

Medical Coverage Policy

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Cardiac Electrophysiological (EP) Studies

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Related Coverage Resources

Implantable Cardioverter Defibrillator (ICD) Nonpharmacological Treatments for Atrial Fibrillation

<u>Transcatheter Ablation for the Treatment of</u> <u>Supraventricular Tachycardia in Adults</u>

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Page 1 of 20 Medical Coverage Policy: 0532 will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses invasive cardiac electrophysiolgical (EP) studies.

Coverage Policy

A cardiac electrophysiological (EP) study is considered medically necessary when ANY of the following criteria are met:

Primary Prevention of Sudden Cardiac Death (SCD) for ANY of the following indications:

- in an individual with ischemic heart disease
 - to determine eligibility for an implantable cardioverter defibrillator (ICD), in an individual with non-sustained ventricular tachycardia (NSVT) due to prior myocardial infarction (MI) >40 days and LVEF between 36% and 40%
- in an individual with coronary artery disease (CAD) and after acute MI
 - to determine eligibility for an ICD with NSVT and 4-40 days out from MI with EITHER of the following:
 - \circ Revascularization performed at time of event AND LVEF \leq 40%
 - $_{\odot}$ Obstructive CAD not re-vascularized and with coronary anatomy not amenable to revascularization

Secondary Prevention of SCD for ANY of the following indications:

- for risk stratification for SCD in an individual with non-ischemic cardiomyopathy (NICM), who experiences syncope presumed to be due to VA and who does not meet indications for a primary prevention ICD
- to determine eligibility for an ICD after a ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) episode during an acute MI (i.e., <48 hours), with non-sustained ventricular tachycardia (NSVT) \geq 4 days after revascularization
- to determine eligibility for an ICD in an individual with ischemic heart disease and unexplained syncope who does not otherwise meet criteria for ICD placement by ejection fraction on guideline directed medical therapy.

Evaluation of Ventricular Arrhythmias (VA)

 to assess the risk of sustained VT in an individual with ischemic cardiomyopathy, NICM, or adult congenital heart disease who has syncope or other VA symptoms and who do not meet indications for a primary prevention ICD

Adult Congenital Heart Disease

- to evaluate the risk of sustained VT/VF in an adult with repaired Tetralogy of Fallot physiology with high-risk characteristics and frequent VA
- to determine eligibility for an ICD for inducible sustained VA, in an individual with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy

Cardiac Sarcoidosis

- to determine eligibility for an ICD, if sustained VA is inducible, in an individual with cardiac sarcoidosis and LVEF \geq 35

Syncope

• for the evaluation of an individual with syncope of suspected arrhythmic etiology

Supraventricular Tachycardia (SVT) of Unknown Mechanism

• for the diagnosis and potential treatment of SVT

Symptomatic Individuals with Manifest Accessory Pathways

• to risk-stratify for life-threatening arrhythmic events

Asymptomatic Individual with Asymptomatic Pre-Excitation

• to risk-stratify for arrhythmic events

Initial clinical evaluation in patients with Atrial Fibrillation (AF)

- to clarify the mechanism of wide-QRS-complex tachycardia
- to identify a predisposing arrhythmia such as atrial flutter or paroxysmal supraventricular tachycardia
- to seek sites for curative AF ablation or atrioventricular (AV) conduction block/modification

Arrhythmogenic Right Ventricular Cardiomyopathy

• in an asymptomatic individual with clinical evidence of arrhythmogenic right ventricular cardiomyopathy

Brugada Syndrome

• asymptomatic Brugada syndrome and a spontaneous type 1 Brugada electrocardiographic pattern

For all other indications including the following, an EP study is considered not medically necessary:

- hypertrophic cardiomyopathy (HCM) for risk stratification
- for the sole reason of inducing VA for risk stratification in an individual who meets criteria for ICD implantation
- for risk stratification for VA in the setting of long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, or early repolarization syndromes

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Literature demonstrates that race has a significant impact on lifetime risk of sudden cardiac death (SCD). Zhao, et al. (2019) conducted a prospective multi-center cohort study (n=15,069) funded

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by the National Heart, Lung, and Blood Institute to compare the lifetime risk of SCD between Blacks and whites and to evaluate racial risk factors. Participants ranged in age from 45–64 years old. There were 2,366 Black women (15.7%), 5,947 white women (39.4%), 1,466 Black men (9.7%), and 5,296 white men (35.1%) who participated in the study and were randomly selected from four United States cities between 1987–1989 to obtain baseline data. Four follow-up visits occurred between 1990–1992, 1993–1995, 1996–1998, and 2011–2013. Participants were excluded from study participation if they self-reported a race other than black or white or if outcome or relevant covariates were missing from data. Participants were followed for SCD as defined as "death from a sudden pulseless condition occurring out of hospital or in the emergency room from a cardiac cause in a previously stable individual without a non-cardiac cause of cardiac arrest." Data was collected from death certificates, annual phone calls, next-of-kin interviews, physician questionnaires, coroner information, and hospital discharges. After a median follow-up of 27.4 years, the cumulative incidence of SCD increased by 8.5% in Black men, 5.9% in Black women, 5.6% in white men, and 2.1% in white women. Socioeconomic factors, cardiovascular risk factors, and electrocardiographic variables accounted for 65.3% of the excess risk of SCD in Blacks compared to whites. Income was found to account for 50.5% of the risk factors followed by education at 19.1%, hypertension at 22.1%, diabetes mellitus at 19.6%, left ventricular hypertrophy at 15.0%, alcohol intake at 12.9%, physical activity at 12.7%, BMI at 6.4%, and smoking at 4.4%. Analysis also found that Blacks were at increased risk of out-of-hospital SCD and also less likely to survive in-hospital SCD. Individuals suffering from out-of-hospital cardiac arrests occurring in low income Black neighborhoods were less likely than high income white neighborhoods to receive bystander cardiopulmonary resuscitation. In-hospital survival of cardiac arrest was also lower in low-income neighborhoods due to lower quality of treatment delivery in those areas. Author noted limitations of the study included the lack of data regarding individual resuscitation procedures and structural or causative arrhythmia underlying the SCD and the use of self-reported means of race identification leading to potential bias in reporting. An additional limitation of the study was the larger number of white men and women compared to Black men and women who participated.

General Background

The heart produces electrical signals that spread through the heart muscle to make the muscle contract. The signals are small but can be picked up on an electrocardiograph machine. The electrocardiogram (ECG) can be helpful but often the signals are so small that they cannot be seen or are hidden on an ECG. Even tests that stretch over a longer period of time, such as a Holter monitor, may not capture an event. A cardiac electrophysiology (EP) study permits a detailed analysis of the mechanism(s) underlying the cardiac arrhythmia, precise location of the site of origin, and, if applicable, definitive treatment via catheter-based ablation techniques.

The indications for an invasive cardiac electrophysiology study can be broken down to two categories: diagnostic and risk stratification. An EP study can accomplish the following goals (Homoud, 2022):

- definitive diagnosis of an arrhythmia
- establish an etiology for syncope
- risk stratification for sudden cardiac death
- evaluate the feasibility or outcome of nonpharmacologic therapy

Absolute contraindications to EP study include (Homoud, 2022):

- unstable angina
- bacteremia or septicemia

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- acute decompensated congestive heart failure not caused by the arrhythmia
- major bleeding diathesis
- acute lower extremity venous thrombosis if femoral vein cannulation is desired

An invasive EP study is generally performed in a dedicated EP laboratory. In addition to the cardiac electrophysiologist, several other staff members are required. Intravenous conscious sedation is typically used, although in some situations (i.e., prolonged catheter ablation procedures) general anesthesia can be used (Homoud, 2022).

The pre-procedure evaluation for an invasive EP study includes a thorough history and physical examination and review of available ECGs, at baseline and, if available, during arrhythmia. In select patients additional evaluation prior to the procedure may include (Homoud, 2022):

- Event monitoring for up to four weeks to document the tachycardia.
- Transthoracic echocardiography to assess for structural heart disease. Cardiac magnetic resonance imaging may be considered for special situations (e.g., suspicion of arrhythmogenic right ventricular cardiomyopathy, hypertrophic cardiomyopathy).
- Exercise testing, if there is a history of exercise-induced arrhythmia.
- Cardiac catheterization and coronary angiography, if indicated by the individual's clinical presentation and symptoms suggesting coronary heart disease.

In most individuals, all atrioventricular (AV) nodal blocking agents, including calcium and beta blockers, digoxin, and class I and III antiarrhythmic drugs are discontinued several days prior to the scheduled procedure. In nearly all EP studies, venous vascular access is required, often from multiple sites. The femoral approach is most common; but the subclavian, internal jugular, or brachial approach may be used, most often for placement of a catheter in the coronary sinus. Multipolar electrode catheters are positioned in the heart (Homoud, 2022).

Complications of an invasive cardiac EP study are rare but potentially life threatening. The risks associated with undergoing an EP study by itself are small. Myocardial perforation with cardiac tamponade, pseudoaneurysms at arterial access sites, and provocation of nonclinical arrhythmias can occur, each with less than a 1/500 incidence. The addition of therapeutic maneuvers (e.g., ablation) to the procedure increases the incidence of complications. Because an EP study carries a relatively small but finite risk of major as well as minor complications and routinely involve the purposeful induction of serious arrhythmias, it is important that their clinical usefulness for diagnosis and therapy of cardiac arrhythmias be carefully considered (Miller, et al., 2019; Homoud, 2022).

Professional Societies/Organizations

The American Heart Association (AHA)/ American College of Cardiology (ACC)/ Health Rhythm Society (HRS) have numerous guidelines that address recommendations for an EP study. The recommendations listed in the clinical practice guidelines are, whenever possible, evidence-based. The Class of Recommendation (COR) indicates the strength of the recommendation, encompassing the estimated magnitude and certainty of benefit in proportion to risk. The Level of Evidence (LOE) rates the quality of scientific evidence that supports the intervention on the basis of the type, quantity, and consistency of data from clinical trials and other sources.

Guideline Class of Recommendation (COR) and Level of Evidence (LOE) are described as follows:

Class (Strength) of Recommendation: Class I (Strong) Benefit >>>Risk Class IIa (Moderate) Benefit>>Risk Class IIb (Weak) Benefit ≥ Risk Class III No Benefit (Moderate) Benefit=Risk Class III Harm (Strong) Risk>Benefit

Level (Quality) of Evidence:

Level A if the data were derived from high-quality evidence from more than one randomized clinical trial(RCT), meta-analyses of high-quality RCTs, or one or more RCTs corroborated by high-quality registry.

Level B-R when data were derived from moderate quality evidence from one or more RCTs, or meta-analyses of moderate-quality RCTs.

Level B-NR was used to denote moderate-quality evidence from one or more welldesigned, well-executed nonrandomized studies, observational studies, or registry studies. This designation was also used to denote moderate-quality evidence from meta-analyses of such studies.

Level C-LD when the primary source of the recommendation was randomized or nonrandomized observational or registry studies with limitations of design or execution, meta-analyses of such studies, or physiological or mechanistic studies of human subjects. Level C-EO was defined as expert opinion based on the clinical experience of the writing group.

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, et al., 2017)

Armythinds and the Prevention of Sudden Cardiac Death (Ar-Khatib, et al., 2017)			
Indication	Recommendation for EP Study	COR/LOE	
Primary Prevention of SCD in Patients With Ischemic Heart Disease	In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected	I/B-R	
Secondary Prevention of SCD in Patients with Ischemic Heart Disease	In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	I/B-NR	
Secondary Prevention of SCD in Patients With Nonischemic Cardiomyopathy (NICM)	In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial if meaningful survival greater than 1 year is expected	IIa/B-NR	
Ventricular Arrhythmias (VA)	In patients with ischemic cardiomyopathy, nonischemic cardiomyopathy (NICM), or adult congenital heart disease who have syncope or other VA symptoms and who do not meet indications for a primary prevention ICD, an electrophysiological study can be useful for assessing the risk of sustained VT	IIa/B-R	
Adult Congenital Heart Disease	In adults with repaired tetralogy of Fallot physiology with high-risk characteristics and frequent VA, an electrophysiological study can be useful to evaluate the risk of sustained VT/VF	IIa/B-NR	
	In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate	IIa/B-NR	

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	ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA is reasonable if meaningful survival of greater than 1 year is expected	
Cardiac Sarcoidosis	In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study and to implant an ICD, if sustained VA is inducible, provided that meaningful survival of greater than 1 year is expected	IIa/C-LD
Arrhythmogenic Right Ventricular Cardiomyopathy	In asymptomatic patients with clinical evidence of arrhythmogenic right ventricular cardiomyopathy, an electrophysiological study may be considered for risk stratification	IIb/B-NR
Brugada Syndrome	In patients with asymptomatic Brugada syndrome and a spontaneous type 1 Brugada electrocardiographic pattern, an electrophysiological study with programmed ventricular stimulation using single and double extra stimuli may be considered for further risk stratification	IIb/B-NR
Hypertrophic Cardiomyopathy (HCM)	In patients with HCM, an invasive electrophysiological study with programmed ventricular stimulation should not be performed for risk stratification	III/B-NR
Ventricular Arrhythmias (VA)	In patients who meet criteria for ICD implantation, an electrophysiological study for the sole reason of inducing VA is not indicated for risk stratification	III/B-R
	An electrophysiological study is not recommended for risk stratification for VA in the setting of long QT syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, or early repolarization syndromes	III/B-NR

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Evaluation and Management of Patients With Syncope (Shen, et al., 2017)				
Indication	Recommendation for EP Study COR/LOE			
Syncope				

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Management of Adult Patients With Supraventricular Tachycardia (Page, et al., 2016)			
Indication Recommendation for EP Study COR/LOE			
SVT of Unknown Mechanism	SVT of UnknownEP study with the option of ablation is useful		
Symptomatic Patients With Manifest AccessoryAn EP study is useful in symptomatic patients with pre-excitation to risk-stratify for life- threatening arrhythmic eventsI/B-NR		I/B-NR	

Asymptomatic Patients	An EP study is reasonable in asymptomatic	IIa/B-NR
With Asymptomatic Pre-	patients with pre-excitation to risk-stratify for	
Excitation	arrhythmic events	

American Heart Association (AHA)/American College of Cardiology (ACC)/Health Rhythm Society (HRS) Guideline for the Management of Patients with Atrial Fibrillation

Class I

• Electrocardiographic documentation is recommended to establish the diagnosis of atrial fibrillation (AF) (Level of Evidence: C).

The guideline states that the diagnosis of AF in a patient is based on the patient's clinical history and physical examination and is confirmed by ECG, ambulatory rhythm monitoring (e.g., telemetry, Holter monitor, event recorders), implanted loop recorders, pacemakers or defibrillators, or, in rare cases, by electrophysiological study. An electrophysiological study can be helpful when initiation of AF is due to a supraventricular tachycardia, such as atrioventricular node (AV) node reentrant tachycardia, AV reentry involving an accessory pathway, or ectopic atrial tachycardia. Electrophysiological study is often warranted in patients with a delta wave on the surface ECG indicating pre-excitation. Some patients with AF also have atrial flutter that may benefit from treatment with radiofrequency catheter ablation. AF associated with rapid ventricular rates and a wide-complex QRS (aberrant conduction) may sometimes be mislabeled as ventricular tachycardia, and an electrophysiological study can help establish the correct diagnosis (January, et al., 2014). Electrophysiological studies were not addressed in the 2019 focused update to the 2014 guideline (January, et al., 2019).

American Heart Association (AHA)/American College of Cardiology (ACC) Guideline for the Diagnosis and Management of Atrial Fibrillation

Class IIb

• In patients with an onset of unexplained AF before 30 years of age, electrophysiological study to evaluate and treat reentrant supraventricular tachyarrhythmias with a targeted ablation may be reasonable because of the high prevalence of reentrant arrhythmias in this group (Level of Evidence B-NR).

The guideline states that patients are being diagnosed with AF at a younger age due to the use of consumer driven wearable devices and that reentrant SVTs are found in 25% of individuals diagnosed at <30 years of age (Joglar, et al., 2024).

American College of Cardiology Foundation (ACCF)/Heart Rhythm Society (HRS)/American Heart Association (AHA)/American Society of Echocardiography (ASE)/Heart Failure Society of America (HFSA)/Society for Cardiovascular Angiography and Interventions (SCAI)/Society of Cardiovascular Computed Tomography (SCCT)/Society for Cardiovascular Magnetic Resonance (SCMR): The 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy described the appropriate use of these devices for selected patient populations (Russo, et al., 2013) and likewise, the appropriateness of the tests used to determine the need for an ICD (e.g., cardiac electrophysiological study).

Recommendations are provided based on the following scoring method:

• Median score 7–9: Appropriate care: An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans, although not always necessary, depending on

physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

- Median score 4–6: May be appropriate for care: At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).
- Median score 1–3: Rarely appropriate care: Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).

Generally, criteria that have been deemed Appropriate or May Be Appropriate in these scenarios often meet Class I, IIa, or IIb criteria in guideline documents, are supported by a critical mass of existing data, or were deemed by the technical panel to meet sufficient clinical judgment to be reasonable and appropriate.

ICD implantation is rated as May Be Appropriate (median score 4-6) for the following indications:

Secondary Prevention

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Coronary artery disease (CAD): ventricular fibrillation (VF) or hemodynamically unstable ventricular tachycardia (VT) associated with acute (< 48 hours) myocardial infarction (MI) (newly diagnosed, no prior assessment of left ventricular ejection fraction (LVEF):

- Total Revascularization Completed After Cardiac Arrest
 - Single episode VF or polymorphic VT during acute (< 48 hours) MI (4)
 - Recurrent VF or polymorphic VT during acute (< 48 hours) MI (5)</p>
 - VF or polymorphic VT during acute (< 48 hours) MI, NSVT 4 days post MI, Inducible VT/VF at EPS ≥ 4 days after revascularization (5)</p>
 - No Revascularization Indicated (No Significant CAD)
 - Single episode VF or polymorphic VT during acute (< 48 hours) MI, LVEF \leq 35% (4)
 - > Recurrent VF or polymorphic VT during acute (< 48 hours) MI LVEF \leq 35% (5)
- Obstructive CAD with coronary anatomy not amenable to revascularization
 > VF or polymorphic VT during acute (< 48 hours) MI, no EPS done. EF ≥ 36% (5)

Pediatric and Congenital Electrophysiology Society (PACES)/HRS Expert Consensus Statement on the Management of the Asymptomatic Young Patient with a Wolff-Parkinson-White (WPW, Ventricular Preexcitation) Electrocardiographic Pattern: The guideline discusses rationale, definition, and techniques for an invasive EP study stating that in the absence of a clear understanding of the accessory pathway anterograde characteristics by noninvasive testing, invasive testing should be considered. The purpose of such an invasive EP study in asymptomatic patients with a WPW ECG pattern is to identify a potential subgroup of patients who may be at increased risk for lethal cardiac arrhythmias and in whom the risk-tobenefit ratio favors ablation (Cohen, et al., 2012).

ACC/AHA Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation

Procedures: Recent textbook literature reports that the basic themes of the 1995 ACC/AHA

Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures remain valid (Miller, et al., 2019).

Guideline recommendations for an electrophysiological study are classified as Class I, Class II, and Class III described as follows:

Class I: Conditions for which there is general agreement that the electrophysiological study provides information that is useful and important for patient treatment. Experts agree that patients with these conditions are likely to benefit from electrophysiological studies.

Class II: Conditions for which electrophysiological studies are frequently performed, but there is less certainty about the usefulness of the information that is obtained. Experts are divided in their opinion as to whether patients with these conditions are likely to benefit from electrophysiological study.

Class III: Conditions for which there is general agreement that electrophysiological studies do not provide useful information. Experts agree that electrophysiological studies are not warranted in patients with these conditions. This classification is assigned to patients with a variety of arrhythmias and clinical syndromes resulting from cardiac electrical abnormalities. Because use of electrophysiological studies in children on occasion differs from that in adults, it is discussed in another section.

1995 ACC/AHA Task Force Report. Guidelines for Clinical Intracardiac Electrophysiological and Catheter Ablation Procedures				
		Electrocardiographic Abnor	malities	
Indication	Class I	Class II	Class III	
Evaluation of sinus node function	Symptomatic patients in whom sinus node dysfunction is suspected as the cause of symptoms, but a causal relationship between an arrhythmia and the symptoms has not been established after appropriate evaluation	Patients with documented sinus node dysfunction in whom evaluation of AV or ventriculoatrial conduction or susceptibility to arrhythmias may aid in selection of the most appropriate pacing modality Patients with electrocardiographically documented sinus bradyarrhythmias to determine whether abnormalities are caused by intrinsic disease, autonomic nervous system dysfunction, or effects of drugs to help select therapeutic options Symptomatic patients with known sinus bradyarrhythmias to	Symptomatic patients in whom an association between symptoms and a documented bradyarrhythmia has been established and the choice of therapy would not be affected by EP study results Asymptomatic patients with sinus bradyarrhythmias or sinus pauses observed only during sleep, including sleep apnea	

		arrhythmias as the cause of symptoms	
Acquired AV block	Symptomatic patients in whom His-Purkinje block, suspected as a cause of symptoms, has not been established Patients with second- or third-degree AV block treated with a pacemaker who remain symptomatic and in whom another arrhythmia is suspected as a cause of the symptoms	Patients with second- or third-degree AV block in whom knowledge of the site of block or its mechanism or response to pharmacologic or other temporary intervention may help in directing therapy or assessing prognosis Patients with premature, concealed junctional depolarizations suspected as the cause of a second- or third-degree AV block pattern (e.g., pseudo-AV block)	Symptomatic patients in whom the symptoms and presence of AV block are correlated by ECG findings Asymptomatic patients with transient AV block associated with sinus slowing (e.g., nocturnal type I second-degree AV block)
Chronic intraventricular conduction delay	Symptomatic patients in whom the cause of symptoms is not known	Asymptomatic patients with bundle branch block in whom pharmacologic therapy that could increase conduction delay or produce heart block is contemplated	Asymptomatic patients with intraventricular conduction delay Symptomatic patients whose symptoms can be correlated with or excluded by ECG events
Narrow-QRS tachycardia (QRS complex <0.12 sec)	Patients with frequent or poorly tolerated episodes of tachycardia who do not adequately respond to drug therapy and for whom information about the site of origin, mechanism, and electrophysiologic properties of pathways of the tachycardia is essential for choosing appropriate therapy (e.g., drugs, catheter ablation, pacing, or surgery) Patients who prefer ablative therapy to pharmacologic treatment	Patients with frequent episodes of tachycardia requiring drug treatment for whom there is concern about proarrhythmia or effects of the antiarrhythmic drug on the sinus node or AV conduction	Patients with tachycardias easily controlled by vagal maneuvers and/or well- tolerated drug therapy who are not candidates for nonpharmacologic therapy

Wide-complex tachycardias	Patients with wide– QRS complex tachycardia in whom the correct diagnosis is unclear after analysis of available ECG tracings and for whom knowledge of the correct diagnosis is necessary for care	None	Patients with VT or supraventricular tachycardia with aberrant conduction or preexcitation syndromes diagnosed with certainty by ECG criteria and for whom invasive electrophysiologic data would not influence therapy; however, data obtained at baseline EP study in these patients might be appropriate as a guide for subsequent therapy
Prolonged-QT interval syndrome	None	Identification of proarrhythmic effect of a drug in patients experiencing sustained VT or cardiac arrest while receiving the drug Patients who have equivocal abnormalities in QT interval duration or T-U wave configuration, along with syncope or symptomatic arrhythmias, in whom the effects of catecholamine may unmask a distinct QT abnormality	Patients with clinically manifest congenital QT prolongation, with or without symptomatic arrhythmias Patients with acquired prolonged-QT syndrome with symptoms closely related to an identifiable cause or mechanism
Wolff- Parkinson- White syndrome	Patients being evaluated for catheter ablation or surgical ablation of an accessory pathway Patients with ventricular preexcitation who have survived cardiac arrest or who have unexplained syncope Symptomatic patients in whom determination of the mechanism of arrhythmia or knowledge of the	Asymptomatic patients with a family history of sudden cardiac death or with ventricular preexcitation but no spontaneous arrhythmia who engage in high-risk occupations or activities and in whom knowledge of the electrophysiologic properties of the accessory pathway or inducible tachycardia may help determine recommendations for further activities or therapy	Asymptomatic patients with ventricular preexcitation, except those in class II

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	electrophysiologic properties of the accessory pathway and normal conduction system would help in determining appropriate therapy	Patients with ventricular preexcitation who are undergoing cardiac surgery for other reasons	
Premature ventricular complexes (PVCs), couplets, and nonsustained VT	None	Patients with other risk factors for future arrhythmic events, such as a low ejection fraction, positive signal-averaged electrocardiogram, and nonsustained VT on ambulatory ECG recordings in whom EP study will be used for further risk assessment and for guiding therapy in patients with inducible VT Patients with highly symptomatic, uniformmorphology PVCs, couplets, and nonsustained VT who are considered potential candidates for catheter ablation	Asymptomatic or mildly symptomatic patients with PVCs, couplets, and nonsustained VT without other risk factors for sustained arrhythmias
	Evaluation	of Clinical Syndromes	
Unexplained syncope	Patients with suspected structural heart disease and syncope that remain unexplained after appropriate evaluation	Patients with recurrent unexplained syncope but without structural heart disease and a negative head-up tilt test result	Patients with a known cause of syncope for whom treatment will not be guided by electrophysiologic testing
Survivors of cardiac arrest	Patients surviving cardiac arrest without evidence of acute Q wave MI Patients surviving cardiac arrest occurring more than 48 hours after acute phase of MI in the absence of recurrent ischemic events	Patients surviving cardiac arrest caused by bradyarrhythmia Patients surviving cardiac arrest thought to be associated with a congenital repolarization abnormality (long-QT syndrome) in whom the results of noninvasive diagnostic testing are equivocal	Patients surviving a cardiac arrest that occurred during acute phase (<48 hr) of MI Patients with cardiac arrest resulting from clearly definable specific causes, such as reversible ischemia, severe valvular aortic stenosis, or noninvasively defined congenital or acquired long-QT syndrome
Unexplained palpitations	Patients with palpitations who have their pulse rate	Patients with clinically significant palpitations, suspected to be of cardiac	Patients with palpitations documented to result

	documented by medical personnel as inappropriately rapid and in whom ECG recordings fail to document the cause of the palpitations Patients with palpitations preceding a syncopal episode	origin in whom the symptoms are sporadic and cannot be documented; studies performed to determine mechanisms of arrhythmias, direct or provide therapy, or assess prognosis	from extracardiac causes (e.g., hyperthyroidism)
Cuidenes of		Deutic Intervention	Detion to with inclusion
Guidance of drug therapy	Patients with sustained VT or cardiac arrest, especially those with prior MI Patients with AVNRT, AV reentrant tachycardia using an accessory pathway, or AF associated with an accessory pathway for whom chronic drug therapy is planned	Patients with sinus node reentrant tachycardia, atrial tachycardia, AF, or atrial flutter without ventricular preexcitation syndrome for whom chronic drug therapy is planned Patients with arrhythmias not inducible during controlled EP study for whom drug therapy is planned	Patients with isolated atrial or ventricular premature complexes Patients with ventricular fibrillation with a clearly identified reversible cause
Patients who are candidates for or who have implantable electrical devices	Patients with tachyarrhythmias before and during implantation and final (predischarge) programming of an electrical device to confirm its ability to perform as anticipated Patients with an implanted electrical antitachyarrhythmia device in whom changes in status or therapy may have influenced the continued safety and efficacy of the device Patients who have a pacemaker to treat a bradyarrhythmia and receive an ICD to test for device interactions	Patients with previously documented indications for pacemaker implantation to test for the most appropriate long-term pacing mode and sites to optimize symptomatic improvement and hemodynamics	Patients who are not candidates for device therapy

Use Outside of the US

The European Heart Rhythm Association (EHRA) and the European Society of Cardiology (ESC) have guidelines that address recommendations for an electrophysiological (EP) study.

Guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: No Benefit. Procedure/Test not helpful/Treatment: no proven benefit
- Class III Harm. Procedure/Test: Excess cost without benefit, or harmful. Treatment: harmful to patients

The weight of evidence supporting each recommendation is classified as follows:

- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

European Heart Rhythm Association (EHRA)/HRS/Asia Pacific Heart Rhythm Society (APHRS) Expert Consensus on Ventricular Arrhythmias (Pedersen, et al., 2014)			
Indication	Recommendation for	COR/LOE	
	electrophysiological (EP) Study		
Non-sustained ventricular arrhythmia (VA)	An invasive EP study should be considered in patients with significant structural heart disease (SHD) and non-sustained VAs especially if accompanied by unexplained symptoms such as syncope, near-syncope, or sustained palpitations	IIa/C	
Sustained monomorphic ventricular tachycardia (SMVT)	For patients with a wide QRS complex tachycardia in whom the diagnosis is uncertain, an invasive EP study should be considered to identify the tachycardia mechanism	IIa/C	

European Society of Cardiology (ESC) Guidelines for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Priori, et al., 2015)

Indication	Recommendation for EP Study	COR/LOE	
Suspected or known ventricular arrhythmias	In patients with coronary artery disease (CAD) for diagnostic evaluation of patients with remote myocardial infarction with symptoms suggestive of ventricular tachyarrhythmias, including palpitations, presyncope and syncope	I/B	
	In patients with syncope when	I/C	
	bradyarrhythmias or tachyarrhythmias are		

	suspected, based on symptoms (e.g. palpitations) or the results of non-invasive assessment, especially in patients with structural heart disease	
	For the differential diagnosis of arrhythmogenic right ventricular cardiomyopathy (ARVC) and benign right ventricular outflow tract (RVOT) tachycardia or sarcoidosis	IIb/B
Risk stratification and management of patients with dilated cardiomyopathy	Invasive EP study with programmed ventricular stimulation (PVS) may be considered for risk stratification of sudden cardiac death (SCD)	IIb/B
Prevention of sudden cardiac death (SCD) in patients with hypertrophic cardiomyopathy	Invasive EP study with PVS is not recommended for stratification of SCD risk	III/C
Indication	Recommendation for EP Study	COR/LOE
Risk stratification and management of patients with arrhythmogenic right ventricular cardiomyopathy	Invasive EP study with PVS may be considered for stratification of SCD risk	IIb/C
Risk stratification and management in Long QT Syndrome	Invasive EP study with PVS is not recommended for SCD risk stratification	III/C
Risk stratification and management in Short QT Syndrome	Invasive EP study with PVS is not recommended for SCD risk stratification	III/C
Risk stratification and management in Catecholaminergic Polymorphic Ventricular Tachycardia	Invasive EP study with PVS is not recommended for stratification of SCD risk	III/C
Management of ventricular arrhythmias in valvular	An EP study with standby catheter ablation should be considered in patients who develop	IIa/C

European Society of Cardiology (ESC) Guidelines for the Diagnosis and Management of Syncope (Brignole, et al., 2018)			
Indication	Recommendation for EP Study	COR/LOE	
Syncope	In patients with syncope and previous myocardial infarction, or other scar-related conditions, EP study is indicated when syncope remains unexplained after non- invasive evaluation	I/B	
	In patients with syncope and bifascicular bundle branch block (BBB), EP study should be considered when syncope remains unexplained after non-invasive evaluation	IIa/B	
	In patients with syncope and asymptomatic sinus bradycardia, EP study may be	IIb/B	

considered in a few instances when non- invasive tests (e.g. ECG monitoring) have failed to show a correlation between syncope and bradycardia	
In patients with syncope preceded by sudden and brief palpitations, EP study may be considered when syncope remains unexplained after non-invasive evaluation	IIb/C

A section of the guideline addresses additional advice and clinical perspectives stating:

- In general, whereas a positive EP study predicts the cause of syncope, a negative study is unable to exclude an arrhythmic syncope and further evaluation is warranted.
- The induction of polymorphic VT or VF in patients with ischemic cardiomyopathy or DCM cannot be considered a diagnostic finding of the cause of syncope.
- EP study is generally not useful in patients with syncope, normal ECG, no heart disease, and no palpitations.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

- This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
- 2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT [®] * Codes	Description
93619	Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia
93620	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted

CPT®* Codes	Description
	induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)
93622	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left ventricular pacing and recording (List separately in addition to code for primary procedure)

*Current Procedural Terminology (CPT $^{\circ}$) ©2023 American Medical Association: Chicago, IL.

References

- Al-Khatib SM, Stevenson WG, Ackerman MJ, Gillis AM, Bryant WJ, Hlatky MA, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2017 Oct 30.
- Brignole M, Moya A, de Lange FJ, Deharo JC, Elliott PM, Fanciulli A, Fedorowski A, Furlan R, Kenny RA, Martín A, Probst V, Reed MJ, Rice CP, Sutton R, Ungar A, van Dijk JG, 2018 ESC Guidelines for the diagnosis and management of syncope, European Heart Journal, Volume 39, Issue 21, 01 June 2018, Pages 1883–1948, Accessed Aug 7, 2024. Available at URL address: https://doi.org/10.1093/eurheartj/ehy037
- Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Aug 7, 2024. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/local-coverage-proposed-lcdsalphabetical-report.aspx?proposedStatus=A&sortBy=title
- 4. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Aug 7, 2024. Available at URL address: https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title
- 5. Homoud MK. Invasive diagnostic cardiac electrophysiology studies. In: UpToDate, Knight BP (Ed), UpToDate, Waltham, MA. Last updated Aug 19, 2022. (Accessed on August 7, 2024.)
- January CT, Wann LS, Alpert JS, Calkins H, Cigarroa JE, Cleveland JC Jr, et al; American College of Cardiology/American Heart Association Task Force on Practice Guidelines. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2014 Dec 2;64(21):e1-76.
- January CT, Wann LS, Calkins H, Chen LY, Cigarroa JE, Cleveland JC Jr, et al. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration With the Society of Thoracic Surgeons. Circulation. 2019 Jul 9;140(2):e125-e151

- Joglar JA, Chung MK, Armbruster AL, Benjamin EJ, Chyou JY, Cronin EM, Deswal A, Eckhardt LL, Goldberger ZD, Gopinathannair R, Gorenek B, Hess PL, Hlatky M, Hogan G, Ibeh C, Indik JH, Kido K, Kusumoto F, Link MS, Linta KT, Marcus GM, McCarthy PM, Patel N, Patton KK, Perez MV, Piccini JP, Russo AM, Sanders P, Streur MM, Thomas KL, Times S, Tisdale JE, Valente AM, Van Wagoner DR. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2024 Jan 2;83(1):109-279.
- Miller JM, Tomaselli GF, Zipes DP. Diagnosis of Cardiac Arrhythmias. In: Libby P, Zipes DP, Bonow RO, Braunwald E. Braunwald's Heart Disease. A Textbook of Cardiovascular Disease. 11th ed. St. Louis, MO: W.B. Saunders Company; 2019. Ch 35. pgs 656-69.
- Page RL, Joglar JA, Caldwell MA, Calkins H, Conti JB, Deal BJ, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2016 Apr 5;67(13):e27-e115.
- Pedersen CT, Kay GN, Kalman J, Borggrefe M, Della-Bella P, Dickfeld T, Dorian P, Huikuri H, Kim YH, Knight B, Marchlinski F, Ross D, Sacher F, Sapp J, Shivkumar K, Soejima K, Tada H, Alexander ME, Triedman JK, Yamada T, Kirchhof P, ESC Scientific Document Group, EHRA/HRS/APHRS expert consensus on ventricular arrhythmias, EP Europace, Volume 16, Issue 9, September 2014, Pages 1257–1283, Accessed Aug 7, 2024. Available at URL address: https://doi.org/10.1093/europace/euu194
- 12. Pediatric and Congenital Electrophysiology Society (PACES); Heart Rhythm Society (HRS); American College of Cardiology Foundation (ACCF); American Heart Association (AHA); American Academy of Pediatrics (AAP); Canadian Heart Rhythm Society (CHRS), Cohen MI, Triedman JK, Cannon BC, Davis AM, Drago F, Janousek J, Klein GJ, Law IH, Morady FJ, Paul T, Perry JC, Sanatani S, Tanel RE. PACES/HRS expert consensus statement on the management of the asymptomatic young patient with a Wolff-Parkinson-White (WPW, ventricular preexcitation) electrocardiographic pattern: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the Canadian Heart Rhythm Society (CHRS). Heart Rhythm. 2012 Jun;9(6):1006-24.
- 13. Priori S, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, Elliott PM, Fitzsimons D, Hatala R, Hindricks G, Kirchhof P, Kjeldsen K, Kuck KH, Hernandez-Madrid A, Nikolaou N, Norekvål TM, Spaulding C, Van Veldhuisen DJ, ESC Scientific Document Group, 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), European Heart Journal, Volume 36, Issue 41, 1 November 2015, Pages 2793–2867, Accessed Aug 7, 2024. Available at URL address: https://doi.org/10.1093/eurheartj/ehv316
- 14. Russo AM, Stainback RF, Bailey SR, Epstein AE, Heidenreich PA, Jessup M, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 appropriate use criteria for implantable

cardioverter-defibrillators and cardiac resynchronization therapy: a report of the American College of Cardiology Foundation appropriate use criteria task force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. J Am Coll Cardiol. 2013 Mar 26;61(12):1318-68.

- 15. Shen WK, Sheldon RS, Benditt DG, Cohen MI, Forman DE, Goldberger ZD, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2017 Aug 1;70(5):e39-e110.
- Zhao D, Post WS, Blasco-Colmenares E, Cheng A, Zhang Y, Deo R, Pastor-Barriuso R, Michos ED, Sotoodehnia N, Guallar E. Racial differences in sudden cardiac death: atherosclerosis risk in communities study (ARIC). Circulation. Volume 139, Issue 14, 2 April 2019; Pages 1688-1697.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	 No clinical policy statement changes. 	10/15/2024
Annual Review	 Added coverage for determining eligibility for an ICD in an individual with ischemic heart disease and unexplained syncope. Removed requirement for meaningful survival of greater than one year is expected from all policy statements. 	10/15/2023

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