re CMS LCD Complaint: Wheelchair Options/Accessories (L11462)*, DAB No. 2389, at 1 (2011). An LCD is issued by a Medicare contractor in a particular region and applies the medical necessity standard for that region but is not binding beyond the issuing contractor. *Id.*

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

Section 1869(f)(2) of the Act and the regulations at 42 C.F.R. Part 426 permit Medicare beneficiaries denied coverage for items or services on the basis of an LCD to challenge the validity of the LCD by filing an "LCD complaint" before an ALJ. 42 C.F.R. §§ 426.110, 426.320, 426.400; *see generally* 42 C.F.R. Part 426, subparts C, D. After an LCD complaint is docketed, the ALJ evaluates whether the complaint is "acceptable." *Id.* § 426.410(b). In order to be acceptable, an LCD complaint must include, among other things, a "copy of a written statement from the treating physician that the beneficiary needs the service that is the subject of the LCD." *Id.* §§ 426.400(c)(3), 426.410(b)(2). The statement "may be in the form of a written order for the service or other documentation from the beneficiary's medical record (such as progress notes or discharge summary) indicating that the beneficiary needs the service." *Id.* § 426.400(c)(3). The regulations define "treating physician" as "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge." *Id.* § 426.110.

If the ALJ determines that the complaint is unacceptable, the ALJ must provide the beneficiary an opportunity to amend the complaint. 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 that complaint. *Id.* § 426.410(c)(2). The beneficiary may then appeal the dismissal to the Board. *Id.* § 426.465(a)(2). The standard of review that the Board applies is "whether the ALJ decision contains any material error." *Id.* § 426.476(b)(1).

Case Background

On July 15, 2011, the beneficiary filed an LCD complaint challenging an LCD that denies Medicare coverage for a urinary dysfunction treatment called posterior tibial nerve stimulation (PTNS). The beneficiary included with his complaint a treatment order for PTNS signed by a physician and a nurse practitioner, and written statements from both practitioners attesting to his need for the treatment. P. Exs. 2, 5. The ALJ initially found the complaint acceptable under the regulations and issued an order setting further procedures. However, over a year later, on September 17, 2012, the ALJ *sua sponte* issued an order finding the complaint unacceptable. Order at 1. The ALJ concluded that the beneficiary had not established that either the physician or the nurse practitioner qualified as his "treating physician." *Id.* at 2. Accordingly, the ALJ determined that the complaint did not include a written statement from a treating physician, as required under section 426.400(c)(3). *Id.* at 1-2. The ALJ gave the beneficiary 30 days to amend his complaint. *Id.* at 2.

The beneficiary submitted an amended written statement from the same physician, in which he described his professional background as an osteopath specializing in urologic surgery and discussed PTNS in general. P. Ex. 2.1 at 1-2. The urologist also detailed his role as the beneficiary's "coordinating urologist," including his prescription of PTNS treatments for the beneficiary and supervision of several of those treatments. *Id.* at 2-3. The urologist explained that he had "been collaborating with" the nurse practitioner on providing incontinence treatments to the beneficiary, was "responsible for overseeing" the beneficiary's incontinence care and "approving" his treatment, and had reviewed the beneficiary's medical records in addition to "personally examining" the beneficiary. *Id.* at 2. The urologist then stated that he had examined the beneficiary on October 4, 2012 and "affirm[ed] that [he] still believe[s] PTNS was and is reasonable and medically necessary" for the beneficiary. *Id.* at 3.

The ALJ dismissed the amended complaint, concluding that it did not include a written statement from the beneficiary's treating physician. ALJ Decision at 1. The ALJ determined that the nurse practitioner could not be the beneficiary's treating physician because she is not a physician and in any event she did not claim to be the beneficiary's "primary clinician" or to have "responsibility for overseeing his care." *Id.* at 2. The ALJ further determined that the urologist does not qualify as the beneficiary's treating physician because his "relationship to the [beneficiary] is far too peripheral to meet the regulatory requirements." *Id.* at 3. The ALJ reasoned that the urologist "has virtually no treating relationship with the beneficiary" and examined the beneficiary only once, after the ALJ gave the beneficiary time to amend his complaint. *Id.* The ALJ noted that Congress twice considered, but rejected, allowing suppliers and providers to challenge LCDs. *Id.* at 3 n.2, citing 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). According to the ALJ, Congress's decision "prohibit[ed] persons and entities that directly profit from expanded Medicare coverage to challenge LCDs," so permitting the urologist to qualify as the beneficiary's treating physician, "where the relationship between [the urologist] and the supplier is not explained, would be inconsistent with" the legislative history. *Id.*

The beneficiary timely appealed the ALJ Decision to the Board. On appeal, the beneficiary challenges the ALJ's determination that the urologist does not qualify as his treating physician.[2] The beneficiary contends that the ALJ "failed to follow the plain language of 42 C.F.R. § 426.110," in that "[n]othing in the regulation requires the treating physician to personally examine the [beneficiary] to qualify as a treating physician for purposes of a challenge to an LCD." Bene. Br. at 4. The beneficiary also argues that the ALJ "ignored" evidence that the urologist "was involved in the approval and supervision of" his incontinence care. *Id.* at 5. According to the beneficiary, this

[2] The beneficiary does not dispute that the nurse practitioner does not qualify as a treating physician.

evidence is sufficient to establish the urologist as his treating physician under section 426.110. *Id.* at 5-6. The beneficiary further argues that, to the extent the ALJ's dismissal was based on the fact that the urologist is not the beneficiary's primary care physician, the dismissal is erroneous because the regulations impose no such requirement. *Id.* at 6.

Although the Board notified the Centers for Medicare & Medicaid Services (CMS) and the contractor of the appeal and gave both entities an opportunity to file a response, neither CMS nor the contractor chose to respond.[3]

Analysis

As we explain below, we conclude that the ALJ erred to the extent that she determined the urologist could not be a treating physician because he is a specialist instead of a primary care physician. We also conclude that the ALJ placed undue weight on whether the urologist personally examined the beneficiary. In addition, we find that evidence in the record establishes that there was an ongoing treating relationship between the beneficiary and the urologist. In view of that evidence, we conclude that the ALJ should have recognized the urologist as the beneficiary's treating physician and accepted the amended complaint.

1. *Section 426.110 does not limit the types of physicians that may qualify as treating physicians.*

The ALJ dismissed the amended complaint because she concluded that the urologist's written statements "establish that he is not the [beneficiary's] primary caregiver, responsible for the beneficiary's overall care." ALJ Decision at 3. To the extent that the ALJ based her conclusion on the fact that the urologist is a specialist rather than a primary care physician, the ALJ interpreted the definition of "treating physician" too narrowly. The Board recently held, on review of decisions by a different ALJ, that section 426.110 "does not restrict the types of physicians that may qualify as treating physicians." *In re CMS LCD Complaint: LCD 29288*, DAB No. 2499, at 7 (2013); *see also In re CMS LCD Complaint: Noncovered Services (LCD 29288)*, DAB No. 2500 (2013); *In re CMS LCD Complaint: Category III CPT Codes (L25275)*, DAB No. 2502 (2013).

The ALJ found support for her analysis in the preamble to the final rule adding Part 426 to 42 C.F.R., but her reliance on the preamble is misplaced. The ALJ stated that, in response to public 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

[3] The contractor filed a copy of the LCD at issue, but did not otherwise respond to the appeal.

practitioner' – is 'best situated to determine "in need" status.'" ALJ Decision at 2, citing 68 Fed. Reg. 63,692, 63,696 (Nov. 7, 2003). As the Board noted in *LCD 29288*, this section of the preamble "responded to the suggestion that non-physician practitioners, as opposed to solely physicians, should be able to document a beneficiary's need for the service at issue in an LCD challenge." DAB No. 2499, at 4, citing 68 Fed. Reg. at 63,696. The drafters rejected the suggestion, explaining that, "we continue to believe that the beneficiary's treating physician – not any treating practitioner – is best suited to determine 'in need' status, both because he or she is the primary caregiver and also is responsible for the beneficiary's overall care." *Id.* Thus, the Board explained, "the regulation did not limit the type of physician that could be a 'treating physician,' but instead made clear that only physicians, and not other practitioners, could qualify." *Id.*

The Board also noted in *LCD 29288* that although the preamble to the final rule "referred to the beneficiary's 'overall care,' the regulatory text simply requires that the physician have responsibility for 'overseeing the beneficiary's care' and the modifier 'overall' does not appear in the text." DAB No. 2499, at 5, citing 42 C.F.R. § 426.110. Moreover, the text uses the term "primary clinician" instead of "primary care physician." "Had the intent been to exclude specialist physicians from certifying medical necessity, different wording could have easily accomplished that result." *Id.*

2. *The regulations do not require a treating physician to have personally examined a beneficiary.*

In determining that the urologist does not qualify as a "treating physician," the ALJ also emphasized that, as she read the urologist's written statements, the urologist examined the beneficiary only once. ALJ Decision at 3. The ALJ found that the urologist signed the treatment order included with the complaint without ever having examined the beneficiary and instead based his opinion on his review of the beneficiary's medical records. *Id.* The ALJ also found that the urologist examined the beneficiary "for the first and only time" approximately three weeks after the ALJ gave the beneficiary time to amend his complaint, "apparently in response" to the ALJ's suggestion that the urologist did "not meet the regulatory definition of 'treating physician.'" *Id.*[4]

The ALJ placed undue emphasis on whether the urologist personally examined the beneficiary. As an initial matter, it is not clear from the urologist's amended written statement that he examined the beneficiary only once, after the LCD complaint was filed.

[4] The beneficiary included with his brief on appeal several medical records that he did not submit to the ALJ. It appears that the beneficiary proffered the records to attempt to refute the ALJ's conclusion that the urologist examined him on October 4, 2013 only in response to the ALJ's suggestion that the urologist did not qualify as his treating physician. *See* ALJ Decision at 3; Bene. Br. at 1, 3. In view of our analysis below, we do not rely on this evidence in reaching our decision.

The urologist explained that, as part of his collaboration with the nurse practitioner on treating the beneficiary's incontinence, he reviewed the beneficiary's medical records "[i]n addition to personally examining" the beneficiary. P. Ex. 2.1, at 2. The urologist also stated that he "personally examined" the beneficiary on October 4, 2012, and that after the examination he "still believe[s] PTNS is reasonable and medically necessary" for the beneficiary. *Id.* at 3. The ALJ read the urologist's statements to mean that he examined the beneficiary only on October 4, 2012. However, another reasonable reading is that the urologist examined the beneficiary more than once, most recently on October 4, 2012, but also in the past as part of his collaboration with the nurse practitioner on the beneficiary's treatment.

In any event, although a physical examination might be part of the treatment process, nothing in section 426.110 specifically requires that a treating physician must have personally examined the beneficiary. As noted above, the regulation defines "treating physician" as "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge."

Moreover, we see no basis for inferring that a physician must personally examine the beneficiary in order to oversee the beneficiary's care and approve or provide the service at issue. As the Board explained in *LCD 29288*, "the treating physician certification requirement was implemented to serve a basic gate-keeping function, making sure that only beneficiaries 'in need' challenge LCDs . . . ." DAB No. 2499, at 6. The Part 426 regulations implemented section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which created a new administrative review process that allows certain beneficiaries to challenge LCDs. *Id.*, citing 67 Fed. Reg. 54,534, 54,536 (Aug. 22, 2002). Under BIPA, an LCD challenge 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." *Id.*, quoting 67 Fed. Reg. at 54,537; Act § 1869(f)(5). These individuals are referred to elsewhere in BIPA as "aggrieved parties." *Id.*, citing Act § 1869(f)(1)(A)(iii), (2)(A)(i), (2)(A)(ii). The preamble to the proposed rule adding Part 426 to the regulations makes clear that the drafters proposed requiring a beneficiary to "include a written statement from his or her treating physician with his or her LCD complaint to 'properly demonstrate that a beneficiary is "in need"' and thus to 'ensure that the individual is an aggrieved party.'" *Id.*, quoting 67 Fed. Reg. at 54,538, 54,540. Nothing in the preamble suggests that a physician must personally examine a beneficiary to determine that the beneficiary is in need of a particular item or service.

It is also significant that several Medicare regulations allow non-physician practitioners to provide medical services to beneficiaries, if those practitioners are working with a physician. For example, section 410.75 provides that a nurse practitioner's services are covered under Medicare Part B if, among other things, the nurse practitioner performs the

services "while working in collaboration with a physician." 42 C.F.R. § 410.75(c)(3). Similarly, section 410.74 provides that a physician assistant's services may be covered if the services are performed "under the general supervision of a physician." *Id.* § 410.74(a)(2)(iv). Neither section requires the physician to be present when the services are provided. *Id.* §§ 410.74(a)(2)(iv), 410.75(c)(3)(iii). These provisions reflect both the increasingly large role that non-physician practitioners play in diagnosing and treating patients and the continued role of physicians with respect to those practitioners' work. In requiring that a treating physician be responsible for "overseeing" a beneficiary's care and that the physician either approve or provide the service at issue, section 426.110 similarly recognizes that a physician need not provide direct care to a beneficiary in order to determine the beneficiary's need for a particular item or service. Thus, we conclude that it is inappropriate to read into section 426.110 a further requirement that a treating physician personally examine the beneficiary.

3. *Evidence in the record undermines the ALJ's conclusion that the urologist does not have a treating relationship with the beneficiary.*

The ALJ Decision reflects a valid concern that a physician who bases his opinion of the appropriate course of treatment solely on a beneficiary's medical records might not have a true treating relationship with the beneficiary. However, we conclude that is not the situation here. Instead, evidence in the record shows that the nature of the relationship between the urologist and the beneficiary was such that the urologist qualifies as a treating physician under section 426.110.

The urologist explained in his amended written statement that he "prescribed" PTNS treatments for the beneficiary, and he "personally supervised several" of the treatments when they were performed by medical staff. P. Ex. 2.1, at 3. In addition, the urologist stated that he is the beneficiary's "coordinating urologist," with responsibility for "overseeing" the beneficiary's incontinence care and "approving the PTNS treatment." *Id.* at 2. The ALJ dismissed these statements as "ambiguous language" (ALJ Decision at 3), but we see, and the ALJ identified, no reason not to fully credit them. The urologist's description of his role in treating the beneficiary aligns with the requirement in section 426.110 that a treating physician "oversee[] the beneficiary's care and either approv[e] or provid[e] the service at issue in the challenge."

The evidence that the urologist was "collaborating with" the nurse practitioner on treating the beneficiary is also probative of a treating relationship between the urologist and the beneficiary. P. Ex. 2.1, at 2. While we agree with the ALJ that the nurse practitioner cannot qualify as a treating physician in her own right, we see no bar to her providing information concerning the urologist's role in the beneficiary's care. The nurse practitioner explained in her written statement that she reviewed the beneficiary's medical records and examined him before "recommend[ing]" that he receive PTNS. P. Ex. 2, at 6. The urologist stated that he also reviewed the beneficiary's medical records

before ultimately "prescrib[ing]" PTNS. P. Ex. 2.1, at 3. Read together, these statements confirm that the urologist oversaw and coordinated the beneficiary's care, relying on staff like the nurse practitioner to conduct examinations and provide treatments, but accepting responsibility for the beneficiary's care by approving the nurse practitioner's recommendations and supervising the treatments. As discussed above, the definition of "treating physician" in section 426.110 – the "primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge" – allows for this sort of division of labor.

Additional evidence not discussed by the ALJ further corroborates the existence of an ongoing treating relationship between the urologist and the beneficiary. The ALJ stated that the beneficiary included with his complaint a treatment order dated February 17, 2011 signed by the urologist and the nurse practitioner, but the ALJ did not address the contents of the order. *See* ALJ Decision at 2-3. In addition to prescribing PTNS treatment for the beneficiary, the order notes that the beneficiary first visited the clinic where the urologist and the nurse practitioner are located in August 2008. P. Ex. 5. The order also enumerates medications that the beneficiary tried from August to October 2008 to relieve his incontinence symptoms and the reasons for discontinuing those medications. *Id.* The record establishes that the urologist has been a "collaborating physician" at the clinic since 2008. *See* P. Ex. 2, at 4. Thus, this evidence suggests that the urologist, or at least his clinic, may have had a treating relationship with the beneficiary as far back as 2008.

We also note that the urologist stated in his amended statement that the beneficiary's medical records document that the beneficiary experienced relief from his incontinence symptoms after receiving five PTNS treatments at the clinic. P. Ex. 2.1, at 3. The urologist also stated that he "personally supervised several" of the treatments. *Id.* The fact that the beneficiary received multiple treatments at the clinic where the urologist is a collaborating physician, under the urologist's supervision, further supports that the urologist had an ongoing treating relationship with the beneficiary.

Thus, evidence in the record establishes that the urologist had an ongoing treating relationship with the beneficiary. Contrary to what the ALJ Decision suggests, there is no basis for finding that the relationship between the urologist and the beneficiary existed solely to establish standing to challenge the LCD.

4. *The amended complaint is acceptable under the regulations.*

We conclude that the urologist's amended written statement confirms that he meets the definition of "treating physician" in section 426.110. As noted above, the urologist explained in the statement that he has been "the coordinating urologist for [the beneficiary] and [is] responsible for overseeing [the beneficiary's] incontinence care and approving the PTNS treatment." P. Ex. 2.1, at 2. The urologist also explained that he

prescribed PTNS treatments for the beneficiary after other treatments failed to relieve the beneficiary's symptoms and "personally supervised several" of the PTNS treatments. *Id.* at 3. These statements establish that the urologist is "the physician who is the beneficiary's primary clinician with responsibility for overseeing the beneficiary's care and either approving or providing the service at issue in the challenge."

We also conclude that the amended written statement fulfills the requirements of section 426.400(c)(3). In the statement the urologist stated that he "believed and believe[s] PTNS was and is medically necessary" for the beneficiary, who "tried and failed to obtain relief" from more conservative treatments. P. Ex. 2.1, at 3. Thus, the signed statement certifies that the beneficiary "needs the service that is the subject of the LCD" the beneficiary is challenging.

Accordingly, the amended complaint is acceptable under the regulations, and the ALJ should not have dismissed it.

Conclusion

For the reasons explained above, we reverse the ALJ Decision and remand the case to the ALJ to consider the amended complaint on its merits. Due to the "extended time" that the case was pending before the ALJ before it was dismissed, the beneficiary requested that the case be remanded to a different ALJ "if necessary for the efficient resolution of" the case. Bene. Br. at 7. We have no reason to think that the ALJ will not give the case prompt attention, so we decline to require that the case be assigned to a different ALJ.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member