CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 63	Date: DECEMBER 15, 2006
	Change Request 5414

NOTE: This instruction was issued earlier today contained an incorrect implementation date on the Business Requirement. The instruction has been revised and all other information remains the same.

SUBJECT: Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB)

I. SUMMARY OF CHANGES: Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare coverage policy of TEB

NEW/REVISED:
EFFECTIVE DATE: NOVEMBER 24, 2006
IMPLEMENTATION DATE: January 16, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/20.16 Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) - Various Effective Dates Below

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-03	Transmittal: 63	Date: December 15, 2006	Change Request: 5414

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SUBJECT Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB)

Effective Date: November 24, 2006
Implementation Date: January 16, 2007

I. GENERAL INFORMATION

A. Background: Following the reconsideration of Medicare coverage policy for Thoracic Electrical Bioimpedance (TEB) for drug-resistant hypertension, CMS has decided to retain current coverage at section 20.16 of the NCD Manual.

B. Policy: CMS will continue to permit contractors to make reasonable and necessary determinations for the use of TEB related to drug-resistant hypertension only. All other coverage and non-coverage policies at section 20.16 remain in effect.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5414.1	Effective for dates of service on and after 11/24/06, contractors shall continue to use the current policies for cardiac output monitoring by TEB at 20.16 of the NCD Manual to process claims.	x			x							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)							
		A/	DM	FI	CA	DM	RH	Shared-System Maintainers	OTHER

								FISS	MCS	VMS	CWF	
5414.2	Contractors shall post this entire instruction, or a direct link to this instruction, on their Web site and include information about it in a listserv message within 1 week of the release of this instruction. In addition, the entire instruction must be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic.	x			x							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Francina Spencer, Francina.spencer@cms.hhs.gov, 410-786-4614 (coverage), Pat Brocato-Simons, patricia.brocatosimons@cms.hhs.gov, 410-786-0261 (coverage)

Post-Implementation Contact(s): Appropriate RO

VI. FUNDING

A. *For TITLE XVIII Contractors*, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*, use only one of the following statements:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

Table of Contents
(Rev. 63, 12-15-06)

20.16 - Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) – *Various Effective Dates Below*

(Rev. 63, Issued: 12-15-06; Effective: 11-24-06; Implementation: 01-16-07)

A. General

Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by non-invasively measuring hemodynamic parameters, including: stroke volume, systemic vascular resistance, and thoracic fluid status. Under *a* previous coverage determination, effective *for services performed on and after* 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, *the Centers for Medicare & Medicaid Services (*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.

B. *Nationally* Covered Indications

Effective for services performed on and after January 23, 2004, TEB is covered for the following uses:

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

C. *Nationally* Non-Covered Indications

1. TEB is non-covered 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 *below*).

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

D. Other

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 *blood pressure* in patients who are adhering to full doses of an appropriate *3*-drug regimen that includes a diuretic. *Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.*

(This NCD last reviewed November 2006.)