

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Advanced Diabetes
Treatment Centers

(Appellant)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiaries)

(HIC Numbers)

First Coast Service Options

(Contractor)

1-392893626

(ALJ Appeal Number)

INTRODUCTION

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated April 20, 2009, because there is an error of law material to the outcome of the associated claims. See 42 C.F.R. § 405.1110. The ALJ provided Medicare coverage for tests for oxygen and carbon dioxide exhaled air analysis (CPT code 94681) provided during clinical trials for Pulsatile Intravenous Insulin Therapy (PIVIT). The ALJ found that services billed under CPT code 94681 were payable by Medicare as routine costs of the trials. In a memorandum dated June 18, 2009, the Centers for Medicare & Medicaid Services (CMS) asked the Council to review the ALJ decision, asserting that these services did not constitute routine costs and are not covered by Medicare.

The Council has carefully considered the record that was before the ALJ, as well as the memorandum from CMS, dated June 18, 2009. The CMS memorandum is hereby entered into the record in this case as Exhibit (Exh.) MAC-1. The Council has also considered written exceptions filed by counsel for the appellant, which are admitted into the record as Exh. MAC-2. See 42 C.F.R. § 405.1110(b)(2). Based on the analysis below, the Council reverses the ALJ decision and finds that Medicare does not cover the appellant's claims for the oxygen uptake/expired gas analysis billed under CPT code 94681.

LEGAL STANDARDS

General Coverage Principles

Section 1862 of the Social Security Act (Act) provides that, "[n]otwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services - which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the service has been proven safe and effective based on authoritative evidence, or alternatively, whether the service is generally accepted in the medical community as safe and effective for the condition for which it is used. See *Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology*, 54 Fed. Reg. 4302, 4304 (January 30, 1989); *Criteria and Procedures for Extending Coverage to Certain Devices and Related Services*, 60 Fed. Reg. 48417 (September 19, 1995); and *Procedures for Medical Services Coverage Decisions; Request for Comment*, 52 Fed. Reg. 15560 (April 29, 1987). See also *Medicare Program Integrity Manual (MPIM)* (Pub. 100-08), Ch. 13, §§ 13.5.1 and 13.7.1.¹

The Act vests in the Secretary the authority to make specific coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that specify whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare.² In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. See preface to *Medicare Coverage Issues Manual* (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Often, these determinations are made in the form of a local coverage determination (LCD). See MPIM Ch. 13.

National Coverage Determination (NCD) 310 - Routine Costs in Clinical Trials (Effective July 9, 2007)

¹ Manuals issued by CMS can be found at <http://www.cms.hhs.gov/manuals>.

² NCDs may be found in the *National Coverage Determinations Manual (NCDM)* (Pub. 100-03) issued by CMS.

NCD 310 provides coverage for the routine costs in clinical trials, in relevant part, as follows:

Effective for items and services furnished on or after July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service, itself *unless otherwise covered outside of the clinical trial*;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.

Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

* * * * *

For non-covered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the non-covered item or service and unrelated reasonable and necessary care. However, if the item or service is not covered by virtue of a national non-coverage policy in [the NCDM] and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

NCD 310.1 (emphasis in original).

NCD 310 sets forth three requirements for a clinical trial to receive Medicare coverage of routine costs. NCD 310.1.A. However, the three requirements are insufficient, standing alone, to warrant coverage, and CMS lists seven additional "desirable characteristics." *Id.* Some clinical trials "are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage." *Id.* One of the seven characteristics is that "[t]he trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use." *Id.*

The NCD then discusses the qualification process for clinical trials, including a multi-agency panel that develops criteria "that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. . . . Trials that meet the qualifying criteria will receive Medicare coverage of their associated routine costs." NCD 310.1.B. The trial's lead principal investigator must certify that the trial meets the criteria. *Id.* Certain trials automatically receive coverage of routine costs (i.e., are "deemed" qualified for coverage), including trials funded by the National Institutes for Health (NIH), the Centers for Disease

Control (CDC), the Agency for Healthcare Research and Quality (AHRQ), CMS, the Department of Defense (DOD), and the Veterans Affairs (VA) or centers for co-operative groups funded by these entities. *Id.* Clinical trials concerning investigational new drug applications (IND) reviewed by the Food and Drug Administration (FDA) may also be deemed as qualified trials. *Id.*

Carrier Local Medical Review Policy (LMRP)/Local Coverage Determination (LCD) for Noncovered Services (Effective March 24, 2003)

Medicare carrier First Coast Service Options (FCSO) issued "LCD for The List of Medicare Noncovered Services (L5780)" that applies to this case.³ LCD L5780 requires that PIVIT must be billed under CPT code 99199 and designates that claims for PIVIT "will always be reviewed, as they must currently be billed with an unlisted procedure code." The precursor Local Medical Review Policy (LMRP) denying coverage for PIVIT is effective for dates of service on or after March 24, 2003. Exh. 14, at 11.⁴ In relevant part, a carrier Medicare Part B Update (Second Quarter 2003) summarizes the LMRP as follows:

NCSVCS: The List of Medicare Noncovered Services

The following changes have been made to the local medical review policy (LMRP) for Medicare noncovered services.

Local Noncoverage Additions

99199 Pulsatile Intravenous Insulin Therapy (PIVIT) also referred to as Hepatic Activation Therapy (HAT), Metabolic Activation Therapy (MAT), or Chronic Intermittent Intravenous Insulin Therapy (CIIIT). The services associated (i.e., office visits, physician directed infusions, blood glucose monitoring) with this therapy are noncovered, as they are associated with the administration of a usually self-administered

³ Local coverage policies issued by Medicare contractors were formerly referred to as LMRPs and are now known as Local Coverage Determinations (LCDs).

⁴ Citations to the record herein shall be to Master Exhibit File No. 1, unless otherwise indicated.

drug (i.e., insulin). All services associated with [this] therapy should be bundled and billed under the CPT code 99199. Individual services should not be billed under their respective payable CPT codes. PIVIT is added to the local noncoverage section of the LMRP effective for services rendered on or after March 24, 2003; however, services rendered prior to that date will also be considered noncovered.

Exh. 14, at 11 (emphasis in original).⁵

The carrier issued additional and more detailed information concerning claims for PIVIT by a clarifying article dated September 2008. Exh. 14, at 12, *citing* LCD L5780. The carrier stated that "[c]laims submitted to FCSO for this service will be denied as not being reasonable and necessary because this service/procedure is not scientifically proven to be effective, and is not within accepted standards of medical practice for the treatment of patients with diabetes. There is inadequate published scientific literature to permit conclusions regarding the effect of PIVIT on health outcomes." *Id.* The carrier explained that insulin was typically a self-administered drug and was therefore not covered incident to a physician's service in an office or clinic. *Id.* The carrier further explained:

The services associated with this therapy are also noncovered (i.e., physician directed infusions, blood glucose monitoring, oxygen uptake, expired gas analysis tests), as they are intrinsic to the service that is noncovered. Also, multiple units of expired gas analysis testing are never covered since it is not medically necessary or reasonable in any episode of care for a patient. All components associated with this therapy should be billed under CPT code 99199. . . . The beneficiary must sign an advance beneficiary notice (ABN) for each date of service.

* * * * *

Certain providers recognizing the local noncoverage of this service have submitted claims to FCSO for services under the routine cost in clinical trials assuming that they have met the requirements of deemed

⁵ Citations to the record herein shall be to Master Exhibit File No. 1, unless otherwise indicated.

clinical trials. CMS Manual System, Pub. 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Section 310.1 outlines this coverage. Services associated with PIVIT (e.g., oxygen uptake, multiple expired gas analysis tests/CPT codes 94681, 90765, 90766, etc.) are noncovered in clinical trials for PIVIT, as these services are never covered incident to in a physician's office for the infusion of insulin for patients with diabetes. These services should not be unbundled and billed to Medicare and the patient should have no liability. Also, the patient should be informed of the Medicare non-coverage of this service based on the LCD of 2003.

Id. (emphasis in original).

ALJ Substantial Deference to LCDs

An ALJ is bound by Medicare statutes, regulations, CMS rulings, and NCDs. 42 C.F.R. § 405.1060(a)(4). An ALJ is not bound by LCDs, "but **will** give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a) (emphasis added). If an ALJ declines to follow an LCD, the decision must explain the basis for not doing so. 42 C.F.R. § 405.1062(b). A decision not to follow an LCD is confined "only to the specific claim being considered and does not have precedential effect." *Id.* An ALJ "may not set aside or review the validity of an [LCD] for purposes of a claim appeal." 42 C.F.R. § 405.1062(c). However, "[a]n ALJ . . . may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title." *Id.*

A challenge to the validity of an LCD, as opposed to an appeal of a particular claim denial, may be undertaken by an aggrieved party pursuant to the rules codified at 42 C.F.R. part 426 subpart D. See Review of National Coverage Determinations and Local Coverage Determinations; Final Rule, 68 Fed. Reg. 63692, 63693. These appeal rights are distinct from the existing appeal rights for the adjudication of Medicare claims. *Id.* An aggrieved party may bring a challenge to an LCD before receiving an item or service or after the LCD has been applied, resulting in a coverage denial. *Id.* at 63694. "[A] successful challenge would permit the individual to have his or her specific claim reviewed without reference to the challenged policy." *Id.*

Liability for Noncovered Services

A beneficiary or supplier may be liable for the cost of an item or service that is not "reasonable and necessary" based upon prior knowledge of noncoverage. Section 1879(a) of the Act; 42 C.F.R. §§ 411.400, 411.404, 411.406; Medicare Claims Processing Manual (MCPM)(Pub. 100-04) Ch. 30, §§ 10-40.

A beneficiary is deemed to have knowledge of noncoverage based upon prior written notice from the supplier containing specific information, this notice sometimes referred to as an Advance Beneficiary Notice or ABN. 42 C.F.R. § 411.404(b); MCPM Ch. 30, § 40.3. A supplier is deemed to have knowledge of noncoverage, in part, when it informs the beneficiary before furnishing the services that the services are not covered. 42 C.F.R. § 411.406(d)(1). A supplier also has actual or constructive knowledge of noncoverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1),(3).

BACKGROUND

Between January 2, 2008, and April 30, 2008, the appellant provided multiple services to 348 beneficiaries listed on the attachment, as part of a clinical trial involving PIVIT. Dec. at 1; see Appendix A to ALJ Decision, Master Exhibit File No. 1. The appellant submitted assigned claims for these services to Medicare, including claims for "respiratory quotient" or "RQ" testing under CPT code 94681 (oxygen uptake, expired gas analysis, including CO2 output, percentage oxygen extracted). Dec. at 1.

Medicare carrier FCSO denied the claims in initial determinations and upon redetermination. Dec. at 1. These denials were upheld upon reconsideration by the Qualified Independent Contractor (QIC), on grounds that the RQ services were found to be an "integral component" of the PIVIT and were thus not covered by Medicare. *Id.*

ALJ Decision

The ALJ stated that the appellant appeared before him on April 16, 2009, on an unrelated matter. Dec. at 2. The ALJ then stated that for reasons of judicial economy, he proceeded with a pre-hearing conference on the instant case, in which he considered the record evidence, the testimony of appellant witnesses, CEO Nathan Nachlas, M.D. and Dawn Villacci, Vice President for Operations, and arguments of counsel Debra Parrish. *Id.* Ms. Parrish waived the right to a hearing. *Id.* The ALJ subsequently received position papers from both the Medicare carrier and the QIC, which he considered. *Id.*; see Exhs. 14 and 15. The ALJ framed the issue for decision as follows: "The issue in this appeal concerns whether Medicare Part B payment is warranted for six respiratory quotient (RQ) tests per treatment episode, claimed under HCPCS code 94681, provided by the Appellant to multiple Medicare beneficiaries enrolled in a clinical trial involving pulsatile intravenous insulin therapy ("PIVIT"), where RQ testing is a routine cost of clinically appropriate monitoring of the effects of the PIVIT treatment, in accordance with the Medicare National Coverage Determination (NCD) 310.1." *Id.*

In his findings of fact, the ALJ noted that the clinical trials were "sponsored by Florida Atlantic University with the purpose of exploring the effects of Pulsatile Intravenous (IV) Insulin." Dec. at 3 (Finding 5). The ALJ next stated that "[t]he clinical trials at issue are designed to monitor the effects of the Pulsatile IV insulin therapy through respiratory quotient (RQ) testing and frequent fingerstick testing." *Id.* (Finding 6). The ALJ further found that "[t]he clinical trial is designed around the 'Harvard Protocol,' which requires three infusions of pulsatile IV insulin per treatment episode with RQ testing before and after each pulsatile IV infusion." *Id.* (Finding 7). The ALJ then found that "[m]onitoring of the respiratory quotient (RQ) is central to the clinically appropriate monitoring of the effects of the Medicare covered clinical trial." *Id.* (Finding 8). The ALJ next found that the RQ measured oxygen inhaled and carbon dioxide exhaled and was "proportionate to the fuel sources being used by the body, primarily the liver over short periods of time." *Id.* (Finding 9). The ALJ finally found that "frequent monitoring of RQ is necessary as these levels change rapidly, depending on the fuel being utilized by the body. IV insulin given in pulses shifts metabolism from primarily fatty acid metabolism to primarily glucose metabolism." *Id.* (Finding 10).

In his analysis, the ALJ noted that PIVIT treatment was pioneered by Thomas Aoki, M.D., at Harvard University, and the development of the treatment was known as "the Harvard protocol." Dec. at 8. Dr. Nachlas, the appellant's CEO, testified that the appellant was "opened in an effort to reproduce results of the Harvard protocol and, through the clinical study, identify the types of diabetic patients who receive the most benefit from PIVIT/MAT treatment." *Id.*

The ALJ determined that that the appellant's clinical trials of PIVIT, sponsored by Florida Atlantic University, met the requirements of NCD 310 for coverage of routine costs. Dec. at 9. The ALJ noted that PIVIT was "investigational" and thus the subject of a clinical trial. *Id.* The ALJ then found that the "QIC denial of the RQ tests upon the premise that the RQ tests are an integral part of the PIVIT test, which is a non-covered, investigational service, is misguided in the context of a clinical trial." *Id.* The ALJ reasoned that the trials at issue "are designed to monitor the effects of the Pulsatile Insulin therapy through respiratory quotient (RQ) testing and frequent fingerstick testing." *Id.* The ALJ later stated that "[t]he RQ test is not part of the PIVIT infusion of pulsated insulin" and noted Dr. Nachlas's testimony that "the RQ test was not an integral component of the PIVIT treatment." *Id.* at 10. The ALJ then concluded that because the RQ testing was not a component of the PIVIT treatment, but was intended to monitor the effects of PIVIT, it fell within the coverage requirements of NCD 310 for routine costs of a clinical trial. *Id.*

The ALJ rejected application of LCD L5780, since "the inclusion of the PIVIT procedure code 99199 . . . does not bear on coverage of the RQ Test (CPT Code 94681)." Dec. at 10. The ALJ again noted that PIVIT was the subject of the clinical trial, whose purpose was "investigational." *Id.* The ALJ reiterated his earlier analysis, then stated that "the 'clinically appropriate monitoring' of the effects of the item or service" in a clinical trial were covered as routine costs. *Id.* The ALJ also noted that the language of the NCD did not prohibit billing for six RQ tests. *Id.* The ALJ found it "clear from the design of the clinical trial and from the testimony offered at the pre-hearing conference that the clinically appropriate monitoring involves six RQ tests per treatment episode." *Id.*

The ALJ stated that the evidence, including the testimony of Dr. Nachlas and Ms. Villacci, indicated that the Medicare carrier "actually asked the Appellant to participate in the clinical

trials which are the subject of this appeal." Dec. at 11. The ALJ then reasoned that "the Carrier either explicitly or implicitly adopted the 'Harvard protocol' which called for RQ testing to be performed at the beginning and the end of each of the three PIVIT treatment sessions (6 total RQ tests per date of service)." *Id.* The ALJ found that no overutilization had occurred. *Id.*

The ALJ concluded that the record evidence, "including the testimony and contentions presented during the hearing, [established that] the respiratory quotient (RQ) testing used to monitor the metabolism of the Medicare beneficiaries enrolled in the PIVIT clinical study qualifies as a routine cost of a clinical trial in accordance with NCD 310." Dec. at 11. The ALJ further concluded that the appellant submitted sufficient documentation to support its claims. *Id.*, citing Section 1833(e) of the Act, 42 C.F.R. § 424.5(a)(6).

Agency Referral and Appellant Exceptions

In its referral memorandum, CMS states that services billed under CPT code 94681 are the only services at issue in the referral. Exh. MAC-1, at 3. CMS argues generally that the ALJ erred in finding the RQ services billed under CPT code 94681 covered by Medicare as routine costs of a clinical trial. *Id.* at 1. CMS first contends that "PIVIT is expressly noncovered by the carrier's LCD, so the appellant's clinical trial does not qualify for routine costs." *Id.* at 2. CMS next contends that RQ testing under CPT code 94681 is a component service of CPT code 99199 under the carrier LCD, which "includes all services associated with PIVIT," and that the carrier instructed suppliers not to bill individual CPT codes separately. *Id.* CMS finally argues that the costs of six units of CPT code 94681 "per treatment session can never be considered routine." *Id.*

The appellant argues in its exceptions that NCD 310 is binding upon the ALJ and the Council, and that the NCD "explicitly states that Medicare will cover monitoring of an investigational service." Exh. MAC-2, at 2, 6. The appellant asserts that RQ testing is not "inherent in PIVIT and is covered by the carrier when PIVIT is not administered." *Id.* at 2. The appellant states that the record evidence, including testimony, establishes that "RQ is used to monitor the treatment." *Id.* The appellant then explains that "LCD L5780 . . . was retired by the carrier. A successor LCD issued by the carrier has been

challenged. The carrier does not have an LCD listing RQ as non-covered." *Id.* at 3.

DISCUSSION

According to CMS, both the carrier and appellant agree that the appellant billed Medicare for a typical PIVIT session with one unit of CPT code 90765 (IV infusion, 1st hour); two units of 90755 (IV infusion, each additional hour); six units of 94681 (respiratory quotient or RQ metabolic measurement); and 10-12 units of 82962 (home blood glucose test). Exh. MAC-1, at 9, *citing* Exhs. 3 and 14, at 4-5. The claims for each date of service do not usually reflect this protocol, but instead show differing amounts of some or all of these services. See, e.g., ALJ Decision, Appendix A, beneficiary G.A. (DOS 4/25/08: 1 CPT code 90765, 1 CPT code 90766, 5 CPT codes 94681, no CPT code 82962); beneficiary W.A. (DOS 3/6/08: 1 CPT code 90765, 1 CPT code 90766, 1 CPT code 94681, 1 CPT code 82962); beneficiary E.A. (DOS 3/26/08: 1 CPT code 90765, 1 CPT code 90766, 1 CPT code 94681); beneficiary J.A. (DOS 4/24/08: 1 CPT code 90765, 1 CPT code 90766, 6 CPT codes 94681, 2 CPT codes 82962). The number of units of CPT code 94681 provided thus varied from the "Harvard protocol" discussed by the ALJ.

The "official title" of the clinical trial is "Effects of Pulsatile IV Insulin *Delivery* on Peripheral Diabetic Neuropathy." Exh. 2, at 1 (emphasis supplied). The study began in February 2005 and is estimated for completion in January 2010. *Id.* The detailed description of the study includes the following:

Pulsatile IV insulin therapy encourages the glucose metabolism in diabetics to normalize in multiple organs, especially muscle, retina, liver, kidney and nerve endings. The process fundamentally requires the administration of high dose insulin pulses similar to those secreted by non diabetic humans by their pancreas into the surrounding portal circulation. Oral carbohydrates are given simultaneously to augment the process and prevent hypoglycemia. The process is monitored by frequent measuring of glucose levels and respiratory quotients (RQ). RQ is measured by a metabolic cart which determines the ratio VCO_2/VO_2 . This ratio is specific for the fuel used at any one time by the body. The glucose levels are monitored to

keep glucose levels appropriate and *the RQ determines the need to readjust the infusion protocol in each patient for subsequent insulin infusion sessions.* Pulsatile IV insulin therapy is done over 1-hour periods with a 1-hour rest period between each treatment. Three treatments are given during a patient visit to the center.

Frequent monitoring of RQ is necessary as these levels change rapidly, depending on the fuel being utilized by the body. IV insulin given in pulses shifts metabolism from primarily fatty acid metabolism to primarily glucose metabolism. This shift is reflected by the increase in respiratory quotient. However during rest periods the RQ may fall back to lower levels. Therefore *RQs are done at the beginning and at the end of each insulin infusion session in order to appropriately monitor and adjust insulin and carbohydrate loads to reach optimal activation in each session.*

The respiratory quotient (RQ) is a measurement of CO₂ exhaled and O₂ inhaled and is proportionate to the fuel sources being used by the body, primarily the liver over short periods of time. The higher the RQ, the more glucose and less alternative fuel sources are being utilized. Following the RQ change helps determine the effectiveness of physiological insulin administration in increasing anabolic functions in diabetic individuals. By improving the body's glucose metabolism and thereby causing beneficial effects of anabolic factors, the possibility of serious complications can be decreased. In addition the use of oral carbohydrate at the same time along with the physiologic insulin administration stimulates the appropriate gut hormones which augment this effect, a response which cannot be duplicated with intravenous glucose. The purpose of our studies is to determine whether the physiologic administration of insulin along with the augmenting effect of oral carbohydrates will normalize metabolism in diabetic patients and correlate with an improvement in their manifestations of diabetic neuropathy.

The RQ is determined by the use of a metabolic cart. Individuals breathe into a mask for 3-5 minutes after

a rest period of 30 or more minutes. The ratio of exhaled volume of CO₂ to the inhaled volume of O₂ is determined as the RQ. The physiologic range is 0.7 to 1.3. Individuals using fat as a primary fuel have a ratio of 0.7, protein or mixed fuels is 0.8 - 0.9 and carbohydrate is 0.9 - 1.0. Those taking excessive calories will have RQs higher than 1.05. *The amount of intravenous insulin and oral glucose given is determined by the RQ changes during the previous session.*

Exh. 2, at 2-3 (emphasis supplied).

The appellant's description of services for a typical PIVIT session, its claims to Medicare for these services, and its discussion of RQ services in the description of the clinical trial all reflect that RQ services were an integral and necessary component of the PIVIT "delivery" system. The appellant provided insulin infusion in addition to the exhaled air analysis billed under CPT code 94681. The clinical trial description states that the purpose of RQ is to measure the source of fuel used by the subject's body and that insulin and carbohydrate administration were changed based upon RQ results.

The Council therefore finds that the ALJ erred in finding that the evidence, including testimony, established that "the RQ testing procedure . . . is not a component of the PIVIT treatment." Dec. at 10. RQ testing was provided during each session for purposes of determining whether the amount of insulin and/or carbohydrates provided should be altered during subsequent PIVIT sessions. The purpose and outcome of the RQ tests were critical components of PIVIT and affected clinical decisions during the process. Such services do not fall within the definition of "monitoring" the subject of a clinical trial for Medicare coverage of routine costs under NCD 310.

The Council also notes that, under the ALJ's interpretation, there can be no item or service that could be the subject of a clinical trial. The appellant submitted claims for IV infusion, RQ testing, and/or home blood glucose testing for the dates of service at issue.⁶

⁶ Because the Council confines its analysis to the exceptions in the agency referral, the Council does not address coverage of other services, including

The appellant thus appears to have intended that each service provided during PIVIT sessions be covered by Medicare as a routine cost associated with a clinical trial. The Council finds that this interpretation, which, in effect, would provide that all services provided during a clinical trial constitute the routine costs of that trial, is contrary to both the NCD and LCD.

The Council's research provides further support for its conclusion that RQ testing is an integral component of PIVIT and thus within the ambit of LCD L5780.⁷ PIVIT is the subject of at least seven current and retired local coverage policies or articles issued by Medicare contractors in other jurisdictions. See "LCD for Diabetes Mellitus Therapy Using Hepatic Activation or PIVIT Therapy (L28252)," (Palmetto GBA - Northern California; Southern California; Hawaii, American Samoa, Guam, and Northern Mariana Islands; and Nevada);⁸ "LCD for Diabetes Mellitus Therapy Using Hepatic Activation or PIVIT Therapy (L9654)," (NHIC, Corp. - Northern California, Southern California) (Retired); "Article for PIVIT, Metabolic Activation, or Hepatic Activation Therapy for Diabetes Mellitus (A27223)," (Regence Blue Cross and Blue Shield of Utah - Utah). In each case, the contractor found that PIVIT was not covered by Medicare, in non-coverage policies dating back to 2002. Each LCD or Article lists CPT codes that are subject to its provisions, and those CPT codes include, in all LCDs, CPT codes 94681 and 82962, as well as CPT codes for IV infusion. The effective dates of the LCDs are prior to the dates of service in this case.

FCSO, the carrier in this case, issued a local noncoverage policy for PIVIT, under global CPT code 99199 for "unlisted special service, procedure or report," that was effective

the use of home blood glucose monitoring tests in a clinical trial. 42 C.F.R. § 405.1110(c).

⁷ Contrary to the appellant's assertion (Exh. MAC-2, at 3), LCD L5780 was in effect during the dates of service at issue, and the appellant provides no evidence of a successful challenge that would preclude application in this case. 68 Fed. Reg. at 63694.

⁸ The ALJ refers to Dr. Thomas Aoki as the originator of PIVIT at Harvard University and "the Harvard protocol." Dec. at 8. Medicare carriers Palmetto GBA, NHIC, Corp. and Regence Blue Cross and Blue Shield of Utah considered Dr. Aoki's research and articles in issuing their LCDs, which provide that PIVIT and its constituent parts are not covered by Medicare. See, e.g., LCD L28252 ("Sources of Information and Basis for Decision").

March 24, 2003. Exh. 14, at 11. The FCSO list of noncovered services stated that all services associated with PIVIT should be bundled into CPT code 99199 in any Medicare claims. *Id.* FCSO subsequently clarified this policy to make explicit the prohibition on separately billing Medicare for PIVIT components, including claims for CPT codes 94681 (RQ testing), 90765 (IV infusion), and 90766 (IV infusion) billed as routine costs of clinical trials. *Id.* at 12.

The Council thus finds that the ALJ erred in concluding that claims submitted by the appellant under CPT code 94681 do not fall within the ambit of LCD L5780's long-standing non-coverage policy for PIVIT, including non-coverage for PIVIT component services that have been unbundled and billed separately. While neither the Council nor the ALJ are bound by local coverage policies or CMS manual or program guidance, the Council sees no basis for not affording substantial deference to LCD L5780 and its predecessor LMRP in these cases. 42 C.F.R. § 405.1062.⁹

The Council also finds that LCD L5780 does not conflict with NCD 310. The NCD provides that routine costs of a clinical trial do not include the investigational item or service itself. NCD 310.1. The NCD also provides that "[f]or non-covered items and services . . . , Medicare only covers the treatment of complications arising from the delivery of the non-covered item or services and unrelated reasonable and necessary care." *Id.* The record establishes that PIVIT therapy, including component infusion and RQ services, are "non-covered items and services" under LCD L5780. The Council finds that the RQ services provided during the clinical trials are not routine costs of those trials under NCD 310 and are not reasonable and necessary under section 1862(a)(1)(A) of the Act.

⁹ Because the Council finds that the services are not covered under the carrier local coverage policy, the Council does not reach the issue of whether the clinical trials "qualify" for coverage of routine costs. NCD 310.1.A. Similarly, because FCSO confirmed and clarified the coverage denial for PIVIT and its component parts in the September 2008 issue of the FCSO Medicare Part B Update (Exh. 14, at 12), the Council rejects the ALJ's finding that the carrier had either implicitly or explicitly adopted the "Harvard protocol" for PIVIT in clinical trials. Dec. at 11.

The record does not reflect, and the appellant does not contend in its exceptions, that the beneficiaries received prior written notice of noncoverage. The Council finds that the beneficiaries are not liable for noncovered services. The Council finds that the appellant had the requisite knowledge of noncoverage based upon CMS and carrier issuances, including LCD L5780, and is liable for the noncovered services.

DECISION

It is the decision of the Medicare Appeals Council that the claims for oxygen uptake, expired gas analysis, including carbon dioxide output, percentage oxygen extracted, provided to the beneficiaries and billed under CPT code 94681, are not reasonable and necessary and are not covered by Medicare. The appellant is liable for the noncovered services. The decision of the ALJ is reversed.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/ M. Susan Wiley
Administrative Appeals Judge

Date: August 26, 2009