

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 88	Date: JULY 25, 2008
	Change Request 6154

SUBJECT: Microvolt T-Wave Alternans (MTWA)

I. SUMMARY OF CHANGES: The Centers for Medicare and Medicaid Services (CMS) was asked to reconsider the national coverage determination (NCD) on microvolt t-wave alternans (MTWA) diagnostic testing to extend coverage to the modified moving average (MMA) method. Following its review, CMS determines that the MMA method of determining MTWA is not reasonable and necessary. Therefore, the current policy remains in place that provides for coverage of MTWA testing for the evaluation of patients at risk for sudden cardiac death only when the spectral analysis method is used.

Section 20.30, is an NCD. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a) (4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f) (1) (A) (i).)

NEW / REVISED MATERIAL

EFFECTIVE DATE: MAY 12, 2008

IMPLEMENTATION DATE: August 25, 2008

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	1/20.30/Microvolt T-Wave Alternans (MTWA)

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 88	Date: July 25, 2008	Change Request: 6154
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SUBJECT: Microvolt T-Wave Alternans (MTWA)

Effective Date: May 12, 2008

Implementation Date: August 25, 2008

I. GENERAL INFORMATION

A. Background: The Centers for Medicare and Medicaid Services (CMS) was asked to reconsider the national coverage determination (NCD) on microvolt t-wave alternans (MTWA) diagnostic testing to extend coverage to the modified moving average (MMA) method. CMS currently covers MTWA when it is performed using the spectral analysis method for the evaluation of patients at risk for sudden cardiac death (SCD) from ventricular arrhythmias, and patients who may be candidates for Medicare coverage of the placement of an implantable cardiac defibrillator (ICD).

B. Policy: Following its review, CMS determines that the MMA method of determining MTWA is not reasonable and necessary for patients at risk for SCD. Therefore, the current policy remains in place that provides for coverage of MTWA testing for the evaluation of patients at risk for sudden cardiac death only when the spectral analysis method is used.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6154.1	Effective May 12, 2008, contractors shall be aware that CMS reaffirms its current NCD; section 20.30, of Pub 100-03, of the NCD Manual, and will continue to cover MTWA only when it is performed using the spectral analysis method for the evaluation of patients at risk for SCD.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	None.										

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Stuart Caplan, coverage, 410-786-8564, stuart.caplan@cms.hhs.gov, Pat Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov.

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs) and Carriers:

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

Section B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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.

20.30 - Microvolt T-Wave Alternans (MTWA)

(Rev. 88; Issued: 07-25-08; Effective Date: 05-12-08; Implementation Date: 08-25-08)

A. General

Microvolt T-wave Alternans (MTWA) testing is a non-invasive diagnostic test that detects minute electrical activity in a portion of the electrocardiogram (EKG) known as the T-wave. MTWA testing has a role in the risk stratification of patients who may be at risk for sudden cardiac death (SCD) from ventricular arrhythmias.

Within patient groups that may be considered candidates for implantable cardioverter defibrillator (ICD) therapy, a negative MTWA test may be useful in identifying low-risk patients who are unlikely to benefit from, and who may experience worse outcomes from, ICD placement.

The test is performed by placing highly sensitive electrodes on a patient's chest prior to a period of controlled exercise. These electrodes detect tiny beat-to-beat changes, on the order of one-millionth of a volt, in the EKG T-wave. Spectral analysis is used to calculate these minute voltage changes. Spectral analysis is a sensitive mathematical method of measuring and comparing time and the EKG signals. Software then analyzes these microvolt changes and produces a report to be interpreted by a physician.

B. Nationally Covered Indications

Microvolt T-wave Alternans diagnostic testing is covered for the evaluation of patients at risk for SCD, only when the spectral analysis method is used.

C. Nationally Non-Covered Indications

Microvolt T-wave Alternans diagnostic testing is non-covered for the evaluation of patients at risk for SCD if measurement is not performed employing the spectral analysis method.

D. Other

N/A

(This NCD last reviewed *May 2008*.)