Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re LCD Complaint:

Services That Are Not Reasonable and Necessary
LCD ID Number: L35094
Contractor: Novitas Solutions, Inc.

Docket No. C-16-901

Decision No. CR4870

Date: June 16, 2017

DECISION

This case involves a Medicare beneficiary (herein "aggrieved party" or "AP") who has challenged the portion of Local Coverage Determination (LCD) L35094, "Services That Are Not Reasonable and Necessary," that pertains to medical treatment by monitoring central blood pressure using arterial pressure waveform analysis (APWA). A Medicare administrative contractor, Novitas Solutions, Inc. (Novitas or "the contractor"), issued the LCD barring coverage for APWA in the geographic territory it oversees, which includes the AP's state of residence, New Jersey. For the reasons stated herein, I find the LCD is reasonable.

I. Background

The AP has chronic hypertension, abdominal aortic ectasia, and atrial fibrillation. AP Exhibit (Ex.) 2 at 3. His treating doctor reports that he has treated the AP for 14 years and that "an examination of his aortic waveform as a source of late systolic load and wave reflection at varying RR intervals would be of therapeutic benefit in managing his conditions." AP Ex. 2 at 3. The treating doctor explained that "[k]nowledge of central blood pressure via the central arterial pressure waveform using the SphygmoCor System has enabled me to obtain better blood pressure control for my patients." AP Ex. 2 at 2. The treating doctor explained that blood pressure measurements obtained through use of a brachial cuff "do not provide precise information about central aortic blood pressure and related indices from the arterial pressure waveform," and that he believes that the SphygmoCor System "is clinically useful and medically necessary for managing patients who are receiving drug therapy for their hypertension." AP Ex. 2 at 1-2.

In January 2016, Novitas revised, as relevant here, LCD 35094, entitled Services That Are Not Reasonable and Necessary. AP Ex. 1 at 30-31. Novitas explained that "the purpose and usefulness of the LCD" is that it "identifies services that have been evaluated and deemed not to meet, as of yet, the reasonable and necessary evidentiary standard, e.g., as is the case for services that have been determined to be clinically ineffective or that are emerging technologies." Novitas Response, at 2. At the time Novitas determined that APWA would be non-covered, it explained that Current Procedural Terminology (CPT) "code 93050 (Art[erial] waveform pressure analys[is]) is replacing Category III code 0311T as non-covered." AP Ex. 1 at 4. Novitas discussed that the American Medical Association had designated CPT Category III codes "to allow for data collection concerning the use of 'emerging technology, services, and procedures,'" and that the designation of a CPT Category III code for a procedure "neither implies nor endorses clinical efficacy, safety or the applicability to clinical practice." AP Ex. 1 at 4. Novitas further explained that it would "initially consider the item, service, or procedures . . . to not be reasonable and necessary." AP Ex. 1 at 4. Novitas explained that it "reserves the right to review the safety and efficacy of the treatment in comparison to existing treatment, both in peer-reviewed literature and in clinical application before making a determination of local coverage," and that "[i]f providers believe that any of the Category III codes have been proven safe and effective, those providers may request removal of the code from the list through the Novitas LCD Reconsideration Process." AP Ex. 1 at 3. Novitas referenced eleven sources in its LCD.[1] AP Ex. 1 at 13.

The AP reports that he filed the Complaint because he believes that Novitas will deny coverage for APWA testing. AP Complaint, at 4. On September 8, 2016, the AP filed the Complaint pursuant to 42 C.F.R. § 426.400, asking that an administrative law judge (ALJ) "invalidate the LCD, or the offending provisions identified herein, thereby allowing him to receive the reasonable and necessary testing he needs."[2] AP Complaint, at 2. In support of his complaint, the AP included 20 exhibits, to include declarations from his treating physician and a registered nurse[3], along with ten "clinical articles where arterial

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[1] Subsequent revisions of the LCD address additional sources. *See* Novitas Exs. 1, 3; Novitas Response, at 7.

[2] The LCD addresses numerous unrelated services that Novitas has determined are not reasonable and necessary. This decision addresses only the service that is the subject of the AP's complaint.

[3] The declarant, an employee of AtCor Medical who is "[r]esponsible for implementation and on-going follow-up with clinical providers related to [the] use of arterial pressure waveform analysis in hypertension management," addressed the SphygmoCor system in her written testimony. AP Ex. 9 at 1, 3.

pressure waveform analysis was used to demonstrate the effectiveness of medication on central blood pressure." AP Exhibit List; AP Exs. 11-20.

In an Order dated September 27, 2016, I determined that the AP had filed an acceptable complaint pursuant to 42 C.F.R. § 426.410(b). Thereafter, in compliance with my September 27, 2016 Order and 42 C.F.R. §§ 426.418 and 426.419, Novitas submitted the LCD Record on November 21, 2016.[4] After it received the LCD record, the AP submitted an additional exhibit, a declaration by a Senior Vice President and General Manager of AtCor Medical, along with its Statement as authorized by 42 C.F.R. § 426.425(a) (AP Statement).[5] *See* AP Ex. 21. Novitas submitted its response as authorized by 42 C.F.R. § 425.425(b) (Novitas Response) on April 12, 2016.

The record of this case is closed. There are no pending evidentiary objections, and neither party has requested a live hearing for the purpose of obtaining testimony or cross-examination. The record consists of the AP's Complaint, the AP's Statement, the Novitas Response, AP Exs. 1 through 21, and Novitas Exs. 1 through 33.

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act ("the Act"), codified at 42 U.S.C. § 1395j, establishes the supplementary medical insurance benefits program for the aged and the disabled known as Medicare Part B. Section 1862 of the Act (42 U.S.C. § 1395y) 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 the Department of Health and Human Services has promulgated implementing regulations, to include

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[4] In an Order dated December 12, 2016, I denied the contractor's motion to seal certain documents pursuant to 42 C.F.R. §§ 426.418(b) and 426.419(b). In consideration of the contractor's concern about the disclosure of personally identifiable information of health care providers, I have not identified the physicians who requested reconsideration of the LCD.

[5] The declarant's curriculum vitae indicates that, as a vice president of AtCor Medical, he "[e]stablished North American subsidiary of Sydney, Australia-based parent, commercializing SphygmoCor central blood pressure/arterial stiffness assessment technology, with sales to researchers, clinical practitioners, and pharmaceutical companies." AP Ex. 21 at 3.

rulemaking 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 Centers for Medicare & Medicaid Services (CMS) has established policy, through the Medicare Benefit Policy Manual (CMS Pub. 100-02, Ch. 16, §§ 10 and 20) that 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. An LCD, as defined by the Act, is "a determination by a fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered" within the area covered by the contractor. Act, Section 1869(f)(2)(B) (42 U.S.C. § 1395ff(f)(2)(B)). The regulations implementing sections 1869(f)(1) and (f)(2) of the Act are found at 42 C.F.R. Part 426. The procedures for review of an LCD are contained in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et seq.*).

In deciding the AP's challenge to the LCD, I must decide whether the LCD satisfies the reasonableness standard of 42 C.F.R. § 426.110. 42 C.F.R. § 426.425(c). The reasonableness standard provides the following, in pertinent part:

> In determining whether LCDs . . . 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 . . . are reasonable based on the LCD . . . NCD record and the relevant record developed before the ALJ . . . .

Additional discussion of the reasonableness standard is contained in the final rule published at 68 Fed. Reg. 63,692, 63,703-04 (November 7, 2003), which includes the following discussion:

> We are using the statutory language from sections 1869(f)(1)(A)(iii) and (f)(2)(A)(i)(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. 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 decision making, 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. 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. 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.

Id. In reviewing the AP's complaint, I must determine whether the LCD record is complete and adequate to support the validity of the LCD provisions under the "reasonableness standard." Consistent with the discussion above, I will find an LCD valid "'if the findings of fact, interpretations of law, and applications of fact to law by the contractor . . . are reasonable' based on the record developed" pursuant to 42 C.F.R. part 426. *LCD Complaint: Glucose Monitors, (L11530/L33822 and Local Coverage Articles A33614/A52464)*, DAB No. 2782 at 4 (2017) (citing 42 C.F.R. §§ 426.110, 426.300(a), 426.425(c)(1), and 426.476(b)(1)). In determining whether the LCD is reasonable, I do not substitute my own policy judgments or determinations regarding whether a procedure should be covered, but rather, I determine whether the LCD is reasonable. Further, I do not determine whether a particular Medicare beneficiary, namely the AP, would individually benefit from the procedure at issue. Rather, I determine whether the LCD is reasonable as applied to all beneficiaries affected by the LCD.

For the reasons stated herein, I find that the LCD record is complete and the LCD satisfies the reasonableness standard. 42 C.F.R. § 426.450(a)(1) and (4).

B. The LCD

The pertinent provisions of the LCD state:

> **Services considered not reasonable and necessary:**
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> The American Medical Association (AMA) develops Current Procedural Terminology (CPT) Category III codes to allow for data collection concerning the use of "emerging technology, services, and procedures." The creation of a CPT Category III code by the AMA neither implies nor endorses clinical efficacy, safety or the applicability to clinical practice. Because of the specific purpose these Category III codes serve, the contractor will initially consider the item, service, or procedure represented by these codes to be not reasonable and necessary.
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> Specific services considered not reasonable and necessary, per the following previous Novitas evaluations:
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> * * *
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> 3. Category III code 0311T (Central Blood Pressure Management) has been denied as not reasonable and necessary. (Position reaffirmed upon reconsideration). CPT code 93050 (Art[erial] pressure waveform analy[is]) is replacing Category III code 0311T as non-covered.

Novitas Ex. 3 at 3; *see also* AP Ex. 1 at 4; Novitas Ex. 1. LCD 35094 precludes reimbursement for APWA under Medicare Part B. Novitas Ex. 3; *see also* AP Ex. 1, Novitas Ex. 1.

C. Issue

The issue in this case is whether the LCD 35094, satisfies the reasonableness standard defined by 42 C.F.R. § 426.110.

D. Findings of fact and conclusions of law[6]

1. The LCD record is complete and adequate to support the validity of the LCD provision at issue and I find the LCD is valid under the reasonableness standard.

Pursuant to Section 1862(a)(1)(A) of the Act, payment may not be made under Medicare Part B for a service that is not reasonable and necessary. Pursuant to 42 C.F.R. § 400.202, a Medicare contractor may issue an LCD determining whether it will cover an item or service under section 1862(a)(1)(A) of the Act. The Medicare Program Integrity Manual (MPIM) instructs that a service is reasonable if the contractor determines that a service meets the following criteria:

• Safe and effective;

• Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and

• Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

• Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

• Furnished in a setting appropriate to the patient's medical needs and condition;

• Ordered and furnished by qualified personnel;

• One that meets, but does not exceed, the patient's medical need; and

[6] Findings of fact and conclusions of law are in italics and bold font.

> • At least as beneficial as an existing and available medically appropriate alternative.

MPIM, § 13.5.1 (Rev. 473, eff. January 15, 2013). The MPIM also instructs contractors of the basis for an LCD, stating:

> Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:
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> • Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
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> • General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
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> > • Scientific data or research studies published in peer-reviewed medical journals;
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> > • Consensus of expert medical opinion (i.e., recognized authorities in the field); or
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> > • Medical opinion derived from consultations with medical associations or other health care experts.
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> Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

MPIM, § 13.7.1 (Rev. 473, eff. January 15, 2013).

The AP argues that APWA is "important and well-proven and accepted," and there are "extensive studies supporting its clinical effectiveness and utility." AP Complaint, at 1. The AP further argues that it is a "safe and effective method to detect, monitor and manage

high central blood pressure." AP Complaint, at 4. The AP also contends that "[w]ithout APWA, Medicare beneficiaries . . . would require a much more invasive, risky, and expensive procedure to assess their central blood pressure." AP Complaint, at 5. The AP argues that two commercial payers cover the procedure, along with CHAMPVA, TRICARE, and a number of other Medicare administrative contractors.[7] AP Statement, at 3-4. The AP argues that the "LCD is contrary to the evolved standard of care." AP Statement, at 6.

Novitas argues that "arterial pressure waveform analysis is an emerging technology with current data demonstrating unclear evidence of clinical efficacy with no determination on long-term health outcomes." Novitas Response, at 1. Novitas further explains:

> Novitas, consistent with its responsibility as a [Medicare Administrative Contractor], cannot determine that arterial pressure waveform analysis is reasonable and necessary under 1862(a)(1) of the Social Security Act . . . to allow coverage for [SphygmoCor] until additional scientifically valid data emerges. Given that the procedure is emerging and more studies are being reported, the Contractor is hopeful that valid studies will become more prevalent in the near future. As such studies become available, the Contractor will be in a position to determine which coverage under the Medicare program is reasonable and necessary for Medicare beneficiaries.

Novitas Response, at 2. Along those lines, Novitas plainly states in its response that "[a]s more evidence develops and higher quality literature is available, the service may be eligible for coverage." Novitas Response, at 12.

The LCD record indicates that since initially including APWA in the LCD, Novitas has reviewed submitted literature and determined that coverage of APWA is not supported. Novitas Exs. 1, 3. Novitas has explained that it is "hopeful that valid studies will become more prevalent in the near future" and that it "will be in a position to determine whether

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[7] Without any citation or reference to supporting evidence, other than a declaration by an AtCor Medical executive (*see* AP Ex. 21), the AP contends that National Government Services (NGS), a Medicare administrative contractor, "currently provide[s] coverage and payment for APWA . . . ." AP Statement, at 4. However, Novitas has cited evidence, through a link to NGS's website, that NGS "explicitly did not cover arterial pressure waveform analysis." Novitas Response, at 13. Likewise, and again without citing to any supporting evidence other than the declaration submitted as AP Ex. 21, the AP claims that Cigna "provide[s] coverage of APWA." AP Statement, at 3. In response, Novitas refers to Cigna's website, which clearly indicates that Cigna *does not* cover APWA. Novitas Response, at 13.

coverage under the Medicare program is reasonable and necessary for Medicare beneficiaries." Novitas Response, at 2. Novitas explained that it considered, in "most to least methodologically rigorous" order, various medical evidence submitted by the AP and considered the evidence to be "moderate to low quality based on study limitations (inadequate controls, small numbers), lack of long term health outcomes and showing of reduction in morbidity and mortality over brachial pressure." Novitas Response, at 6. Novitas has accepted and reviewed 22 studies involving APWA and determined that "[n]one of the studies were randomized controlled trials comparing the arterial pressure waveform analysis to standard brachial cuff pressure standard pressure analysis" and that the "initial studies submitted were a manuscript from a symposium and not a case study or random controlled trial or any sort of trial evidence." Novitas Response, at 7-8. Novitas observed that patients who underwent APWA in the submitted studies "typically are small studies of health populations with age ranges and geography that do not correlate to the Medicare population." Novitas Response, at 8.

While the AP contends that APWA is the "standard of practice," it has not supported this contention or otherwise supported its claim that there is general acceptance of APWA by the medical community. AP Statement, at 3-4. For example, a November 2015 article cited by Novitas in the LCD takes an apparently favorable view of central blood pressure monitoring, yet nonetheless indicates that "[a]lthough data on direct [cardiovascular] beneficial impact of central [blood pressure] treatment in randomized clinical trials *are still lacking*, the above mentioned indirect indices support the clinical importance of central [blood pressure] assessment." Novitas Ex. 6 at 5 (emphasis added); *see* CMS Ex. 3 at 14. The same article noted that findings in other studies "highlight *the need* for the identification of *specific populations* that might benefit more from central [blood pressure] assessment and provide the basis for further investigations," and that clinical trials "*might* pave the way for the consideration to enter central [blood pressure] assessment in the clinical management of hypertension." Novitas Ex. 6 at 5 (emphasis added). A study such as this one provides support for the contractor's position that APWA is an emerging procedure and that it is hopeful that "valid studies will be prevalent in the near future." Novitas Response, at 2.

A review of the literature submitted by the parties supports that the LCD is reasonable, particularly the articles primarily relied upon by physicians who requested reconsideration of the LCD.[8] In fact, the AP relies on the reconsideration requests submitted by six

[8] The AP states that "APWA has been the subject of hundreds of peer-reviewed publications in the medical literature which show APWA is safe and effective for the treatment of hypertension, many highlighting key distinctions between brachial and central pressures among individuals." AP Statement, at 5. While the AP has not referenced hundreds of peer-reviewed articles in support of this assertion, it referenced AP Exs. 11,

12, 17, 18, and 20. Further, the AP cites to AP Exs. 11 and 12 in support of its statement that "APWA provides a noninvasive method for monitoring central blood pressure and the aortic pressure waveform, thus allowing physicians to add vital information to the hypertension management decision process." AP Statement, at 3. While I will not discuss every cited article in the LCD record or that has been submitted by the AP, I note that articles discussed below do not support that coverage by Medicare Part B for APWA is "reasonable and necessary."

AP Ex. 11: The authors, in a 2015 symposium manuscript that is based on only *six* clinical case examples, state: "The use of pulse wave analysis may guide the provider in making choices about blood pressure treatment in prehypertensive or hypertensive patients. However, there is little clinical guidance on how to interpret and use pulse wave analysis data in the management of these patients." AP Ex. 11 at 1. The authors conclude that "there is little in terms of practical guidance in the published literature, outside of research studies, on using central pressure readings clinically." AP Ex. 11 at 10. I note that the primary author of this paper requested reconsideration of the LCD. *See* Novitas Ex. 27. The manuscript includes a disclosure that the symposium was "supported by an unrestricted grant to North American Artery from AtCor Medical, which covered travel costs and a small stipend for attendees." AP Ex. 11 at 10.

AP Ex. 12: The study, which was funded in part by AtCor Medical (AP Ex. 12 at 7), reports: "To our knowledge, this is the first randomized trial specifically designed to test the efficacy of using central BP monitoring to guide therapy in patients with hypertension." AP Ex. 12 at 6. The study determined that its "findings provide extra impetus to undertake large, hard-end point trials on the efficacy of central [blood pressure] assessment in hypertension management." AP Ex. 12 at 7. The study's authors acknowledged a limitation that "[s]tudy participants comprised relatively healthy, older white, lower-to-moderate-risk patients with uncomplicated hypertension, and the results should not be generalized to populations beyond this presentation." AP Ex. 12 at 7. The primary author of the study disclosed that he "received a grant from AtCor Medical to support this study." AP Ex. 12 at 7.

AP Ex. 17: The study was not designed to assess the effectiveness of APWA in a population representative of the Medicare beneficiary population. Rather, the researchers "assessed whether aortic [blood pressure] enhances the ability to identify independent relationships between [blood pressure] and target organ chances in the normotensive range and whether 'optimal' aortic [blood pressure] thresholds may refine the ability to identify organ damage in the normal/high-normal range." AP Ex. 17 at 2. The study participants included "nuclear families of black African ancestry consisting of siblings with a minimum age of 16 years [who] were randomly recruited from the South West Township

doctors as support for this assertion. Novitas Exs. 26-33. However, the medical articles relied on by the physicians who requested reconsideration of the LCD do not demonstrate acceptance of APWA as the "standard of practice," particularly for the Medicare beneficiary population. Five of the submitted reconsideration requests cite to a November 2015 study submitted as AP Ex. 19. (AP Exs. 27, 28, 29, 30, and 31). The study's authors acknowledged that the "study population is limited to American Indians" (AP Ex. 19 at 4), and I observe that the study participants in the Strong Heart Study included "13 American Indian Tribes and communities in four states: Arizona, Oklahoma, South Dakota, and North Dakota" with a population age of 45-74. AP Ex. 19; *see* *http://strongheart.ouhsc.edu/#_Participating_Communities* (last visited June 6, 2017); Novitas Response, at 11. While this study is cited by several of the physicians who argued against the LCD, it is noteworthy that the study was not a randomized control trial and involved a homogeneous population with a younger age than the typical Medicare beneficiary (with approximately two thirds of the participants being under age 65). AP Ex. 19 at 4. Such a study, which reported that "preliminary evidence *suggests* that achievement of a lower central BP for a given level of brachial [blood pressure] *may b*e more effective . . . ," does not make any definitive finding supporting that monitoring of central blood pressure through APWA is reasonable and necessary, or is the "standard of care," as alleged by the AP. AP Ex. 19 at 5. The AP, and the physicians who requested reconsideration, rely on another study, submitted as AP Ex. 20.[9] *See* AP Exs. 27, 29, 30. This study involved a population with a mean age of 63 (AP Ex. 20 at 5), which is again considerably younger than the Medicare beneficiary population. More importantly, the study focused on the effectiveness of medications on central pressure rather than the use of the APWA procedure. AP Ex. 20 at 12. Additionally, the study did not show there were improved outcomes with the use of central pressure assessment versus brachial pressure assessment, and thereby, the study does not support that APWA is reasonable and necessary. AP Ex. 20. Finally, two of the doctors who submitted reconsideration requests cited to AP Ex. 18 in support of their requests. *See* AP Exs. 27, 29. However, the study submitted as AP Ex. 18 involved a small trial of 80 patients with an age ranging from 35 to 65, which is yet again well below the typical age of the Medicare population, and the study focused on the use of beta blockers; the study did not address whether central blood pressure monitoring is more effective than brachial blood pressure monitoring, nor did it address whether APWA is an effective means of measuring central blood pressure. AP Ex. 18.

(SOWETO) of Johannesburg, South Africa," and therefore, the study participants were not representative of the overall Medicare beneficiary population. AP Ex. 17 at 2.

[9] One author disclosed that he "is the founder and medical director and a board member" of AtCor Medical and is an AtCor Medical shareholder. AP Ex. 12 at 12.

I therefore find that the portion of the LCD at issue is valid and reasonable under the reasonableness standard.

2. The AP's challenge to LCD 35094 is denied.

Since I find that the LCD record is complete and adequate to support the validity of the challenged LCD under the reasonableness standard, "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). I therefore deny the challenge to LCD 35094, Services That Are Not Reasonable and Necessary.

/s/
Leslie C. Rogall
Administrative Law Judge