MEDICAL POLICY

POLICY TITLE	T-WAVE ALTERNANS TESTING
POLICY NUMBER	MP 2.057

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2024**

I. POLICY

T-wave alternans testing 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 general 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 Cardiac Ion Channelopathies

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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III. DESCRIPTION/BACKGROUND

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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, heart failure, or cardiomyopathy. High-risk patients may be treated with medications 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.

In 2017, the American Heart Association, American College Society, and the Heart Rhythm Society convened to publish a Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death. In this guideline, they note “data on the use of microvolt T wave alternans and the signal averaged ECG are inconclusive, as such these tests are not routinely used in clinical practice.”

EU-CERT-ICD is a nonrandomized, controlled, prospective multicenter study (ClinicalTrials.gov identifier: NCT02064192), funded by the European Community's Seventh Framework Programme. The researchers of the study highlighted the need for improved identification of patients who may benefit from a primary prophylactic implantable cardioverter-defibrillator and hypothesized that TWA might be associated with benefit from ICD implantation in primary prevention. The results were described in a May 2024 publication of the Journal of the American Heart Association titled “Lack of Prognostic Value of T-Wave Alternans for Implantable Cardioverter-Defibrillator Benefit in Primary Prevention.” After enrolling and

evaluating 2327 candidates, the study concluded that "T-wave alternans is poorly prognostic in patients with a primary prophylactic ICD. Although it may be prognostic of life-threatening arrhythmias and sudden cardiac death in several patient populations, it does not seem to be useful in assessing benefit from ICD therapy in primary prevention among patients with an ejection fraction of ≤35%." The article goes on to describe clinical implications, noting that "Based on our results, TWA cannot be used to select patients for primary prophylactic ICD therapy with reduced left ventricular ejection fraction among a contemporary patient population" and that "Other methods beyond TWA are needed to identify patients with or without true benefit from primary prophylactic ICD implantation among patients with a left ventricular ejection fraction ≤35%."

IV. RATIONALE

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Summary of Evidence

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.

V. DEFINITIONS

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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.

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

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are

different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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:

Procedure Codes							
93025							

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.057	**09/14/2020 Consensus Review.** No change to policy statement. Coding reviewed, no changes. References reviewed, updated.Product Variation Statement updated. FEP statement updated.
	08/16/2021 Consensus Review. No change to policy statement. References updated.
	01/05/2022 Consensus Review. Policy statement unchanged. Background and References updated. FEP language revised.
	05/11/2023 Consensus Review. No changes to policy statement. References updated. No coding changes.
	06/03/2024 Consensus Review. Minor editorial changes to policy statement, intent unchanged. Background and references updated. Coding reviewed, no changes.

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