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# Medicare

## Comments and Responses Regarding Draft Local Coverage Determination: Cardiac Output Measurement Thoracic Electrical Bioimpedance

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Cardiac Output Measurement Thoracic Electrical Bioimpedance LCD. The official notice period for the final LCD begins on October 1, 2007, and the final determination will become effective on December 1, 2007.

*Comment:* A commenter questions the decision of non-coverage for drug-resistant hypertension, saying that 70% of states cover this. He asks that we reconsider and provide some form of limited coverage for drug-resistant hypertension. If inappropriate utilization is a concern, consider covering only the most severe cases (malignant hypertension) or those in which significant comorbidities exist (heart failure and renal disease). Also consider requiring manual submission of records to demonstrate that the patient was indeed on three drugs including a diuretic and that the information was used in the management of the patient.

If we cover this, he notes that they previously submitted a list of payable ICD codes for drug resistant hypertension.

It is accepted by Medicare providers that ICD-9 codes that are not listed in an LCD as supporting medical necessity are not covered. By listing the ICD-9 codes that Cardiodynamics proposed to NGS under the section titled "ICD-9-CM Codes that DO NOT Support Medical Necessity," you have taken an unnecessary step that no other carrier has in developing their TEB policy. Therefore we request that this section be removed.

*Response:* We recognize the variation of this service across the many jurisdictions. However, it is the responsibility of each contractor (per the NCD) to make its own determination. A review of the national coverage database (on August 11, 2007) revealed that there were only 19 jurisdictions with LCDs for this service (93701). Of these, 17 did not cover drug resistant hypertension, one did cover it and the other was silent covering only some hypertension ICD-9 codes. National Government Services

has not received sufficient new peer-reviewed literature to cover TEB for treatment of “drug resistant” hypertension.

As the commenter has indicated these ICD-9 codes are not covered since they are not included in the covered section. Their listing in this section does not change the intent of the LCD. However, it does serve to further clarify the limits of coverage for providers. This technique is used in other National Government Services LCDs where we believe such clarification is helpful to the providers in recognizing the extent of reimbursement for the service in question. We will retain the codes listed in the “DO NOT Support Medical Necessity” section.

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*Comment:* The commenter asks that we remove or revise limitations related to:

(Limitation #2): Professional component not being covered in hospital as it does not require performance by a physician; he states that for code 93701, the professional component does require a physician. Prior to the American Medical Association’s approval of CPT code 93701 in 2002, the HCPCS code for TEB was level II code, M0302. When Medicare established the RVUs for the TEB service in the 2000 Federal Register (Volume 65, No. 212, pages 65411-65412), they stated the following: “The physician work required for performance of this service involves reading and interpreting a series of numerical measurements... We believe that this physician work is most similar to the work of interpreting an EKG and have assigned a work RVU of 0.17 for the professional component of cardiac bioimpedance.” However, the 2000 Federal Register notice did state: “We will also bundle the professional component into critical care when critical care services are furnished, since critical care service includes the review of such tests.” Therefore, we suggest your final LCD state language to this effect.

*Response:* (Limitation #2) The measurement of cardiac output and other hemodynamic parameters by this methodology requires the hook-up of the equipment to a patient by a nurse or technician. The test is run automatically without physician involvement and the results are automatically printed in a graphic and numeric output. There is no physician involvement required to determine the results. The results of the test are immediately available to be used by the medical and nursing staff treating a patient. These results are used in the medical decision-making portion of an E&M service to treat the patient. Since the test does not require the services of a physician to perform or output usable results, it is not payable to a physician in this setting, and the test is reimbursed to the hospital under Part A payments to the hospital.

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*Comment:* (limitation #7): Tests performed during the course of anesthesia monitoring are excluded from reimbursement per NCD 20.16. There is no specific exclusion of reimbursement for TEB, only during cardiac bypass surgery.

*Response:* (limitation #7) The test is not separately paid to physicians providing anesthesia as this is included in the “anesthesia care” as monitoring of the patient. Those services that are separately billable are discreet procedures such as the insertion of a pulmonary catheter and arterial catheters for

monitoring. The monitoring of patients using these special lines is not separately payable. The same logic is true here. The use of any specialized device to monitor patients during anesthesia is not separately reimbursed. It is part of the anesthesia care.

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*Comment:* (limitation #8): Tests performed incident to other diagnostic tests or therapeutic procedures are not covered for monitoring, except for patients treated with inotropic support at home. While TEB is not typically performed incident to other tests or therapies, there is no specific exclusion of reimbursement per NCD 20.16 in these cases. If the patient meets one of the nationally-approved indications, the TEB test is considered reasonable and necessary – independent of whether other tests and therapies are being administered during the same visit.

*Response:* (limitation #8) The TEB is not separately payable as part of other diagnostic tests. Such use would not be consistent with the NCD on this service.

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*Comment:* (limitation #11): TEB is considered not medically necessary when performed on patients with compensated CHF, compensated cardiomyopathy, or hypertension. TEB is nationally covered for “Optimization of fluid management in patients with congestive heart failure when medical history, physical examination and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data is necessary for appropriate management of the patient.” All congestive heart failure patients in need of fluid management are compensating to some extent to maintain their cardiac output through the neurohormonal system, the renin-angiotensin-aldosterone system, and/or cardiac function (heart rate, electro-mechanical timing, filling pressures). Therefore, we believe it is inappropriate to state the TEB test is not covered in compensated heart failure. Instead, if we read your intention correctly, we suggest you state the test is not covered for the patient without signs or symptoms of congestive heart failure.

*Response:* (limitation #11) The national coverage determination does allow for the use of TEB for the fluid management of patients with congestive heart failure. However, it remains silent on the definition of congestive heart failure and “fluid management.” It is up to the contractor to define these issues, and which patients require TEB for fluid management. The NCD permits coverage only for optimization of fluid management in patients with congestive heart failure when medical history, physical examination and standard assessment tools provide insufficient information. This requirement does not include patients whose heart failure is not decompensated. While we recognize the scientific validity of the commenter’s discussion of “compensated”, his suggestion that we substitute “without signs or symptoms of congestive heart failure” could be inconsistent with the concept of management that requires additional data. In a patient who is at a stable level of function, and for whom optimal therapy is achieved (although possibly still symptomatic or with continuing signs of heart failure) this test would be considered to be not medically necessary, consistent with the NCD. Consequently, we will amend the language to indicate that TEB is not covered for the optimization of fluid management in those patients in whom heart failure is stable or has not

*decompensated* (i.e., the endogenous mechanisms plus standard of care have failed to optimize the patient's heart failure.)

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*Comment:* (limitation #12): If the use of TEB is not supported by documented changes in the clinical exam and provide for a level of clinical decision-making beyond the findings of the history and physical examination, then the service will be denied as not medically necessary. Like all diagnostic tests, TEB information may or may not change clinical decision-making. Whether a test changes clinical decision-making is unrelated to whether a provider receives reimbursement for the test. A requirement that clinical decision-making must change as a result of the TEB test places an inappropriate burden on the provision of the test that is not applied to other diagnostic tests. For example, one might assume from your proposed language that the TEB test is not covered, whereas the physician, who has completed a clinical examination and has equipoise with regard to the patient's status, may order a TEB test only to confirm the clinical examination findings and maintain current therapeutic plan. Medicare has stated in NCD 20.16 that the burden that is required for the test to be covered is "when medical history, physical examination and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data is necessary for appropriate management of the patient." While carriers could request that the provider document why the TEB test was necessary, they cannot require that clinical decision-making change as a result of the TEB test. By definition, the technical and professional components of TEB test must already have been conducted in order to determine whether the test results should indeed alter clinical decision-making.

*Response:* (limitation #12) We believe that the restriction that the use of bioimpedance must be supported by documented changes in clinical examination and provide for a level of clinical decision making beyond the findings of the history and physical examination is consistent with the requirements of the NCD (20.16), and will be retained in the LCD.

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*Comment:* The commenter asks that we delete some Sources of Information that are not peer reviewed or are outdated, modify certain sources, and suggests adding some sources.

*Response:* The commenter has requested the removal of older references, and the inclusion of additional references. We will retain the past references as they provide insight into the development and history of this LCD. We will review the additional suggested references and include them as appropriate.

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*Comment:* The cardiology CAC representative stated that the American College of Cardiology feels that TEB is investigational and not medically necessary. At one academic hospital (NJ) the equipment was used to program pacemakers, but it was not beneficial. The use for detecting allograft rejection is not appropriate and should be removed as an indication.

*Response:* We appreciate the frankness of the statements of the NJ Chapter of the American College of Cardiology, and for bringing the ACC technology evaluation to our attention.

The use of TEB for detecting cardiac alloplant rejection is covered under NCD 20.16.B: "Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB."

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*Comment:* A commenter states that his cardiology practice uses ICG in assessing, diagnosing and monitoring heart failure, hypertension and other cardiac disorders, and finds it useful in keeping patients out of hospital.

*Response:* We appreciate the commenter sharing their anecdotal experience with us. They did not submit any additional literature or study to support their view.