

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 182</b>	<b>Date: May 22, 2015</b>
	<b>Change Request 9162</b>

**SUBJECT: NCD20.30 Microvolt T-wave Alternans (MTWA)**

**I. SUMMARY OF CHANGES:** Effective January 13, 2015, CMS decided that no national coverage determination (NCD) is appropriate at this time for for microvolt t-wave alternans (MTWA) testing using the modified moving average (MMA) method for the evaluation of patients at risk for sudden cardiac death (SCD). As a result, national non-coverage of the MMA method was removed, leaving Medicare coverage of MTWA using MMA and methods of analysis other than spectral analysis (SA) for the evaluation of patients at risk for SCD from ventricular arrhythmias to be determined by the local Medicare Administrative Contractors (MACs).

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, 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) of the Social Security Act.)

**EFFECTIVE DATE: January 13, 2015**

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

**IMPLEMENTATION DATE: June 23, 2015**

*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-*Only One Per Row.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/Table of Contents
R	1/20.30/Microvolt T-Wave Alternans (MTWA)

**III. FUNDING:**

**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**

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 182	Date: May 22, 2015	Change Request: 9162
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**EFFECTIVE DATE: January 13, 2015**

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## 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 (SA) 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:** Effective January 13, 2015, CMS decided that no NCD is appropriate at this time for MTWA testing using the MMA method for the evaluation of patients at risk for SCD. As a result, national non-coverage of the MMA method was removed, leaving Medicare coverage of MTWA using MMA and methods of analysis other than SA for the evaluation of patients at risk for SCD from ventricular arrhythmias to be determined by the local Medicare Administrative Contractors (MACs).

Refer to the Pub.100-04, Claims Processing Manual Section Chapter 32, section 370, for claims processing information.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared- System Maintainers				Other
		A	B		F I S S	M C S	V M S	C W F	
9162 - 03.1	Effective for claims with dates of service on and after January 13, 2015, contractors shall determine coverage at their discretion of MTWA diagnostic testing for the evaluation of patients at risk for SCD using analysis methods other than SA. Refer to Pub. 100-03 National Coverage Determination Manual, Section 20.3 for further policy information. Refer to Pub. 100-04, Claims Processing Manual, Chapter 32, Section 370, for	X	X						

Number	Requirement	Responsibility							
		A/B MAC		D M E M A C	Shared- System Maintainers				Other
		A	B		H H H	F I S S	M C S	V M S	
	claims processing information.								

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
9162 - 03.2	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Patricia Brocato-Simons, 410-786-0261 or [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov) (Coverage) , William Ruiz, 410-786-9283 or [william.ruiz@cms.hhs.gov](mailto:william.ruiz@cms.hhs.gov) (Institutional Claims Processing) , Kim Long, 410-786-5702 or [Kimberly.Long@cms.hhs.gov](mailto:Kimberly.Long@cms.hhs.gov) (Coverage) ,

Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims Processing)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## **VI. FUNDING**

### **Section A: 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.

**ATTACHMENTS: 0**

# **Medicare National Coverage Determinations Manual**

## **Chapter 1, Part 1 (Sections 10 – 80.12)**

### **Coverage Determinations**

**Table of Contents**  
*(Rev.182, Issued: 05-22-15)*

20.30 - Microvolt T-Wave Alternans (MTWA)

## **20.30 - Microvolt T-Wave Alternans (MTWA)**

*(Rev. 182, Issued: 05-22-15, Effective: 01-13-15, Implementation: 06-23-15)*

### **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 (ECG) known as the T-wave. MTWA testing has a role in the 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.

Spectral analysis (SA) is a sensitive mathematical method of measuring and comparing time and the ECG signals. *It requires specialized proprietary electrodes* to calculate minute T-wave voltage changes. Software then analyzes these microvolt changes and produces a report to be interpreted by a physician. *The Modified Moving Average (MMA) method uses a temporal domain in which T-wave alternans are assessed as a continuous variable along the complete ECG. The MMA method of MTWA testing is performed using standard ambulatory ECG equipment.*

### **B. Nationally Covered Indications**

*Effective for dates of service on and after March 21, 2006,* MTWA diagnostic testing is covered for the evaluation of patients at risk for SCD, only when the SA method is used.

### **C. Nationally Non-Covered Indications**

*N/A*

### **D. Other**

*Effective for dates of service on and after January 21, 2015, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of MTWA diagnostic testing for the evaluation of patients at risk for SCD using all other methods.*

(This NCD last reviewed *January 2015.*)