Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re LCD Complaint:

External Infusion Pumps (LCD ID No. L11570),

Contractor: Noridian Administrative Services

Region X, Jurisdiction D

Docket No. C-12-144

Decision No.: CR2659

Date: November 7, 2012

DECISION

The record of the local coverage determination (LCD) titled "External Infusion Pumps," LCD Database ID No. L11570 (LCD L11570), issued by the Medicare Administrative Contractor, Noridian Administrative Services (Noridian), is complete and adequate to support the validity of the LCD provisions at issue under the reasonableness standard. Review of the challenged LCD is complete with the issuance of this decision and the Aggrieve Party (AP)[1] is entitled to request further review by the Appellate Division of the Departmental Appeals Board (the Board).

I. Background

On November 20, 2011, the AP filed this LCD complaint (Complaint). The case was assigned to me on November 29, 2011. I advised the AP by letter dated December 20, 2011, that his LCD complaint was unacceptable and I granted him one opportunity to file an amended, acceptable complaint. On February 27, 2012, the AP filed documents to amend and correct his complaint. On March 20, 2012, I issued an "Acknowledgement of Receipt of Acceptable Complaint and Order to File LCD Record."

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[1] The names of Medicare beneficiaries are not listed in published decisions to protect their privacy. 68 Fed. Reg. 63,691, 63,709 (Nov. 7, 2003).

On April 19, 2012, Noridian filed the LCD record, marked as CMS Exhibits (CMS Exs.) 1 and 2. On June 1, 2012, the AP filed his statement with documents he previously submitted as part of his amended complaint. The AP failed to mark his submission as evidence. Rather than return the documents to the AP, I have directed that the AP's documents be marked AP Exhibit (AP Ex.) 1, pages 1 through 53. On June 9, 2012, the AP filed an additional statement (AP Statement) with documents attached, some of which duplicate those previously submitted, some of which do not, and none of which are properly marked for consideration as evidence. I have directed that the documents filed with the AP's statement on June 9, 2012, be marked as AP Ex. 2, pages 1 through 24. Noridian filed a response on August 17, 2012. No objections have been raised to my consideration of the offered documents and CMS Exs. 1 and 2 and AP Exs. 1 and 2 are admitted.

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act (the Act) (42 U.S.C. § 1395j), establishes the supplementary medical insurance benefits program for the aged and the disabled known as Medicare Part B. Qualified individuals must elect to participate in the Medicare Part B program, which is funded by enrollees' premiums and appropriations from the federal government. The coverage or benefits of Medicare Part B are described in sections 1832, 1833, and 1834 of the Act (42 U.S.C. §§ 1395k, 1395l, and 1395m). However, section 1862 of the Act (42 U.S.C. § 1395y), which is applicable to both Medicare Part A and Part B, provides that no payment may be made for items or services "which . . . are not reasonable and necessary for the diagnosis or treatment of illnesses or injury or to improve the function of a malformed body member. . . ." The Secretary of the Department of Health and Human Services (the Secretary) has provided by regulation that any services not reasonable and necessary for one of the purposes listed in the regulations are excluded from coverage under Medicare. 42 C.F.R. § 411.15(k). The Medicare Benefit Policy Manual, CMS pub. 100-02, ch.16, §§ 10 and 20, provides that no payment may be made for items and 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.

The administration of Medicare Part B is through contractors. Act §§ 1842, 1874A (42 U.S.C. §§ 1395u, 1395kk-1). The Act provides for both National Coverage Determinations (NCD) and LCDs. Act § 1869(f)(1)(B) and (2)(B) (42 U.S.C. §1395ff(f)(1)(B) and (2)(B)). A LCD is a determination by a Medicare contractor, either a fiscal intermediary or a carrier, applicable to the area served by the contractor "respecting whether or not a particular item or service is covered," i.e., whether or not the item or service is reasonable and necessary within the meaning of section 1862(a)(1)(A)

of the Act. Act § 1869(f)(2)(B). In the absence of a NCD or a LCD, individual claims determinations are made based upon an individual beneficiary's particular factual situation. 68 Fed. Reg. 63, 691, 63,693 (2003) citing *Heckler v. Ringer*, 466 U.S. 602, 617 (1984) (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication); 42 C.F.R. §§ 426.420(a), (b), (e)(1), 426.460(b)(1), 426.488(b).

Review of a LCD is distinct from review of an individual claim determination. 68 Fed. Reg. 63,691, 63,692-94 (2003). The right to administrative and judicial review of individual claims determinations is established by sections 1869(a) through (d) of the Act and the regulations of the Secretary governing review are at 42 C.F.R. §§ 405.1000 through 405.1140. Individual claim determinations are not subject to review under the LCD process. 68 Fed. Reg. 63,691, 63,707 (2003). Pursuant to the Act and the Secretary's implementing regulations, the Departmental Appeals Board (the Board) has the authority to review NCDs, administrative law judges (ALJs) assigned to the Civil Remedies Division of the Board have the authority to review LCDs subject to further review by the Board, and individual claims determinations are reviewed by ALJs assigned to the Office of Medicare Hearings and Appeals (OMHA) subject to further review by the Medicare Appeals Counsel.[2] OMHA ALJs are not bound by LCDs when conducting individual claim review, although they are instructed to give substantial deference to LCDs. 42 C.F.R. § 405.1062. However, NCDs are binding upon the Medicare contractor, ALJs, and the Medicare Appeals Council. 42 C.F.R. § 405.1060.

Section 1869(f)(2)(A) of the Act (42 U.S.C. §1395ff(f)(2))[3] provides for the review of a LCD by an ALJ subject to the limitations that (1) a complaint must be filed by an AP; (2) the ALJ must review the record of the LCD; (3) only if the record is determined by the ALJ to be incomplete or to lack adequate information to support the validity of the LCD, will the ALJ permit discovery and the taking of evidence to evaluate the reasonableness of the LCD; (4) the ALJ may consult appropriate scientific and clinical experts; and

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[2] Benefit appeals under Parts A, B, and C were previously adjudicated by ALJs assigned to the Social Security Administration (SSA). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173, § 931(a) and (b) required that the Secretary and the Commissioner of Social Security transfer the responsibility for adjudicating such appeals from SSA to the Department of Health and Human Services. OMHA was the result. 70 Fed. Reg. 36,386 (June 23, 2005) (Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority).

[3] Provisions for the review of NCDs and LCDs were added to section 1869 of the Act by the Benefit Improvement and Protections Act of 2000 (BIPA), Pub. L. 106-554, § 522.

(5) the ALJ will "defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(2)(A)(i)(III). An AP may request that the Board review an adverse ALJ determination. Act § 1869(f)(2)(A)(ii).

An AP is one who has standing within the meaning of section 1869(f)(5) to obtain review of a NCD or LCD:

> 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 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 for the review of NCDs and LCDs. 68 Fed. Reg. 63,691 (2003); 42 C.F.R. § 426.100. The regulations are found at 42 C.F.R. Part 426. The procedures for review of a LCD are in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et. seq.*). The regulatory history for the new regulations states that the regulations expanded the definition of an aggrieved party "to include a beneficiary who received a service, but whose claim for the service was denied, extending an opportunity to that beneficiary" to file a complaint for a NCD or LCD review. 68 Fed. Reg. at 63,693-95.

Section 1869(f)(2) of the Act establishes a two-phase LCD review process by the 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, the 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. The Secretary's regulations establish a review procedure consistent with that specified by Congress. The regulations provide that after an AP files a statement as to why the LCD is not valid[4] 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

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[4] The aggrieved party may file copies of clinical or scientific evidence in support of its complaint that a LCD is not reasonable. 42 C.F.R. §§ 426.400(c)(6), 426.403.

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 review. 68 Fed. Reg. at 63,700, 63,710.

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.

Further clarification of the reasonableness standard intended by the drafters is provided by the notice of final rule making at 68 Fed. Reg. 63,691, 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.
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> 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.
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> 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.
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> 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. Pursuant to 42 C.F.R. § 426.330, the AP bears the burden of proof and persuasion, which is judged by a preponderance of the evidence.

B. Issue

At this phase in 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.[5]

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[5] I have shortened the statement of the issue to "whether the LCD satisfies the reasonableness standard" throughout the decision. The short-form of the issue is for ease in drafting and reading only and the correct characterization of the issue is as stated here.

C. Findings of Fact, Conclusions of Law, and Analysis

The AP's medical history is not relevant to this decision other than to establish his standing as an AP, which has not been challenged. However the AP's history does provide context for his complaint. The AP submitted a letter from his physician dated August 5, 2011. The physician explains that the AP had a lumbar fusion of L2-S1 (vertebrae of the lower spine) and removal of hardware at L3-L5 on November 29, 2010, with discharge from the hospital on December 6, 2010. However, the AP was readmitted to the hospital with fever, shaking chills, and increased pain and assessed as suffering a paraspinal abscess at L4 that required treatment with vancomycin and ertapenem (both antibiotics) for six weeks. The physician states that the infection was life-threatening and required an infusion pump rather than gravity feed due to potential side-effects of vancomycin and the need to obtain therapeutic blood levels. The physician states that inpatient and outpatient treatment were not available and treatment in the home was therefore necessary. AP Ex. 2 at 22-23.

According to the AP, his physician ordered the infusion of antibiotics twice a day for 60 days. The AP was told he could not remain in the hospital simply to receive the antibiotics and he was advised he had two alternatives – admission to a skilled nursing facility or hospital outpatient treatment. The AP states that no facility to provide outpatient antibiotic infusions could be located in the Los Angeles area. However, he learned that he could receive infusions by a home health care nurse with drugs provided by a pharmacy and he elected this treatment option. The AP submitted a letter from the Risk Manager for the hospital that states that he elected home infusion at his own expense as the only feasible option at the time. AP Ex. 2 at 24. The AP admits that he was told by the pharmacy that Medicare would not cover their charges and that he would have to pay. The AP admits that the pharmacy provided him with a copy of LCD11570. The home health care company did not ask him for reimbursement because Medicare paid the home health agency charges, and they are not at issue in this case. The AP alleges he called CMS and was told that the treatment was covered. The AP alleges that, based on the advice from CMS, he believed that the pharmacy would eventually reimburse him for all charges and so he insisted that the pharmacy file claims with Medicare. The AP was treated with infused antibiotics for 58 days. The pharmacy claims were denied but the pharmacy could not seek payment from the AP as to some. AP Complaint at 2-3; AP Statement at 1-2.

AP Exs. 1 at 3-17, and 2 at 1-10 show that Noridian determined that the AP could be billed in excess of $20,000 related to his antibiotic treatment. The AP's evidence shows that he requested reconsideration but, on November 23, 2011, Medicare coverage was denied for an external infusion pump, maintenance and supplies for the pump, ertapenmen sodium (an antibiotic also known as Invanz) injections that were not administered by infusion (AP Ex. 2 at 11), and vancomycin. The notice of the

reconsideration decision advised the AP of the right to request review by an OMHA ALJ. AP Ex. 2 at 12-20. The AP did not present evidence that he requested review of his claim denial by an OMHA ALJ.

My conclusions of law are set forth in bold followed by the pertinent facts and analysis.

> **1. Based upon the evaluation required by 42 C.F.R. § 426.425(c)(1), I conclude that the LCD record is complete and adequate to support the validity of the LCD provisions at issue under the reasonableness standard. 42 C.F.R. § 426.450(a)(4).**
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> **2. No proprietary or privileged data was submitted under seal or considered in this case.**
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> **3. Issuance of this 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).**

My jurisdiction or authority in this case is clearly delineated at 42 C.F.R. §§ 426.405, 426.450, and 426.455. I am limited to addressing the issues of whether or not a LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard and whether the provision of the LCD is valid or invalid under the reasonableness standard. 42 C.F.R. § 426.450(a).

Section 1862(a)(1)(A) of the Act provides that Medicare Parts A and B may not pay for any items or services that are "not reasonable and necessary for the treatment of illness or injury or to improve the function of a malformed body member." Section 1869(f)(2)(B) of the Act provides:

> For purposes of this section, the term "local coverage determination" means 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)**.

(Emphasis added.) The Secretary defined a LCD consistently with section 1869(f)(2)(B) of the Act, as follows:

> *Local coverage determination (LCD)* means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with

> **section 1862(a)(1)(A) of the Act**. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

42 C.F.R. § 400.202 (emphasis added).

The definition of LCD under the Act and regulations is precise. A LCD is a determination of the Medicare contractor as to whether or not a particular item or service meets the reasonable and necessary requirement of section 1862(a)(1)(A) of the Act. A LCD is used by a contractor to determine Medicare coverage for an item or service without individual medical review. I am limited to reviewing a LCD. Act § 1869(f)(2)(A); 42 C.F.R. §§ 426.325(b)(4), (5), (12), & 425.405(d)(5).

The regulation provides that after receiving the LCD record; the AP's statement of why the LCD is not valid, including evidence submitted in support of that position; and the contractor's response to the AP's statement, I am to apply 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). I conclude after review that the LCD record is complete and adequate to support the validity of the LCD in this case. Accordingly the LCD review process ends with this decision subject to any further appeal to the Board. 42 C.F.R. §§ 426.425(c)(2); 426.465.

LCD L11570 is Noridian's determination that an external infusion pump is reasonable and necessary and covered by Medicare under the conditions specified in the LCD. CMS Ex. 1, at 2-7. LCD L11570 states that "[e]xternal infusion pumps and related drugs and supplies will be denied as not reasonable and necessary" when the conditions specified in the LCD are not met. CMS Ex. 1, at 7. LCD L11570 does not specifically address the use of an infusion pump for the delivery of vancomycin. However, LCD L11570 refers to the NCD for Infusion Pumps (280.14), CMS pub. 100-3, ch.1, pt. 4, § 280.14 (NCD 280.14), which provides that effective September 1, 1996, external infusion pumps are not covered for the delivery of vancomycin. The rationale stated in the NCD for non-coverage is that there is insufficient evidence to support the need for using an external infusion pump rather than a disposable elastomeric pump or gravity drip, for the delivery of vancomycin in a safe and appropriate manner. NCD 280.14 is binding upon Noridian and me. 42 C.F.R. § 405.1060(a)(4). LCD L11570, which was issued by Noridian, must be construed and applied consistently with NCD 280.14.

> 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 63,704. Accordingly, I conclude that the interpretation of LCD L11570 that it does not permit approval of coverage for an external infusion pump and related drugs and supplies for the delivery of vancomycin, meets the reasonableness standard and must be upheld.

In his November 20, 2011 complaint, the AP argues that LCD L11570 does not clearly state what is not covered and that it is only decipherable by lawyers or medical claims personnel. AP Complaint at 4. Even if I agreed with the AP that LCD L11570 is not a model of clarity that is not an authorized basis for me to conclude that the LCD does not meet the reasonableness test. Contrary to what the AP represents he was told, LCDs are neither written nor rewritten by ALJs. The AP concedes that after his claims were denied he carefully read the LCD and he recognized that the LCD establishes a list of which uses of infusion pumps are covered by Medicare. Petitioner also complains that various publications of CMS regarding coverage of infusions pumps are not clear or are misleading; that the regulations are not readily accessible; that LCDs are not readily accessible; that CMS provided misleading information; and that it is inconsistent for Medicare to pay for his home health services and the antibiotics but not the infusion pump and supplies and the formulation of the antibiotics. AP Complaint at 4-5. My jurisdiction is limited to determining whether provisions of LCD L11570 meet the reasonableness standard and I have no authority to comment upon the additional arguments raised by the AP.

In his statement dated June 9, 2012, the AP argues that he was told five times when he called Medicare that the infusion of antibiotics would be covered. He concedes that the pharmacy, IV League, Inc., told him that the external infusion pump and supplies would not be covered by Medicare. He states that the antibiotics, vancomycin and ertapenem, were billed to Medicare Part D. The AP argues that the notices of denial of coverage were so unclear that he could not pursue an appeal. He argues that there has been no explanation for the denial of coverage for supplies related to the gravity infusion of ertapenem. He also renews his complaint about accessibility of LCDs and regulations. AP Statement at 1-5. My jurisdiction is limited to determining whether provisions of LCD L11570 meet the reasonableness standard. I have no authority to conduct a review of the denial of coverage for the AP's Medicare claims – the AP was entitled to request review by an OMHA ALJ under the regulations previously discussed. The AP's arguments evince his frustration, but they provide no bases on which to conclude that LCD L11570 does not meet the reasonableness standard.

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, and I must uphold the validity of the LCD if the contractor's findings, interpretations of law, and application of fact to law are reasonable in light of the LCD record and the evidence submitted by the AP. I conclude that the LCD record for LCD L11570 is complete and adequate to support the validity of the LCD provisions at issue under the reasonableness standard. 42 C.F.R. § 426.450(a)(4).

4. Appeal rights. 42 C.F.R. §§ 426.462, 426.465.

Pursuant to 42 C.F.R. § 426.465(a), an AP may request review by the Board. Except upon a showing of good cause, a request for review by the DAB must be filed within 30 days of the date of this decision (42 C.F.R. § 426.465(e)) and must comply with the requirements of 42 C.F.R. § 426.465(f).

III. Conclusion

The LCD record is complete and adequate to support the validity of the LCD provision at issue under the reasonableness standard and review of the challenged LCD is complete.

/s/
Keith W. Sickendick
Administrative Law Judge