T-wave alternans is considered investigational as a technique of risk stratification for primary or secondary prevention* of fatal arrhythmias and sudden cardiac death in patients with a history of myocardial infarction, congestive heart failure, cardiomyopathy or other cardiac disorders such as long-QT syndrome (e.g., Brugada syndrome).

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

*Primary prevention refers to patients that have not experienced a life-threatening arrhythmia. Secondary prevention refers to patients that have experienced a life-threatening arrhythmia.

Cross-references:
MP-1.081 Cardioverter-Defibrillators (Implantable and External)
MP-2.233 Genetic Testing for Congenital Long QT Syndrome

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO*  BlueJourney PPO*  FEP PPO**
**MEDICAL POLICY**

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* Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 20.30 for coverage on T-Wave Alternans. Microvolt T-wave Alternans (MTWA) diagnostic testing is covered for the evaluation of patients at risk of sudden cardiac death, only when the spectral analytic method is used.

**The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

**III. DESCRIPTION/BACKGROUND**

Microvolt T-wave alternans (MTWA) refers to a beat-to-beat variability in the T-wave amplitude. Because a routine electrocardiogram (EKG) cannot detect these small fluctuations, this test requires specialized sensors to detect the fluctuations and computer algorithms to evaluate the results. T-wave alternans is a provocative test that requires gradual elevation of the heart rate to above 110 beats per minute. The test can be performed in conjunction with an exercise tolerance stress test. Test results are reported as the number of standard deviations by which the peak signal of the T-wave exceeds the background noise. This number is referred to as the "alternans ratio." An alternans ratio of 3 or greater is typically considered a positive result, an absent alternans ratio is considered a negative result, and anything in between is considered indeterminate.

The presence of T-wave alternans has been investigated as a risk factor for fatal arrhythmias and sudden cardiac death in patients with a history of myocardial infarction, congestive heart failure, or cardiomyopathy. High-risk patients may be treated with drugs to suppress the emergence of arrhythmias or undergo implantation of cardiac defibrillators to terminate tachyarrhythmias when they occur. Since sudden cardiac death is one of the most common causes of death after a myocardial infarction (MI) or in patients with dilated cardiomyopathy, there is intense interest in risk stratification to target therapy.

Patient groups are categorized into those who have not experienced a life-threatening arrhythmia (i.e., primary prevention) and those who have (i.e., secondary prevention). Those who have already experienced an arrhythmia are already at high risk and probably do not require testing. T-wave alternans is one of many risk factors that have been investigated for identifying candidates for primary prevention. Others include left ventricular ejection fraction, arrhythmias detected on Holter monitor or electrophysiologic studies, heart rate variability, and baroreceptor sensitivity. Signal-averaged electrocardiography (SAECG) is another technique for risk stratification. SAECG measures beat-averaged conduction, while T-wave alternans measures beat-to-beat variability.
T-wave alternans has also been investigated as a diagnostic test for patients with syncope of unknown origin and as a noninvasive test to identify candidates for further invasive electrophysiology testing of the heart.

IV. RATIONALE

Prognostic or risk stratification test evaluation consists of: 1) appraising test technical performance, including definitions of positive and negative results and reproducibility of the test; 2) determining how accurately the test discriminates patients who will, from those who will not, experience the event of interest; and 3) evaluating the impact of test results on clinical management of the patient and a determination whether changes in clinical management result in an improvement of overall health outcomes.

Primary prevention implantable cardioverter-defibrillators (ICD) trials (e.g., MADIT-II and SCD-HeFT) have changed the perspective on selection and risk stratification for use of ICDs. (1) In the MADIT-II trial, implantable defibrillators were shown to be effective in patients selected on the basis of prior myocardial infarction (MI) and reduced ejection fraction; SCD-HeFT inclusion criteria required reduced ejection fraction but not previous MI. Prior studies of implantable defibrillators had selected patients using results of electrophysiologic testing and symptoms. (2, 3) Given results from these trials, it is critical whether any additional risk stratification tool(s) can identify with sufficient accuracy patients who might or might not benefit from ICD implantation. For example, can T-wave alternans testing identify patients who would otherwise be appropriate for an ICD based in trial inclusion criteria, but who would actually not benefit from an ICD? (Note: Policy No. 7.01.44 addresses the use of ICDs and patient selection criteria.)

The rationale for T-wave alternans testing is primarily that patients with a negative result will not benefit from an ICD. Accordingly, the most convincing evidence would be obtained from a randomized trial restricted to alternans-negative patients. Such a trial is lacking. Evidence from prospective cohort studies can accurately define the predictive ability of MTWA for sudden cardiac death. This evidence on risk may impact clinical management, if there are well-defined levels of risk that are linked to different management strategies.

Literature Review

TEC Assessments. A June 2005 TEC Assessment evaluated the use of microvolt T-wave alternans (MTWA) to risk stratify patients in whom ICDs would be used for primary prevention of sudden cardiac death. (4) The Assessment identified 18 studies using MTWA to prospectively stratify the risk of a subsequent event (total N=2,931). Most studies interpreted MTWA blinded to other information. The incidence of endpoints (either ventricular tachyarrhythmic events [VTEs] or death) ranged from 3% to 51% across studies. Six studies included patients with ischemic cardiomyopathy, 4 nonischemic cardiomyopathy, and 8 patients selected by a variety of means, such as those referred for electrophysiologic testing.
Two patient indications were considered: 1) patients eligible for ICD placement for primary prevention of sudden death, and 2) patients not eligible for ICD placement. It is possible that the negative or positive predictive value (NPV, PPV) of MTWA results might be used to support decision making regarding ICD placement. Specifically, for the first patient indication, negative MTWA results might be used to identify a subset of patients at low likelihood of subsequent VTEs and thus unlikely to benefit from ICD placement. While a few studies found that MTWA testing had high sensitivity and high NPV for future VTE, there was considerable variation in diagnostic performance in the published literature. Reported sensitivities ranged from 75% to 100%, negative predictive values from 73% to 100%, and likelihood ratios for a negative test result varied between 0 and 0.42. The reasons for variation in diagnostic performance characteristics are not well-established (recently suggested related to varied use of beta blockers during testing (5) as later discussed). Differences in pretest risk of VTE would most influence NPV; however, the Assessment also noted that it would also be important to understand whether MTWA diagnostic performance might vary according to population characteristics, such as etiology of cardiomyopathy. The diagnostic characteristics derived from the studies evaluated may not directly apply to patients eligible for ICD therapy.

The 2005 TEC Assessment concluded the evidence insufficient to determine whether the use of MTWA leads to improved net health outcomes or whether it is as beneficial as any established alternatives. Therefore, the use of MTWA testing for risk stratifying patients being considered for ICD therapy for primary prevention of sudden death did not meet the TEC criteria.

A 2006 TEC Assessment (6) reviewed a smaller number of studies addressing the question of whether MTWA can identify patients who would otherwise meet clinical indications for ICDs but whose risk of death is so low that they would not benefit. The critical evidence sought was the absolute risk of VTE or sudden death in those patients who have a negative MTWA test, and whether it can be determined whether this risk is consistent with no potential benefit from ICD therapy. Three studies were reviewed restricting analyses to patients who met criteria for ICD therapy.

Bloomfield et al. (7) followed 177 patients over an average of 20 months for all-cause mortality. Hohnloser et al. (8) selected ICD-eligible patients from two previously published studies and followed them over 2 years for sudden cardiac death or cardiac arrest. Among those with a negative MTWA test, the actuarial 2-year mortality rate was 3.8%. For those with a non-negative MTWA test, the actuarial 2-year mortality rate was 17.8%. Arrhythmic outcomes were not reported in this study.

In Hohnloser et al. (8), patients who met MADIT-II criteria were pooled from two previously published studies. The study reported all-cause mortality, rates of sudden cardiac death or cardiac arrest, and rates of VTE. For all-cause mortality estimated at 2 years, those with negative MTWA tests had a mortality rate of 12.5%, whereas those with non-negative MTWA tests had a mortality rate of 21.4%. For the primary outcome of sudden death or cardiac arrest,
patients with negative MTWA tests had a 0% rate, and those with non-negative MTWA tests had a 15.6% rate. For the secondary outcome of all ventricular arrhythmic events, those with a negative MTWA test had a 5.7% rate, and those with non-negative tests had a 31.1% rate.

In Chow et al. (9), a total of 768 consecutive patients with ischemic cardiomyopathy (left ventricular ejection fraction [LVEF] <35%) and no prior history of ventricular arrhythmia were followed up for a mean of 18 months. Because event rates in the patients with and without ICDs are not comparable, only outcomes for the 376 patients who received only medical therapy were reported in the TEC Assessment. Thus the results might be accompanied by potential selection bias. It appeared that the MTWA-negative patients who did not receive ICDs compared to the MTWA-negative patients who did receive ICDs had less severe heart failure (mean LVEF: 29.3% vs. 26.9%, respectively). At 18 months’ mean follow-up, the all-cause mortality rate was 8.4% in MTWA-negative patients and 21.8% in MTWA non-negative patients. For arrhythmic deaths, the rate was 3.4% in MTWA-negative patients and 11.2% in MTWA non-negative patients.

The 2006 TEC Assessment concluded that although MTWA does stratify risk in ICD-eligible patients, evidence of sufficient accuracy to infer clinical utility was lacking. A modeling study by Chan et al. (10) assumed a 2.7% annual sudden death rate among MTWA-negative patients and calculated that patients would still benefit from ICD therapy. Although modeling is not definitive, the study suggests that even the lower risk of arrhythmia in MTWA-negative patients is not low enough to preclude some benefit from ICD therapy.

Other Systematic Reviews. Results from two meta-analyses (5, 11) suggest that some discrepancies in prior study results can be explained by lower predictive performance of MTWA in studies where beta-blockers were withheld prior to testing. The subgroup finding, although plausible, requires confirmation. Merchant et al. (12) conducted a patient-level analysis identifying studies enrolling more than 100 patients studied by the spectral method. Studies with 15% or more patients having ICDs were excluded, as were those in which 15% or more of the arrhythmic outcomes were attributed to appropriate ICD therapy. Studies (n=2) using older protocol and instruments were also excluded. Of 17 identified studies, 5 met inclusion criteria. Patients with ICDs were excluded from the final analysis, yielding a sample of 2,883. Among patients with LVEF ≤35% (n=1,004) and negative MTWA testing, the annual sudden cardiac death rate was 0.9% versus 4.0% and 4.6% in the positive and indeterminate groups. The report did not state whether all selection criteria were established a priori. In addition, no sensitivity analyses were reported accounting for excluded patients and studies. Gupta et al. (13) performed a study-level meta-analysis including 20 prospective cohort studies collectively enrolling 5,945 patients with MTWA obtained by the spectral method. They estimated that a negative MTWA decreased the annual fatal and non-fatal ventricular tachyarrhythmic event (VTE) rate from 5.9% to 2.6% in SCD-HeFT-like patients, and from 8.9% to 6.4% in MADIT-II-like patients. The authors concluded that spectral MTWA testing would not “sufficiently modify the risk of VTE to change clinical decisions.”
Prospective Cohort Studies. Since the 2006 TEC Assessment, results from 5 multicenter studies provide the most informative evidence regarding the potential clinical utility of MTWA for risk stratification prior to ICD placement.

Between June 2001 and July 2004, the T-Wave Alternans in Patients with Heart Failure (ALPHA) registry enrolled 446 patients with New York Heart Association (NYHA) class II and III heart failure and LVEF equal to or less than 40% from 9 centers across Italy. (14) Heart failure etiologies included idiopathic dilated cardiomyopathy (n=326), hypertensive cardiomyopathy (n=72), valvular causes (n=9), and others (n=39). The primary endpoint was a composite of cardiac death and life-threatening ventricular arrhythmias. Mean patient age was 59 (SD=12.5) years; 78% were male; and median follow-up was 19 months. MTWA results were negative in 34.6%, non-negative in 65.4% (44.8% positive, 20.6% indeterminate). The primary endpoint occurred in 29 (9.9%) of 292 with non-negative results, compared to 4 (2.6%) of 154 in the negative group. A survival model attempting to adjust for between-group differences in prognostic factors yielded a relative hazard of 4.0 (95% confidence interval [CI]: 1.2 to 13.3). The test’s NPV through 18-months’ follow-up was 97.3% (95% CI: 95.4 to 99.8%). Thirty-three patients with non-negative and 6 with negative results received ICDs. Sensitivity analyses accounting for the impact of ICD implantation on differential event occurrence yielded similar results—those with ICDs had more events recorded. These findings are consistent with most prior observational research finding negative MTWA results associated with fewer arrhythmic outcomes in nonischemic cardiomyopathy. Limitations of the study include lack of a randomized comparison or using MTWA results to direct ICD placement, and between-group differences in prognostic factors including age, LVEF, use of angiotensin-converting enzyme (ACE) inhibitors and digitalis, and QRS duration. Although the investigators attempted to control for imbalances, the number of events (n=33) was insufficient to obtain valid estimates while accounting for more than a single prognostic factor or variable reflected in the wide confidence intervals. Furthermore, ICD placement is not indicated for primary prevention among individuals with LVEF greater than 35%. For these reasons, there is substantial uncertainty accompanying the results and few conclusions can be drawn.

The Alternans Before Cardioverter Defibrillator (ABCD) (15) cohort study enrolled primary prevention candidates for ICD implantation (sponsored by St. Jude Medical and Cambridge Heart). All patients underwent MTWA and an electrophysiological study (EPS). The primary goal was to demonstrate noninferiority of MTWA EPS testing in selecting primary prevention patients for ICD implantation—that the PPV and NPV of MTWA would be not worse than 10% of EPS PPV and NPV. A total of 629 participants were enrolled at 43 centers in the U.S., Germany, and Israel with ischemic cardiomyopathy, ejection fraction less than 40%, and no history of cardiac arrhythmia (a primary prevention sample). Due to protocol violations, 63 participants were excluded, yielding an analytic sample of 566. Following EPS and MTWA testing, ICDs were implanted if results were positive for either test. When both tests were negative, ICD placement was left to the discretion of the treating physician—70% of this
group received ICDs. Patients were followed up a median of 1.9 years. The primary outcome was a composite of appropriate ICD therapy (n=55) or arrhythmic death (n=10). EPS testing was positive in 39% and negative in 61%. For MTWA results, a “MTWA strategy” was defined whereby patients with indeterminate tests were subsequently judged positive or negative based on the EPS result. These “strategies” had similar positive and negative predictive values for the composite outcome at 1 year—MTWA strategy: PPV 9%, NPV 95%; EPS: PPV 11%, NPV 96%. The results raise a number of issues. First, current evidence does not warrant ICD for primary prevention in patients with ejection fractions of 35% to 40%. Second, predictive values for MTWA reported were not independent of EPS results—those with indeterminate MTWA results were classified according to EPS results. Patients receiving ICDs for primary prevention would, however, not undergo EPS testing. Additionally, in the 30% of the MTWA-negative patients not receiving ICDs, the diagnosis of arrhythmic events was likely underestimated due to lack of electrogram recording. Finally, in some cases, approximately 50% of “appropriate” ICD shocks may be unnecessary, as many arrhythmias terminate spontaneously. (16) While of interest, the study does not inform questions regarding the clinical utility of MTWA testing.

Microvolt T-Wave Alternans Testing for Risk Stratification of Post-MI Patients (MASTER I) (17) was designed to determine whether MTWA predicted life-threatening ventricular tachyarrhythmic events (LTVTEs) in MADIT-II type patients (LVEF ≤30% post-MI) treated with an ICD. Patients were enrolled at 50 centers across the U.S. (n=575); mean age was 65 years (SD=11), 84% were male, and average follow-up was 2.1 (SD=0.9) years. MTWA results were non-negative in 63% (51% positive and 12% indeterminate)—initially indeterminate tests were repeated. All patients received ICDs. In MTWA non-negative and negative patients, LTVTE occurred at annual rates of 6.3% and 5.0%, respectively; a non-negative MTWA result was not significantly associated with LTVTE. Although mean follow-up exceeded 2 years, there were few (n=7, 1.2%) arrhythmic deaths. In contrast, the 2-year sudden cardiac death rate in the MADIT-II ICD arm was 4.9%. (18) Reasons for this difference are not clear but could reflect improved medical care, better defibrillator technology and programming, or patient selection. Finally, some critique use of LTVTE as an endpoint, as not all will result in sudden cardiac death if left untreated. However, to alter these results would require differential rates of spontaneous termination in MTWA-negative and MTWA-positive patients—currently no evidence supports that suggestion.

The companion MASTER II results were presented at a late-breaking session of the 2008 American College of Cardiology (ACC) meeting and remain only in abstract form. (19) The study enrolled 348 patients, mean age 64 years (SD=10), 85% male, at 50 centers with ischemic-related LVEF of 31–40%. MTWA results were indeterminate in 45, positive in 132, and negative in 171; 48% of participants received ICDs. LTVTE occurred in 7 MTWA-positive and 4 MTWA-negative patients. Event rates among patients with indeterminate tests were not reported. When patients with positive and negative MTWA results were compared, there was no association with LTVTE (hazard ratio: [HR]: 1.22, 95% CI: 0.34 to 4.39),
although event rates were low. It is unclear why patients with indeterminate test results were excluded from the reported analyses. (Registered as NCT00305214, as of April 2013, neither study results nor indication of complete publication were posted at online site ClinicalTrials.gov. A complete publication was also not identified in the search conducted for the 2013 policy update.)

A substudy of the SCD-HeFT trial evaluated the prognostic value of MTWA in 490 patients at 37 sites (of 2,521 patients enrolled in the trial). (20) The sample was similar to the larger SCD-HeFT population—76% male, mean age 59 years (SD=12), mean LVEF 24% (SD=7), 49% had ischemic heart disease, and 71% NYHA class II heart failure. MTWA results were positive in 37%, negative in 22%, and indeterminate in 41%. Protocol recommended indeterminate tests to be repeated. Proportions MTWA-positive, MTWA-negative, or MTWA-indeterminate results were similar in those randomly assigned to ICD/placebo and amiodarone. The primary composite endpoint included first appropriate ICD discharge, sustained ventricular tachycardia/fibrillation, or sudden cardiac death; patients randomly assigned to amiodarone were excluded from analysis of the primary endpoint due to inability to ascertain appropriate discharge. Over a median 30-month follow-up in the ICD/placebo arm, MTWA-positive patients (n=139) did not have a distinguishable increase in events compared to MTWA-negative group (n=72) (HR: 1.24, 95% CI: 0.60 to 2.59); nor MTWA-non-negative (n=272) compared to MTWA-negative (n=72) (HR: 1.28, 95% CI: 0.65 to 2.53). MTWA was not associated with all-cause mortality in the combined ICD/placebo and amiodarone sample. While commentators have pointed out the high proportion of indeterminate results, these results do not support clinical utility for MTWA prior to ICD placement in SCD-HeFT eligible patients.

Conclusions. Evidence from prospective cohort studies and systematic reviews establishes that MTWA can be used to risk stratify patients on the risk of sudden cardiac death. In patients who have indications for an ICD, a negative MTWA test lowers the risk of sudden cardiac death, while a positive test increases the risk. However, this risk stratification is unlikely to result in management changes that improve outcomes. The negative predictive value (NPV) of MTWA is not high enough to forego ICD placement in patients with a negative MTWA test. Other management changes, such as medication adjustments, may be made on the basis of this test, but the impact of these management changes is uncertain.

Practice Guidelines and Position Statements

The 2006 American College of Cardiology (ACC)/American Heart Association (AHA)/European Society of Cardiology (ESC) 2006 Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death include T-wave alternans testing as IIa recommendation: “It is reasonable to use T-wave alternans for improving the diagnosis and risk stratification of patients with ventricular arrhythmias or who are at risk for developing life-threatening ventricular arrhythmias. (Level of Evidence: A).” (21)
A 2011 Consensus Guideline issued by the International Society for Holter and Noninvasive Electrocardiography concludes, “[overall, although TWA appears to be a useful marker of risk for arrhythmic and cardiovascular death, there is as yet no definitive evidence that it can guide therapy].” (22)

**Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers**

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2008. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The three reviewers disagreed with the proposed policy statement.

**Summary**

Microvolt T-wave alternans is one available method to risk stratify patients who may be at risk for sudden cardiac death and has been proposed to assist in selecting patients for ICD treatment. Results from prospective multicenter studies enrolling various patient populations undergoing ICD placement as part of primary prevention strategies do not support clinical utility from MTWA used to risk stratify and therefore guide placement. This conclusion, expressed in the 2006 TEC Assessment, is also supported by recent prospective studies designed to evaluate the utility of MTWA and by pooled analyses. Therefore, this technology is considered investigational.

**2016**

Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

**V. DEFINITIONS**

**ARRHYTHMIA** is an irregularity or loss of rhythm, especially of the heart.

**CARDIOMYOPATHY** refers to a disease of the myocardium (heart muscle) causing enlargement.

**DEFIBRILLATOR** is an electrical device that produces defibrillation of the heart. It may be used externally or in the form of an automatic implanted cardioverter defibrillator.

**MYOCARDIAL INFARCTION** refers to the loss of living heart muscle as a result of coronary artery occlusion.

**PRIMARY PREVENTION** refers to patients that have not experienced a life-threatening arrhythmia. Secondary prevention refers to patients that have experienced a life-threatening arrhythmia.

**SECONDARY PREVENTION** refers to patients that have experienced a life-threatening arrhythmia.
MEDICAL POLICY

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T WAVE is the portion of the electrical activity of the heart that reflects repolarization of the ventricles.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

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*Please see Medicare LCD or NCD for additional covered procedures and diagnoses.*
IX. REFERENCES


X. POLICY HISTORY

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