Anthem

Clinical UM Guideline

Subject: Cardiac Electrophysiological Studies (EPS) and Catheter Ablation
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Description

This document addresses two cardiac electrophysiological procedures and studies, including electrophysiological studies (EPS) and catheter ablation. EPS with programmed ventricular stimulation (PVS) is used as a complement to a full workup, to document the inducibility and type of induced arrhythmia, (for example, atrial fibrillation, ventricular tachycardia, etc.). EPS is also used to assess the risks for recurrent ventricular tachycardia or sudden cardiac death; to evaluate symptoms, such as syncope; and to guide catheter ablation procedures in selected individuals when arrhythmias are suspected to be the etiology. EPS can also be used, in appropriate individuals, for the purpose of assessment for eligibility for treatments, such as implantable cardioverter defibrillator therapy.

Note: This document addresses non-emergent elective EPS and catheter ablation procedures *only*.

Note: This document does not address transcatheter ablation of arrhythmogenic foci in the pulmonary veins.

For information related to other technologies associated with cardiac disease evaluation or management, see:

- CG-MED-64 Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins
- CG-THER-RAD-07 Intravascular Brachytherapy (Coronary and Non-Coronary)

Clinical Indications

Medically Necessary:

Cardiac electrophysiological procedures and studies may include the following when criteria are met (A and B):

A. Electrophysiological studies (EPS); **and**
B. Intracardiac catheter ablation.

EPS are considered **medically necessary** for **ANY** of the following indications when criteria are met (A through G):

A. For the evaluation of syncope in individuals with any of the following (1 through 7):
    1. Ischemic heart disease or structural heart disease based on prior positive history, physical examination, and noninvasive testing (for example, electrocardiography, echocardiography) and with impaired left ventricular (LV) function (left ventricular ejection fraction [LVEF] less than or equal to 35%); **or**
    2. For risk stratification in coronary artery disease (CAD) in survivors of myocardial infarction (MI) with preserved LV function (LVEF greater than 35%); **or**
    3. Sinus bradycardia suspected to be associated with Sick Sinus Syndrome (SSS);**or**
    4. When bradyarrhythmias or tachyarrhythmias are suspected as the cause of symptoms with inconclusive prior test results, particularly in the setting of structural heart disease; **or**
    5. Bifascicular block (left or right bundle branch block [BBB] and hemifascicular block) when prior noninvasive testing has been inconclusive or equivocal; **or**
    6. Cardiac sarcoidosis and syncope of suspected arrhythmic etiology; **or**
    7. Moderate or severe adult congenital heart disease (CHD) with unexplained syncope

    or

B. In survivors of sudden cardiac death (SCD) when no diagnostic cause has been confirmed by medical history or prior testing **or** when Pre-excitation Syndrome, (for example, Wolff-Parkinson-White [WPW]) is suspected;

    or

C. For the evaluation of supraventricular tachyarrhythmias (SVT) when criteria 1 **or** 2 are met:
    1. For the evaluation of symptomatic paroxysmal SVT without an identifiable reversible cause; **or**
    2. To identify and localize the arrhythmic substrate when the SVT is recurrent, symptomatic and refractory to medical management with any of the following (a through f):
        a. Suspected Pre-excitation Syndrome, (such as WPW); **or**
        b. Suspected accessory pathways as the cause of the SVT; **or**
        c. Adult individuals with congenital heart disease (CHD);**or**
        d. Atrial flutter; **or**
        e. Paroxysmal or persistent Atrial fibrillation (AF); **or**
        f. AF when symptomatic due to paroxysmal, recurrent or persistent AF for any of the following (i. through iii.):
            i. Hypertrophic cardiomyopathy (HCM); **or**
            ii. With Pre-excitation syndrome (such as WPW) with an accessory pathway;**or**
            iii. Heart failure (NYHA Class II or III) with tachycardia-induced cardiomyopathy (CM) with LVEF less than or equal to 35% when AV nodal ablation is planned (with permanent ventricular pacing);

    or

D. For the evaluation of symptomatic recurrent sustained or nonsustained ventricular tachycardia (VT) that is predominantly monomorphic to determine the source of the arrhythmic substrate when refractory to medical management and implantable cardioverter defibrillator (ICD) therapy (or not a candidate for ICD) for any of the following (1 through 8):
    1. CAD with or without prior history of MI when symptoms are suspicious for VT (for example, palpitations, presyncope, syncope); **or**
    2. CHD when either of the following are present (a or b):

a. LV dysfunction (LVEF equal to or less than 35%) and frequent premature ventricular contractions (PVCs) to assess the efficacy of catheter ablation; **or**
b. In individuals with an ICD who do not wish long-term drug therapy;**or**

3. Structural heart disease with LV dysfunction (LVEF equal to or less than 35%) and frequent PVCs;**or**
4. Dilated cardiomyopathy (DCM) with bundle branch re-entrant VT episodes;**or**
5. Predominantly monomorphic PVC-induced CM manifested by high PVC burden (greater than 24%) with LV dysfunction (LVEF equal to or less than 35%) and a short coupling interval of the PVCs (less than 300 ms); **or**
6. Ischemic heart disease as adjunctive therapy in individuals with an ICD who are receiving multiple shocks as a result of sustained VT that is not manageable by reprogramming the ICD or changing drug therapy or who do not wish long-term drug therapy; **or**
7. Following valvular surgery with bundle branch re-entry VT; **or**
8. PVCs triggering recurrent ventricular fibrillation (VF) leading to ICD interventions.

or

E. In children and adolescents less than 18 years of age with any of the following conditions (1 through 6):
1. Incessant or recurrent SVT associated with ventricular dysfunction;**or**
2. With frequent PVCs or VT thought to be causative of ventricular dysfunction;**or**
3. In symptomatic idiopathic right ventricular outlet tract (RVOT)-VT/PVCs or verapamil-sensitive left fascicular VT or with declining LV function due to RVOT-PVC burden when medical management has been ineffective or not well tolerated; **or**
4. In symptomatic idiopathic left ventricular outflow tract (LVOT), aortic cusps or epicardial VT/PVC when medical management has failed or as an alternative to chronic medical management; **or**
5. As additional therapy or as an alternative to ICD in individuals with CHD who have recurrent monomorphic VT or appropriate ICD therapies that are not manageable by device reprogramming or drug therapy; **or**
6. In suspected Pre-excitation Syndrome, (such as WPW).

or

F. For management or evaluation of individuals with any of the following (1 through 5):
1. Pre-excitation that is asymptomatic to risk stratify for arrhythmic events; **or**
2. Idiopathic VT: palpitations or suspected outflow tract VT in the absence of structural heart disease;**or**
3. LVOT/aortic cusp/epicardial VT/PVCs that is symptomatic and refractory to medical management or in individuals not wanting long-term anti-arrhythmic drug therapy; **or**
4. Papillary muscle tachycardia or mitral and tricuspid annular tachycardia that is symptomatic and refractory to medical management or who do not wish long-term drug therapy; **or**
5. Accessory pathways or atrial tachycardia (AT) in individuals with SVT who are undergoing surgical repair of Ebstein anomaly;

or

G. For the evaluation of first line rhythm control treatment (that is, before medical management has been tried for treatment of the arrhythmia and proven to be ineffective) in individuals with any of the following (1 through 8):
1. Recurrent symptomatic paroxysmal AF; **or**
2. Recurrent symptomatic non-cavotricuspid isthmus (non-CTI) dependent atrial flutter;**or**
3. CTI-dependent atrial flutter, symptomatic or refractory to pharmacological rate control;**or**
4. Recurrent symptomatic AV nodal re-entrant tachycardia (AVNRT);**or**
5. An accessory pathway and symptomatic arrhythmias including orthodromic AV re-entry tachycardia (AVRT), antidromic AVRT, and pre-excited AF or atrial flutter; **or**
6. Symptomatic idiopathic left VTs; **or**
7. Symptomatic focal AT; **or**
8. Frequent non-sustained ventricular arrhythmias (for example, PVC 10,000 per 24 hours with significant symptoms or LV dysfunction [LVEF equal to or less than 35%]).

Cardiac catheter ablation is considered **medically necessary** for the treatment of arrhythmias associated with any of the above indications when the source of the arrhythmic substrate is identified and localized by EPS studies and considered amenable to ablation treatment.

Note: See Definitions section for detailed information about the classifications of AF and other terminology.

Not Medically Necessary:

Cardiac EPS and catheter ablation procedures are considered **not medically necessary** when the criteria are not met and for all other applications, including for risk stratification for SCD in HCM and other cardiac conditions not included in the medically necessary criteria in this document.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

	Electrophysiological studies:
93600	Bundle of His recording
93602	Intra-atrial recording
93603	Right ventricular recording
93609	Intraventricular and/or intra-arterial mapping of tachycardia site(s) with catheter manipulation to record from multiple sites to identify origin of tachycardia
93613	Intracardiac electrophysiologic 3-dimensional mapping

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 induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium
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
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy, including induction or attempted induction of arrhythmia
	Catheter ablation procedures:
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia

ICD-10 Procedure

	Catheter ablation procedures:
02553ZZ	Destruction of atrial septum, percutaneous approach
02563ZZ	Destruction of right atrium, percutaneous approach
02573ZZ	Destruction of left atrium, percutaneous approach
02583ZZ	Destruction of conduction mechanism, percutaneous approach
02593ZZ	Destruction of chordae tendineae, percutaneous approach
025F3ZZ	Destruction of aortic valve, percutaneous approach
025G3ZZ	Destruction of mitral valve, percutaneous approach
025H3ZZ	Destruction of pulmonary valve, percutaneous approach
025J3ZZ	Destruction of tricuspid valve, percutaneous approach
025K3ZZ	Destruction of right ventricle, percutaneous approach
025L3ZZ	Destruction of left ventricle, percutaneous approach
025M3ZZ	Destruction of ventricular septum, percutaneous approach
	Electrophysiological studies:
02K83ZZ	Map conduction mechanism, percutaneous approach
02K84ZZ	Map conduction mechanism, percutaneous endoscopic approach
4A023FZ	Measurement of cardiac rhythm, percutaneous approach
4A028FZ	Measurement of cardiac rhythm, via natural or artificial opening endoscopic

ICD-10 Diagnosis

D86.85	Sarcoid myocarditis
I20.0-I25.9	Ischemic heart disease
I42.0-I42.9	Cardiomyopathy
I43	Cardiomyopathy in diseases classified elsewhere
I44.0-I44.7	Atrioventricular and left bundle-branch block
I45.0-I45.9	Other conduction disorders
I47.0-I47.9	Paroxysmal tachycardia
I48.0-I48.92	Atrial fibrillation and flutter
I49.01-I49.9	Other cardiac arrhythmias
I50.1-I50.9	Heart failure
I51.0-I51.9	Complications and ill-defined descriptions of heart disease
Q20.0-Q24.9	Congenital malformations of cardiac cambers and connections, cardiac septa, pulmonary, tricuspid, aortic and mitral valves, heart
R55	Syncope and collapse
Z86.74	Personal history of sudden cardiac arrest

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Cardiac catheter ablation is a treatment option for individuals with certain types of arrhythmias and is performed following imaging and electro-anatomic mapping, which is done during EPS to identify the specific location of the ectopic excitable foci. Catheter ablation

utilizes radiofrequency or cryoablation energy to eradicate or ablate the arrhythmogenic foci in the heart that is the source of the arrhythmia. In this way, catheter ablation reduces or prevents recurrent episodes of certain supraventricular and ventricular arrhythmias that have demonstrated therapeutic response to this treatment modality in clinical practice.

The medically necessary criteria within this document are based on a review of the following evidence-based guidelines and other specialty society guidance documents:

- ACCF/AHA Guidelines for the Management of Heart Failure (Yancy, 2013);
- ACCF/AHA Focused update incorporated into the ACCF/AHA 2007 Guidelines for the Management of patients with Unstable Angina/non–ST-elevation Myocardial Infarction (Anderson, 2013);
- PACES/HRS Expert Consensus Statement on the Management of the Asymptomatic young patient with a Wolff-Parkinson-White (WPW, ventricular preexcitation) electrocardiographic pattern (Cohen, 2012);
- PACES/HRS Expert Consensus Statement on the use of Catheter Ablation in Children and Patients with Congenital Heart Disease (Saul, 2016);
- HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up (Calkins, 2012);
- EHRA/HRS Expert Consensus on Catheter Ablation of Ventricular Arrhythmias (Aliot, 2009);
- ACC/AHA/ESC Guidelines for Management of patients with Ventricular Arrhythmias and the prevention of sudden cardiac death (Zipes, 2006);
- EHRA and AEPC-Arrhythmia Working Group joint consensus statement: Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population (Brugada, 2013);
- ACC/AHA 2006 Update of the Clinical Competence Statement on invasive Electrophysiology studies, Catheter Ablation, and Cardioversion (Tracy, 2006);
- ESC Guidelines for the Management of patients with Ventricular Arrhythmias and the prevention of sudden cardiac death (Priori, 2015);
- ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia (Page, 2016);
- AHA/ACC/HRS Guideline for the Management of patients with Atrial Fibrillation (January, 2014);
- ESC/EHRA/HFA/HRS Guidelines for the Diagnosis and Management of Syncope (Moya, 2009);
- ACC/AHA/NASPE Guidelines for clinical Intracardiac Electrophysiological and Catheter Ablation procedures (Zipes, 1995);
- ESC Guidelines for the Management of Atrial Fibrillation (Kirchhof, 2016);
- ESC Guidelines for the Diagnosis and Management of Atrial Fibrillation (Hindricks, 2020);
- ACC/AHA/HRS Guideline for the Evaluation and Management of Patients with Syncope (Shen, 2017).

According to the American College of Cardiology and the American Heart Association (ACC/AHA) 2006 Update of the Clinical Competence Statement on invasive Electrophysiology studies, Catheter Ablation, and Cardioversion:

> Because sustained arrhythmias are often episodic in nature or can terminate spontaneously or require intervention before full clinical evaluation, invasive EPS have become a standard means of reproducing an arrhythmia in a controlled laboratory setting. EPS is an interventional procedure that involves the recording of intracardiac electrical signals and programmed electrical stimulation. The EPS may either be performed for diagnostic purposes only or may be part of a combined diagnostic and therapeutic procedure, that is EPS and intracardiac catheter ablation… An EPS requires the placement of electrode catheters for pacing and recording in multiple cardiac chambers. The designs of the catheters and the sites appropriate for their placement are determined according to the nature of the arrhythmia under investigation… A potentially important part of an EPS is the use of intracardiac recordings to determine activation sequences during arrhythmias. This process is usually called “mapping.” Analysis of the responses of an arrhythmia to various pacing techniques is also a component of the mapping process. EPS studies provide clinically valuable diagnostic information… EPS are useful to determine the mechanisms, physiological characteristics and drug responses of supraventricular tachycardias (SVT) and to determine whether arrhythmias are suitable for drug, device, or ablation therapy. In patients with ventricular tachycardia, EPS are useful to confirm the mechanism of the arrhythmia, to assess the effects of pharmacologic therapy, and to select patients for nonpharmacologic treatment… EPS have also been used to assess the future risk of serious antiarrhythmic events, to provide data on which prophylactic therapy may be effective and to assess the patient’s predisposition for spontaneously occurring arrhythmias (Tracy, 2006).

Management of Atrial Fibrillation (AF) and Atrial Flutter:

According to the AHA/ACC/HRS Guideline for the Management of patients with Atrial Fibrillation:

> An EPS can be helpful when initiation of AF is due to a supraventricular tachycardia (SVT), such as AV node reentrant tachycardia, AV reentry involving an accessory pathway, or ectopic atrial tachycardia. Ablation of the SVT may prevent or reduce recurrences of AF. EPS 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 EPS can help establish the correct diagnosis (January, 2014).

According to the ACC/AHA/HRS Guideline for the Management of Adult Patients with Supraventricular Tachycardia, the following is noted:

> Rate control can be difficult to achieve in atrial flutter, and a rhythm control strategy is often chosen. Catheter ablation of CTI-dependent atrial flutter is often preferred to long-term pharmacological therapy; in this rhythm, the CTI represents the optimal target for ablation because a line of ablation between the tricuspid valve annulus and inferior vena cava can effectively interrupt the circuit (Page, 2016).

A Class I (LOE: B-R) recommendation was given for, “Catheter ablation of the CTI (cavotricuspid isthmus dependent) as useful in patients with atrial flutter that is either symptomatic or refractory to pharmacological rate control” which has been added to the medically necessary indications within this document.

Management of Arrhythmias in the Pediatric Population:

According to the European Heart Rhythm Association (EHRA) and the Association for European Pediatric and Congenital Cardiology (AEPC), the EHRA/AEPC Arrhythmia Working Group published a joint consensus statement regarding catheter ablation in the pediatric population with excerpts as follows:

> Focal atrial tachycardia (FAT) is a common cause of supraventricular tachycardia (SVT) in childhood, and the underlying substrate is a distinct autonomic focus anywhere in the atria…Congenital heart disease (CHD) and post-

> surgical electro-anatomical situations can create almost any kind of macro-reentrant circuitry…The aim of EPS is the localization of the accessory pathway within the myocardium and permanent interruption by radiofrequency current delivered directly at the atrial or ventricular insertion of the pathway…In the last decades, radiofrequency catheter ablation (RFCA) has been progressively used as curative therapy for tachyarrhythmias in children and adults with CHD. Even in young children, RFCA procedures can be performed with high success rates and low complication rates (Brugada, 2013).

Management of Ventricular Arrhythmias:

According to the European Society of Cardiology (ESC) Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death, the following is noted:

> EPS may be used to document the arrhythmic cause of syncope and should be used to complement a full syncope workup. It is most useful in patients with coronary artery disease (CAD) and left ventricular (LV) dysfunction. EPS can be used to document or provoke bradyarrhythmias or atrioventricular (AV) block when other investigations have failed to provide conclusive information. The diagnostic yield varies greatly with the selected patient populations and is low in the absence of structural heart disease or abnormal electrocardiogram (ECG). In CAD, the diagnostic yield may reach 50%. In patients with syncope, chronic bundle branch block (BBB) and reduced ejection fraction (LVEF < 45%), ventricular tachycardia (VT) may be induced during EPS in up to 42% of cases. In patients with syncope and BBB, false-negative EPS is common. EPS can provoke nonspecific tachyarrhythmic responses in patients with preserved LV function who do not have structural heart disease… EPS is useful in patients with LV dysfunction due to a previous myocardial infarction (MI) with LVEF < 40% but is not sensitive in patients with non-ischemic cardiomyopathy (NICM)…An EPS is of considerable clinical importance in patients who develop VT following valvular surgery. In up to 30% of patients, VT (occurring mostly within 1 month of surgery) was due to bundle branch reentry, which is an arrhythmia that is potentially curable with catheter ablation…The utility of EPS to determine prognosis and to guide therapy in patients with cardiomyopathies and inherited primary arrhythmia syndromes is less certain. EPS might play a role in ARVC (arrhythmogenic right ventricular cardiomyopathy) and DMC (dilated cardiomyopathy) while it does not contribute to identifying high-risk patients in HCM (hypertrophic cardiomyopathy). Among the channelopathies, EPS is not indicated in LQTS (long QT syndrome), CPVT (catecholaminergic polymorphic ventricular tachycardia) and SQTS (short QT syndrome) while its utility is debated in Brugada syndrome (BrS) (Priori, 2015).
>
> While catheter ablation is an accepted treatment option for a wide range of VT substrates, there is a lack of evidence from prospective, randomized trials that catheter ablation reduces mortality… Several techniques, including point-by-point ablation at the exit site of the re-entry circuit (scar dechanneling), deployment of linear lesion sets or ablation of local abnormal ventricular activity to scar homogenization, can be used…In patients with CAD, the success rate of catheter ablation for VT is determined by the amount of infarct-related scar burden, represented as low-voltage areas on electro-anatomic mapping systems (Priori, 2015).

In 2020 the U.S. Food and Drug Administration (FDA) granted 510(k) clearance to a new EPS system, the Ensite™ X EP system (Abbott Medical, St. Paul, MN) as a legally marketed predicate device. The EnSite X EP System is described as a new generation cardiac mapping system that incorporates Abbott Medical's proprietary EnSite Omniopolar Technology (OT), which allows for a detailed three-dimensional (3D) model of an individual's cardiac anatomy in real-time. This new cardiac mapping platform was designed to help physicians better identify areas where abnormal heart rhythms originate. The system was created to be upgradable via new software to allow physicians to consistently have access to the latest technology without the need for entirely new systems. EnSite uses the Advisor HD Grid Catheter which is indicated to allow the device to provide detailed images irrespective of the orientation of an inserted catheter.

This cardiac mapping platform is the first mapping system that allows physicians to choose between two methods of cardiac visualization, unipolar or bipolar measurement principles. Traditional mapping systems use either unipolar or bipolar measurement principles. While unipolar measurements have multiple advantages, including direction and speed, bipolar measurements provide local signal measuring to pinpoint areas of concern. This EPS system is used in conjunction with additional devices (Advisor™ VL Circular Mapping Catheter, Sensor Enabled™, Advisor™ FL Circular Mapping Catheter, Sensor Enabled™, Advisor™ HD High Density Mapping Catheter, and Sensor Enabled™) for the following approved indications:

- As a suggested diagnostic tool in individuals for whom EPS studies have been indicated.
- The EnSite™ X EP System provides information about the electrical activity of the heart and displays catheter location during conventional electrophysiological (EP) procedures (FDA, 2020).

Definitions

Atrial Fibrillation (AF): A supraventricular tachyarrhythmia (originating in the atria) characterized by uncoordinated atrial activation and ineffective atrial contraction. Characteristics on an ECG include 1) irregular R-R intervals (when atrioventricular [AV] conduction is present), 2) absence of distinct repeating P waves, and 3) irregular atrial activity. The classifications of AF are defined by the AHA/ACC/HRS Guidelines for the management of AF as follows (January, 2014):

> Paroxysmal AF – AF that terminates spontaneously or with intervention within 7 days of onset. Episodes may recur with variable frequency.
>
> Persistent AF – Continuous AF that is sustained greater than 7 days.
>
> Long-standing persistent AF – Continuous AF greater than12 months in duration.
>
> Permanent AF – The term "permanent AF" is used when the individual and clinician make a joint decision to stop further attempts to restore and/or maintain sinus rhythm. Acceptance of AF represents a therapeutic attitude on the part of the individual and clinician rather than an inherent pathophysiological attribute of AF. Acceptance of AF may change as symptoms, efficacy of therapeutic interventions, and individual and clinician preferences evolve.
>
> Nonvalvular AF – AF in the absence of rheumatic mitral stenosis, a mechanical or bioprosthetic heart valve, or mitral valve repair.

Atrial Flutter: A macro-reentrant atrial tachycardia that produces predominantly negative "saw tooth" flutter waves on ECG and involves a typical atrial heart rate between 240 and 300 beats per minute.

Atrial Tachycardia (also known as supraventricular tachycardia [SVT]): A rapid arrhythmia emanating from an excitable foci (or

substrate) in the atria at or above the AV (atrioventricular) node. SVT is characterized by an atrial rate of greater than or equal to 100 beats per minute with discrete P waves and atrial activation sequences seen on ECG patterns. Atrial activation is most commonly the same from beat to beat. There are multiple types of SVT based on the anatomic site of origin and physiologic etiology of the arrhythmia. Some examples are:

- Focal atrial tachycardia (FAT) which comes from a focal point of origin in the atria and is characterized by regular, organized atrial activity with discrete P waves, typically with an isoelectric segment between P waves on ECG.
- Multifocal atrial tachycardia (MAT) which refers to atrial activation sequence and P-wave morphology that varies. MAT originates from a focus in the atria; this arrhythmia is caused by irritable/excitable foci outside the normal sinoatrial (SA) node and is commonly seen in the elderly and often associated with chronic lung disease.
- Paroxysmal supraventricular tachycardia (PSVT) is characterized most commonly by the following two types of SVT:
    - AV nodal re-entrant tachycardia (AVNRT) or atrioventricular nodal re-entrant tachycardia: This most common type of SVT is caused by a re-entry circuit near the AV node that involves two pathways both in the right atrium; and
    - AV re-entrant tachycardia or AV reciprocating tachycardia (AVRT): This type of SVT is most commonly associated with Wolff-Parkinson-White syndrome (WPW), in which an accessory pathway allows electrical signals from the ventricles to enter the atria and cause premature contraction and repeat stimulation of the AV node. AVRT is referred to as either:
        - Orthodromic AVRT where the atrial impulses are conducted down through the AV node and re-enter the atrium in a retrograde fashion via the accessory pathway; or
        - Antidromic AVRT where atrial impulses are conducted down through the accessory pathway and re-enter the atrium in a retrograde fashion via the AV node.

Brugada syndrome (BrS): An autosomal-dominant inherited arrhythmic disorder characterized by ST elevations with successive negative T waves in the right precordial leads without structural cardiac abnormalities. Individuals with BrS are at risk for sudden cardiac death (SCD) due to ventricular fibrillation (VF). Mutations in the SCN5A gene represent the most common genotype responsible for BrS but mutations in additional genes have also been associated with BrS and risk for SCD.

Congenital heart disease: A general term describing abnormalities in the structure of the heart that are present at birth. The abnormalities can include abnormal heart valves or abnormal communications between the different chambers of the heart.

Congestive heart failure (CHF) or Heart Failure (HF): A condition in which the heart no longer adequately functions as a pump. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the lungs and other organs.

Coronary artery disease (CAD): This cardiac disease involves the atherosclerotic build-up of plaque on the inside walls of the coronary arteries which results in partial or complete occlusion or stenosis of the vessel and often leads to myocardial infarction (MI) if untreated.

Electro-anatomical Mapping Systems: Two mapping systems currently in use with clearance from the U.S. Food and Drug Administration (FDA) are the CARTO® System (Biosense Webster®, Inc., Diamond Bar, CA) and the non-contact mapping system, the NavX®/Ensite 3000® (St Jude Medical®, Inc., St. Paul, MN). These systems permit construction of a virtual 3D map of the cardiac chambers and precise assessment of the excitable anatomic locations or foci. These alterations in the reentrant circuitry (or pathways), responsible for atrial and ventricular reentrant tachycardia can then be targeted during EPS for catheter ablation.

Fractional Flow Reserve (FFR): A diagnostic measurement that assesses the clinical significance (severity) of coronary artery stenosis associated with CAD. FFR is defined as the ratio of coronary flow (pressure) proximal to the stenotic lesion relative to the coronary pressure distal to the stenotic lesion, under maximal coronary vasodilation (hyperemia). Small ultrasound transducers are used which enable intracoronary Doppler ultrasound to measure the flow velocity across a coronary lesion (*See FAME trial;* Tornino, 2010). Coronary stenoses with FFR less than or equal to 0.75 or 0.80 are considered significant (Levine, 2011).

Guideline-directed medical therapy (GDMT): *For context within this document,* this terminology, which was formerly referred to as “Optimal medical therapy,” is defined as the use of at least 2 classes of medication to reduce symptoms, (for example, in the treatment of angina symptoms, drugs such as beta blockers, calcium channel blockers, nitrate preparations, ranolazine are used). In the event that an individual is unable to tolerate the medications, the maximum tolerated level of medical therapy will be considered to be maximal GDMT.

Imaging procedure: This is a general term describing a technique to provide an image of a structure, in this case, a picture of the heart or coronary arteries. Angiography and right and left heart catheterization produce images by injecting dye into the heart chambers or coronary arteries, respectively. Other types of cardiac imaging procedures include echocardiography, CT or MRI scans.

Left heart: Describes the two chambers on the left side of the heart, the left atrium, which receives oxygenated blood from the lungs, and the left ventricle, which pumps the blood through the circulation.

Left ventricular ejection fraction (LVEF): The measurement of the heart's ability to pump blood through the body. Normal LVEF readings would be in the 58-70% range.

Myocardial infarction (MI): The medical term for heart attack. A heart attack occurs when the blood supply to part of the heart muscle (the myocardium) is severely reduced or blocked which is seen in advancing CAD.

New York Heart Association (NYHA) definitions:
The NYHA classification of heart failure is a 4-tier system that categorizes subjects based on subjective impression of the degree of functional compromise; the four NYHA functional classes are as follows:

- Class I - patients with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- Class II - patients with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III - patients with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- Class IV - patients with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Right heart: Describes the two chambers on the right side of the heart, the right atrium, which receives the blood returning from the rest of the body, and the right ventricle that pumps this blood to the lungs.

Risk Stratification for adverse events from CAD: The following definitions of risk are taken from the ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT 2012 Appropriate Use Criteria for Coronary Revascularization focused update (Patel, 2012):
High Risk (> 3% annual mortality rate):

1. Severe resting left ventricular dysfunction (LVEF < 35%);
2. High-risk treadmill score (score ≤ -11*);
3. Severe exercise left ventricular dysfunction (exercise LVEF < 35%);
4. Stress-induced large perfusion defect (particularly if anterior);
5. Stress-induced multiple perfusion defects of moderate size;
6. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201);
7. Stress-induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201);
8. Echocardiographic wall motion abnormality (involving > 2 segments) developing at low dose of dobutamine (≤ 10 mg/kg/min) or at a low heart rate (< 120 beats/min);
9. Stress echocardiographic evidence of extensive ischemia.

Intermediate-risk (1% to 3% annual mortality rate):

1. Mild/moderate resting left ventricular dysfunction (LVEF 35% to 49%);
2. Intermediate-risk treadmill score (score between -11 and < 5*);
3. Stress-induced moderate perfusion defect without LV dilation or increased lung intake (thallium-201);
4. Limited stress echocardiographic ischemia with a wall motion abnormality only at higher doses of dobutamine involving less than or equal to 2 segments.

*The Duke Treadmill Score (DTS) is a weighted index combining treadmill exercise time using standard Bruce protocol, maximum net ST segment deviation (depression or elevation), and exercise-induced angina. It was developed to provide accurate diagnostic and prognostic information for the evaluation of individuals with suspected CAD as follows:
≥ +5 Low risk
+4 to -10 Moderate risk
≤ -11 High risk.
Additional information available at: https://www.mdcalc.com/calc/3991/duke-treadmill-score. Accessed on June 27, 2023.

Sick Sinus Syndrome (SSS): This condition encompasses various forms of arrhythmia that result from sinoatrial node dysfunction. Individuals may suffer from syncope and require lifelong pacemaker therapy. Heritable SSS is associated with loss-of-function mutations in SCN5A and are often linked to compound heterozygous mutations in individuals with severe symptoms at a relatively young age.

Structural heart disease: A general term describing abnormalities in the structure of the heart, which includes diseases of the valves or congenital heart disease (present at birth). A cardiac catheterization procedure can evaluate the structure and function of the heart by assessing the left ventricular ejection fraction (see definition above), as well as the movement of the valves of the heart and of the chamber walls.

Transcatheter intravascular ultrasound (IVUS): This imaging technique involves passage of a miniaturized ultrasound transducer mounted on the tip of a catheter, directly into an artery or vein to produce either 2-dimensional tomographic images or 3-dimensional computer-assisted reconstructions of planar IVUS images. IVUS is used as an adjunct to angioplasty, atherectomy, or stent placement.

Unprotected left main CAD: This term refers to an occlusion (or stenosis) of the left main coronary artery. The left main is considered, “Protected” when collateral blood flow or a patent bypass graft exists which connects either the left anterior descending or circumflex artery to the blood flow through the coronary arterial system.

Ventricular Tachycardia (Polymorphic): VT is defined as a continually changing QRS morphology often associated with acute myocardial ischemia, acquired or inheritable channelopathies or ventricular hypertrophy.

Wolf–Parkinson–White Syndrome (WPW): This condition is the second most common cause of supraventricular arrhythmias in the Western world. WPW is characterized by a double excitation of the heart induced by pre-excitation (antesystole) along existing accessory excitation pathways bypassing the normal, that is, orthodromic, AV conduction pathway. The additional AV connection fulfils the anatomic and functional requirements for movement or reentry. Clinically, this usually takes the form of supraventricular reentry tachycardia via the atrium, AV node, ventricle, accessory bundle, and atrium. Each case of WPW is highly individual and can have a variety of manifestations.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion/General Information, Definitions and References sections.
Reviewed	08/11/2022	MPTAC review. The Discussion, Index and References sections were updated. Updated Coding section with 10/1/2022 ICD 10 DX changes. Add I20.2 (in range); Delete I47.2 and add I47.20, I47.21, I47.29 (in range).
	12/29/2021	Updated Coding section with 01/01/2022 CPT descriptor changes for 93653, 93654.
Revised	08/12/2021	MPTAC review. The words, “Intracardiac” and “Transcatheter” have been removed from the Title, Scope and Clinical Indications section for statements regarding electrophysiological procedures and catheter ablation for clarification. A note was added to clarify that ablation of the pulmonary veins is not addressed in this document.
Revised	05/13/2021	MPTAC review. Revised Criterion C to clarify that EPS testing is for evaluation of SVT when either Criteria 1 or 2 are met.
Revised	02/11/2021	MPTAC review. Criterion C was reformatted for clarification with no revisions. CTI-dependent atrial flutter, symptomatic or refractory to pharmacological rate control was added to Criterion G. Discussion and References sections were updated. Reformatted Coding section.
Reviewed	02/20/2020	MPTAC review. References were updated.
Reviewed	03/21/2019	MPTAC review. References were updated. Updated Coding section; added ICD-10-PCS 4A028FZ.
Reviewed	05/03/2018	MPTAC review. The document header wording was updated from “Current Effective Date” to “Publish Date.” References were updated.
Revised	05/04/2017	MPTAC review. Updated the formatting in the Clinical Indications section. The criterion for EPS (No. F 2) was revised to clarify that this is for evaluation of idiopathic VT. Two additional indications for EPS were added in the evaluation of syncope for cardiac sarcoidosis and moderate/severe adult CHD. The evaluation of first-line rhythm control treatment was moved from catheter ablation to indications for doing EPS studies. The Discussion and References sections were updated.

Revised	08/04/2016	MPTAC review. Updated the formatting in the Clinical Indications section. The medically necessary criteria for catheter ablation were expanded to include as first line treatment of frequent non-sustained ventricular arrhythmias when criteria are met. References were updated.
New	05/05/2016	MPTAC review. Initial guideline development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.