Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD COMPLAINT: Pulsatile Intravenous Insulin Therapy,
LCD No. L29299 (formerly L5780),
The List of Medicare Noncovered Services.

Contractor: First Coast Service Options, Inc. (Carrier)

Oversight Region IV,

Docket No. C-09-258

Decision No. CR2104

Date: April 02, 2010

DECISION

The Aggrieved Party's (AP) complaint is dismissed for lack of jurisdiction pursuant to 42 C.F.R. § 426.444(b)(5).

I. Background

On February 16, 2009, counsel for the AP filed a complaint to challenge the provisions of the local coverage determination (LCD) that denied Medicare coverage on a carrier-wide basis for Pulsatile Intravenous Insulin Therapy (PIVIT), also known as Hepatic Activation Therapy (HAT), Metabolic Activation Therapy (MAT), or Chronic Intermittent Intravenous Insulin Therapy (CIIIT), and related services. The LCD was published by the Medicare contractor, First Coast Service Options (First Coast), in "The List of Medicare Noncovered Services," LCD No. L29299, effective February 2, 2009, which replaced LCD No. L5780 also titled "The List of Medicare Noncovered Services," which was retired February 1, 2009.[1] LCD L29299 specifically states that it replaced LCD L5780.

---

[1] LCDs, current and retired, are available at http://www.cms.hhs.gov/mcd/indexes.asp.

The case was assigned to me on February 23, 2009. I advised the AP by letter dated March 13, 2009, that his complaint was unacceptable and that he had one opportunity as authorized by 42 C.F.R. § 426.410(b) and (c), to file an amended complaint. The AP filed an amended complaint on April 24, 2009 (Complaint) with exhibits (AP Exs.) 1 through 69.[2] On June 2, 2009, I advised Petitioner that his amended complaint was acceptable, and I ordered that the LCD record be produced, set a schedule for production of the LCD record, and ordered that the parties file the statement and response required by the regulations. On June 23, 2009, the Office of General Counsel (OGC), U.S. Department of Health and Human Services (HHS), Region IV, notified me that OGC was not representing the Centers for Medicare and Medicaid Services (CMS) or First Coast in this case.

On June 29, 2009, First Coast submitted approximately 1,000 pages of documents, purportedly the LCD record, and a letter, dated June 29, 2009, discussing the LCD provisions in issue. On July 8 and 27, 2009, I extended the prehearing schedule to give First Coast time to properly mark the LCD record in accordance with the Civil Remedies Division Procedures. The contractor subsequently filed documents marked R. Ex. 1 through R. Ex. 119. On August 29, 2009, the AP filed his "Beneficiary's Statement Regarding the LCD Record" (AP Brief), in accordance with 42 C.F.R. § 426.425(a), with AP Exs. 70 through 83.[3] On September 25, 2009, First Coast filed its response to the AP Brief, in which First Coast advised me that CMS had released a proposed national coverage determination (NCD) that would provide for noncoverage of PIVIT and related services on a national-level.

CMS issued a NCD,[4] "NCD for Outpatient Intravenous Insulin Treatment (40.7)," with an effective date of December 23, 2009, that provides that outpatient intravenous insulin therapy (OIVIT)[5] and related services are not covered by Medicare.

_____

[2] The AP filed copies of various documents with his complaint and amended complaint. The AP resubmitted his exhibits, including those previously submitted, properly marked on June 17, 2009, and he filed the correct number of copies on June 30, 2009.

[3] Because I conclude that I have no jurisdiction to decide this case on the merits, I do not admit any of the exhibits offered by the parties.

[4] NCDs are available at http://www.cms.hhs.gov/mcd/indexes.asp.

[5] The NCD states that OIVIT includes PIVIT, HAT, MAT, CIIIT, and Cellular Activation Therapy (CAT).

On February 22, 2010, I issued an Order to Show Cause to the parties directing them to show cause in writing by not later than March 10, 2010, why I should not dismiss this case for lack of jurisdiction. The parties did not respond to the Order to Show Cause.

II. Discussion

A. Law

Section 1831 of 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 illness or injury or to improve the functioning of a malformed body member. . . ." The Secretary of HHS (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 Publication 100-02, Chapter 16, §§ 10 and 20 provide 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 that process claims for benefits. Act §§ 1842, 1874A (42 U.S.C. §§ 1395u, 1395kk-1). The Act provides for both NCDs and LCDs. Act § 1869(f)(1)(B) and (2)(B) (42 U.S.C. §1395ff(f)(1)(B) and (2)(B)). A NCD is a determination by the Secretary as to whether an item or service is covered nationally, i.e., whether or not the item or service is reasonable and necessary within the meaning of section 1869(a)(1)(A) of the Act. Act § 1869(f)(1)(B). A LCD is a determination by a Medicare contractor applicable to the area served by the contractor as to 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 1869(a)(1)(A) of the Act. Act § 1869(f)(2)(B). In the absence of a NCD or a LCD, individual claim 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); 426.426.488(b).

Congress has established a procedure for APs to obtain administrative and judicial review of NCDs and LCDs. Act § 1869(f). Pursuant to section 1869(f)(1)(A) of the Act, NCDs may not be reviewed by an ALJ but, upon the filing of a complaint by an AP, a NCD will be reviewed by the Departmental Appeals Board (Board). LCDs are subject to review by an ALJ, with an appeal to the Board. Act § 1869(f)(2). Review of a NCD or 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 of individual claims are at 42 C.F.R. §§ 405.1000 through 405.1140. Individual claim determinations are not subject to review under the NCD or LCD review process established by section 1869(f) of the Act. 68 Fed. Reg. 63,691, 63,707 (2003). The Secretary has issued regulations that provide that the Board has the authority to review NCDs. ALJs assigned to the Civil Remedies Division of the Departmental Appeals Board have the authority to review LCDs, subject to appeal to the Board. Individual claim determinations are reviewed by ALJs assigned to the Office of Medicare Hearings and Appeals (OMHA), subject to further review by the Medicare Appeals Council.[6]

Section 1869(f)(2)(A) of the Act[7] provides for the review of a LCD by an ALJ subject to the limitations that: (1) a complaint must be filed by an aggrieved party; (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 (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 aggrieved party may request that the Board review an adverse ALJ determination. Act § 1869(f)(2)(A)(ii).

---

[6] Benefit appeals under Medicare 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 Secretary. 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).

[7] 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.

An aggrieved party is one who has standing within the meaning of section 1869(f)(5) of the Act:

> 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 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. 63,691, 63,693-95 (2003).

Section 1869(f)(2) of the Act establishes a two-phase LCD review process by the ALJ. The ALJ reviews the LCD record, and, if he or she determines that the record is complete with adequate information to support the validity of the LCD, 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, then 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 the aggrieved party files a statement as to why the LCD is not valid[8] 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 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. 63,691, 63,700, 63,710 (2003).

---

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

An AP may appeal an ALJ decision to the Board pursuant to 42 C.F.R. § 426.465(a) and subject to the conditions specified by that regulation.

B. Issue

Whether the complaint must be dismissed for lack of jurisdiction?

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

My conclusions of law are in bold followed by pertinent findings of fact and analysis.

1. **The NCD has superseded and replaced the LCD at issue.**

2. **I have no jurisdiction to review a NCD.**

3. **Dismissal for lack of jurisdiction is required.**

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 the LCD record is complete and adequate to support the validity of the LCD under the reasonableness standard and whether the LCD is valid or invalid under the reasonableness standard. 42 C.F.R. § 426.450(a). I have no authority to review billing and coding issues, such as those raised by the AP related to the appropriate code to be used for services or whether services may be unbundled and submitted separately for payment. Furthermore, I have no authority to conduct a review of a NCD, as Congress specifically granted jurisdiction to the Board for NCD reviews.

The LCD challenged by the AP provided for the noncoverage of PIVIT and associated services, such as blood glucose monitoring, oxygen uptake, and expired gas analysis tests. The noncoverage determination was the same under both "The List of Medicare Noncovered Services," LCD No. L29299, effective February 2, 2009, which replaced LCD No. L5780 also titled "The List of Medicare Noncovered Services," which was retired February 1, 2009. The LCD applied to the Medicare contractor's service area. The NCD issued by CMS "NCD for Outpatient Intravenous Insulin Treatment (40.7)," with an effective date of December 23, 2009, provides that OIVIT, which is also known as PIVIT, and related services are not covered by Medicare, because CMS has determined that OIVIT does not improve health outcomes for Medicare beneficiaries and that OIVIT is therefore not reasonable and necessary for the treatment of any Medicare covered condition. The NCD issued by CMS applies nationally and supersedes an individual contractor's LCD. Pursuant to CMS guidance to its Medicare contractors published in the Medicare Program Integrity Manual, CMS Publication 100-08, Chapter 13, section 13.1.1, NCDs are binding upon all Medicare contractors. When a NCD is published, the contractor is responsible to notify the provider community as soon as

possible and to amend affected LCDs. Contractors are directed by CMS not to repeat a NCD in a LCD to avoid confusion about whether the coverage or noncoverage provision is a NCD or a LCD.

The law is clear that I have no authority or jurisdiction to review a NCD. Jurisdiction of review of NCDs lies with the Board. Were I to conduct the review of the LCD provision challenged by the AP, I would effectively be reviewing the NCD provision that provides for noncoverage of PIVIT. Pursuant to 42 C.F.R. § 426.444(b)(5), I must dismiss any complaint if the complaint challenges a provision or provisions of an NCD.

Accordingly, I conclude that I must dismiss the AP's complaint.

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 Board 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

For the above reasons, I dismiss the AP's complaint for lack of jurisdiction.

/s/
Keith W. Sickendick
Administrative Law Judge