NEW/REVISED MATERIAL - EFFECTIVE DATE: January 23, 2004
*IMPLEMENTATION DATE: February 23, 2004

I. SUMMARY OF CHANGES: Section 20.16 of Pub. 100-03, Medicare National Coverage Determinations Manual (NCDM), is revised in response to a request for reconsideration to offer more explicit guidance and clarification for coverage of Thoracic Electrical Bioimpedance (TEB) based on a complete and updated literature review. Effective for services performed on or after January 23, 2004, TEB is covered for specific indications as outlined in §20.16 of Pub. 100-03.

This revision to §20.16 of Pub. 100-03 is an NCD. The NCDs are binding on all Medicare carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

Provider Education: Contractors shall inform affected provider communities by posting either a summary or relevant portions of this instruction on their Web sites within 30 days of the issuance date of this transmittal. In addition, the same information shall be published in their next regularly scheduled bulletin. If they have a listserv that targets the affected provider communities, they shall use it to notify subscribers that a revised NCD for Thoracic Electrical Bioimpedance is available on their Web site.

Disclaimer: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. SCHEDULE OF CHANGES (R = REVISED, N = NEW, D = DELETED)

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III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

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Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by noninvasively measuring hemodynamic parameters, including: stroke volume, systemic vascular resistance, and thoracic fluid status. Under the previous coverage determination, effective July 1, 1999, use of TEB was covered for the “noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease.” In reconsidering this policy, CMS concluded that this use was neither sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on a complete and updated literature review.

A. Covered Indications

1. TEB is covered for the following uses:

   a. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

   b. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

   c. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.

   d. 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.

   e. 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 are necessary for appropriate management of the patient.
2. Contractors have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal BP in patients who are adhering to full doses of an appropriate three-drug regimen that includes a diuretic.

B. Noncovered Indications

1. TEB is noncovered when used for patients:

a. With proven or suspected disease involving severe regurgitation of the aorta;

b. With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;

c. During cardiac bypass surgery; or

d. In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined above).

2. All other uses of TEB not otherwise specified remain non-covered.

(This NCD last reviewed January 2004.)