

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Crystal Lake Healthcare and
Rehabilitation Center

(Appellant)

(Beneficiary)

Riverbend GBA

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Numbers)

(ALJ Appeal Numbers)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated September 28, 2006, because there is an error of law material to the outcome of the case. See 42 C.F.R. § 405.1110.

The Council has carefully considered the record that was before the ALJ, as well as the memorandum from the Centers for Medicare & Medicaid Services (CMS) dated November 21, 2006. The CMS memorandum, a copy of which was sent to the parties, is hereby entered into the record in this case, and marked as Exh. MAC-1.

EXHIBITS

The ALJ's decision refers to exhibits, but an exhibit list is not attached. Rather, a handwritten exhibit list is included in each beneficiary's file. The record before the ALJ consisted of a claim file for each beneficiary that includes exhibits 1-7 in each file, and a binder submitted by the appellant containing its request for ALJ hearing, which the ALJ refers to as exhibit 8.

The Council reprints the ALJ's exhibit lists below for reference:

- Exh. 1: Reconsideration decision
- Exh. 2: Request for reconsideration
- Exh. 3: Medical records
- Exh. 4: Correspondence
- Exh. 5: Billing Statements
- Exh. 6: Redetermination
- Exh. 7: Medicare Claim History
- Exh. 8: Binder (Request for Hearing)

BACKGROUND AND PROCEDURAL HISTORY

The provider, a skilled nursing facility (SNF) submitted claims to Medicare for one month of daily blood glucose testing (HCPCS code 82962) for each of three beneficiaries (June, October, and November, 2004, respectively). Exh. 7. The services were billed under Medicare Part B as none of the beneficiaries' nursing home stays were covered by Medicare Part A during the period at issue. Exh. 8. All three beneficiaries had a diagnosis of diabetes and "other comorbidities . . . that warranted frequent blood glucose testing . . . for adequate glycemic control." Exh. 8. The testing was performed by the provider up to four times a day, using the finger stick method and a blood glucose monitor. Exhs. 3, 7. The provider performed the services under a standing order from the treating physician. Exh. 3. The appellant does not dispute that the physician was not informed of each test result immediately after the test was performed. Rather, the physician "incorporated the test results into the overall management of the care of these patients when reviewing orders at monthly patient visits and when making interim order changes, if necessary, between visits." Exh. 8.

Code 82962 is defined in the 2004 HCPCS as a test for "glucose, blood by glucose monitoring device cleared by the FDA specifically for home use." The Medicare carrier denied coverage of the blood glucose testing claimed under HCPCS code 82962 because the testing "is considered part of routine personal care and is not a separately reportable or billable procedure." Exh. 7. In its denial, the carrier referenced its local coverage determination (LCD) concerning blood glucose testing. The provider requested a redetermination, and the carrier affirmed its denial of coverage for the claimed services, citing the Medicare Benefit Policy Manual (MBPM), chapter 6, § 20, and the National Coverage Determinations Manual (NCDM), § 190.20. Exh. 6.

The provider appealed to a Qualified Independent Contractor (QIC). Exh. 4. In separate decisions, the QIC concluded that the claimed laboratory services provided to each beneficiary did not meet Medicare coverage criteria because the laboratory test results were not promptly reported to the physician. Exh. 1. In each decision, the QIC noted that routine glucose testing is "never covered in a SNF unless it meets all the conditions of a covered laboratory service." The QIC cited Medicare Claims Processing Manual (MCPM), chapter 7, § 90.1 in support of its decisions. Exh. 1.

The appellant requested a consolidated decision by an ALJ, and waived its right to a hearing. Exh. 8. In its letter of appeal dated June 30, 2006, the appellant asserted that the NCD's policy on blood glucose testing supplanted the limitations in the LCD, and that the services were performed and met Medicare coverage criteria under the NCD.

The ALJ issued a favorable decision on the record. He found that in each case, "the physician ordered injections of various units of insulin dependent on the results from the glucose testing" and the beneficiaries' "test results varied on a daily basis." The ALJ referred only to the NCD in his analysis, particularly the provision that "it may be reasonable and necessary to measure quantitative blood glucose up to four times annually." The ALJ decided that, based on the beneficiary's condition and varying glucose levels, "more frequent testing than four times annually is considered reasonable and necessary." He concluded that because "the requirements set forth in the NCD are met to support glucose testing," the testing was reasonable and necessary and covered by Medicare. Dec. at 5-13.

CMS referred the ALJ's decision to the Council for its review under the provisions of 42 C.F.R. § 405.1110(b). In its referral memorandum, CMS argued that the ALJ erred in not affording substantial deference to the carrier's LCD, CMS manual instructions, and CMS program memoranda, and instead "based his decision . . . solely on his reading of the related NCD." Exh. MAC-1. According to CMS, the LCD and program guidance all indicate that for coverage of blood glucose testing in a Part B SNF setting, the physician must

be notified of the test results promptly and use each result to manage patient treatment. In this case, "[n]othing in the record indicates that the services at question were not anything other than routine orders . . . nor does the judge explain why the LCD and CMS policies should not apply in this particular case." Exh. MAC-1 at 4.

AUTHORITIES

Since the applicability of several authorities has been disputed in this case, and since multiple authorities have been cited in the determinations below, the Council finds it necessary to review and consider all of the relevant authorities in chronological order.

The Medicare carrier first issued a LCD concerning blood glucose testing in 1997, and periodically reviewed and revised the LCD thereafter.¹ The policy states:

The routine or standing order of a home glucose monitoring device (82962) will only be considered medically necessary as a laboratory procedure when the physician is PROMPTLY informed of the result PRIOR to the next testing episode. Blood glucose monitoring by 82962 without this reporting is part of the patients' self-care. If the patient is in a skilled nursing facility, routine glucose monitoring (including any tests, which are not promptly reported) is a part of routine personal care and is not a separately reportable or billable procedure.

L1316 (eff. 1/14/03-7/22/05) (emphasis in original).

In 2000, CMS issued a Program Memorandum entitled, "Glucose Testing." PM AB-00-108. The purpose of the memorandum was to "review Medicare coverage and payment policy for glucose monitoring for a patient whose stay is not covered by Medicare Part A but who is eligible for services under Medicare Part B."

The memorandum recognized that glucose monitoring for managing insulin therapy "often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. . . . Administration of the service several

¹ Prior to the publication of a final rule on November 11, 2003, which established LCDs, contractor policies were called Local Medical Review Policies (LMRPs). Riverbend's blood glucose policy effective during the period at issue in this case was published as LMRP L1316 and later converted to a LCD.

times a day is common in order to maintain tight control of glucose." However, the memorandum made clear that, for separate payment as a Part B laboratory service, "the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; *this includes the physician's order for another laboratory service. . . . A standing order is not usually acceptable documentation for a covered laboratory service.*" (Emphasis added.) Accordingly, the memorandum instructed carriers to review their local coverage policies "to clarify, if necessary, that a glucose monitoring laboratory service must be performed in accordance with laboratory service coverage criteria including the order and clear use of a laboratory result prior to a similar subsequent laboratory order in order to qualify for separate payment under the Medicare laboratory benefit."

On November 23, 2001, CMS published a final rule concerning coverage of clinical diagnostic laboratory services under Medicare Part B. See Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services, 66 Fed. Reg. 58788 (November 23, 2001). As an addendum to the rule, CMS issued 23 NCDs that became effective on November 25, 2002, including an NCD on blood glucose testing. See NCDM § 190.20.

NCD § 190.20 applies generally to "blood samples used to determine glucose levels." NCD § 190.20 (Version 1, eff. 11/25/02-1/1/05). As recited in the ALJ's decision, the NCD recognizes that the convenience of a home blood glucose monitor "allows a patient to have access to blood glucose values in less than a minute or so and has become the standard of care for control of blood glucose, even in the inpatient setting." The NCD, however, does not specifically address Part B payment of finger stick blood glucose testing in a SNF setting. Under the heading "Limitations," the NCD provides the following:

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four times annually.

Depending on the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four times annually may be reasonable and necessary.

In some patients presenting with nonspecific signs, symptoms, or diseases not normally associated with disturbances in glucose metabolism, a single blood glucose test may be medically necessary. Repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition. If repeat testing is performed, a specific diagnosis code (e.g., diabetes) should be reported to support medical necessity. However, repeat testing may be indicated where results are normal in patients with conditions where there is a confirmed continuing risk of glucose metabolism abnormality (e.g., monitoring glucocorticoid therapy).

Id.

CMS subsequently issued a Program Memorandum to guide the local contractors' implementation of the NCDs that were published in the final rule. PM AB-02-110 (July 31, 2002). The Program Memorandum instructs contractors to "[r]eview existing [LCDs] to ensure that they are consistent with these NCDs. You may employ [LCDs] subject to the provision of Chapter 1, section 2.1 C of the Program Integrity Manual, to supplement these NCDs. For example, some of the NCDs are silent regarding frequency. You may develop [an LCD] that provides guidance regarding appropriate frequency." *Id.*

According to the Revision History Explanation in the LCD, the Medicare carrier revised and reissued LCD L1316 several times since the CMS clinical laboratory final rule was published in November, 2001. The LCD makes clear that, "[t]his policy represents [Riverbend's] implementation of the National Coverage Decision (NCD) on Blood Glucose Testing and interpretation of the Program Memorandum on Blood Glucose Testing (82962) for Skilled Nursing Facilities."

The Medicare Claims Processing Manual (MCPM) also addresses coverage of laboratory tests under Part B. MCPM ch. 7, § 90. It specifically addresses blood glucose testing:

Routine glucose monitoring of diabetics is never covered in a SNF, whether the beneficiary is in a covered Part A stay or not. Glucose monitoring may only be covered when it meets all the conditions of a covered laboratory service, including use by the physician in modifying the patient's treatment.

MCPM, ch. 7, § 90.1. The Council notes that although NCD § 190.20 had been published before the last revision to the Manual, MCPM section 90.1 continues to cite to PM AB-00-108 for its authority.

DISCUSSION

An NCD is binding on the ALJ and the Council pursuant to 42 C.F.R. § 405.1060(a)(4). Thus, the question is whether any part of the NCD addresses the specific issue in this case and therefore "supersedes" the LCD, as the appellant has argued. The Council finds that the ALJ erred in relying on the language in NCD § 190.20 concerning "quantitative" glucose testing in the home by a clinical diagnostic laboratory, to support his decision that the services billed under HCPCS code 82962 were covered when a SNF uses a home glucose monitoring machine to test a resident multiple times a day. As the 2000 Program Memorandum explains, a separate quantitative blood glucose test sent to a clinical laboratory is a different test from the home glucose machine monitoring reflected in HCPCS code 82962:

At certain times a physician may also order a *separate quantitative blood glucose test* to enhance a physician evaluation and management service for the patient. A specimen collection of venous blood may be sent to an independent laboratory for testing and the laboratory reports the result to the provider and the ordering physician. This is a separate laboratory service billed with a different code than a home-use glucose monitoring service and is also paid under the laboratory fee schedule.

PM AB-00-108 (emphasis added). The beneficiaries' medical records also reflect this distinction between the two tests. For example, beneficiary A.P.'s medication order form reflects that, in addition to daily finger stick testing, there was also a standing order for a fasting blood sugar laboratory test to be performed monthly. A.P. claim file, Exh. 3.

The Council finds that the NCD does not mandate separate Part B coverage of finger stick glucose testing in a SNF, nor does it address the reasonableness and necessity of routine testing in that setting. In fact, in addressing frequency, the NCD states only that "repeat testing may not be indicated unless abnormal results are found or unless there is a change in clinical condition." Thus, even after the publication of the NCD, the Medicare carrier was acting within its authority in re-issuing an LCD that described more

specific parameters for frequency of testing, particularly where a provider claimed separate Part B payment for the service as a clinical laboratory test. The LCD is neither superceded by, nor conflicts with, the broad provisions of the NCD.

The LCD's restrictions are also consistent with CMS policy concerning Part B payment for clinical laboratory services, and specifically, blood glucose testing, as articulated in the Medicare Claims Processing Manual and the 2000 Program Memorandum. (The provisions of the Memorandum incorporated and supplemented "material previously issued" in prior memoranda. PM AB-00-108, at 1.) Even after the publication of the NCD, CMS continues to refer to and rely on PM AB-00-108 as a correct statement of policy.²

While ALJs and the Council are not bound by LCDs or CMS program guidance, they must give those policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow a policy in a particular case, the reasons why such policy was not followed must be explained. 42 C.F.R. § 405.1062(b). The Council finds that the ALJ erred in not considering the applicable LCD and CMS program guidance in this case and giving them substantial deference, or explaining why they were not followed.

The Council recognizes the medical necessity for frequent glucose testing in patients with diabetes. However, as the CMS Program Memorandum issued in 2000 noted, "nursing and physician duties [related to testing] . . . are paid predominately under other payment systems, such as the state nursing home payment system or the physician payment system." PM AB-00-108, at 3. Therefore, the

² We also note the revision of 42 C.F.R. § 424.24, effective January 1, 2007. The new subsection reads:

(f) *Blood glucose testing.* For each blood glucose test, the physician must certify that the test is medically necessary. A physician's standing order is not sufficient to order a series of blood glucose tests payable under the clinical laboratory fee schedule.

In promulgating this new rule, the agency referred to its longstanding policy on coverage of blood glucose testing and cited Program Memorandum AB-00-108 as the most recent explanation of this policy. Medicare: Physician Fee Schedule (CY 2007), 71 Fed. Reg. 69624, 69704 (December 1, 2006).

Council finds it reasonable that "a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for *separate payment* under the Medicare laboratory benefit." *Id.* (emphasis added). The daily testing of the beneficiaries in this case did not comport with the Medicare coverage parameters of the Medicare Part B laboratory benefit, i.e., the physician was not informed promptly of each result before any subsequent test. Therefore, the Council concludes that the claimed services are not covered by Medicare.

FINDINGS

The Medicare Appeals Council has carefully considered the entire record and makes the following findings:

1. The provider, Crystal Lake Healthcare and Rehabilitation Center, furnished multiple daily blood glucose tests using a home glucose monitor to three beneficiaries during the following periods: M.B., November 1, 2004, to November 30, 2004; A.P., October 1, 2004, to October 31, 2004; and C.D., June 1, 2004, to June 30, 2004.

2. The provider billed Medicare for Part B payment of the blood tests under HCPCS code 82692.

3. None of the beneficiaries were in a Medicare Part A covered stay during the period at issue.

4. The tests were performed under a standing order from the treating physician, and the physician in each case was not informed of each test result promptly and prior to the subsequent test.

5. Medicare does not cover separate Part B payment of routine blood glucose testing under a standing order unless the physician is informed of the results of each test promptly and prior to the performance of the next test, and the results are used to manage the beneficiary's treatment.

6. The blood tests the provider furnished to the three beneficiaries during the periods of service at issue are not covered as clinical laboratory diagnostic tests under Medicare Part B.

DECISION

It is the decision of the Medicare Appeals Council that the daily blood glucose testing performed by the provider in this case is not covered by Medicare.

MEDICARE APPEALS COUNCIL

Thomas E. Herrmann
Administrative Appeals Judge

Clausen J. Krzywicki
Administrative Appeals Judge

Date: February 15, 2007