

Cohere Medicare Advantage Policy - Electrophysiological Study (EPS)

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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Guideline Name: Cohere Medicare Advantage Policy - Electrophysiological Study (EPS)

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Type: $[\underline{\mathbf{X}}]$ Adult (18+ yo) | $[\underline{\mathbf{X}}]$ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Electrophysiological Study (EPS)

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the <u>CMS Medicare Coverage Database</u> for the most current applicable CMS National Coverage.

 There are no applicable NCDs and/or LCDs for electrophysiological study (EPS).

Recommended Clinical Approach

An electrophysiology study (EPS) is a procedure used to evaluate the electrical activity within the heart. It involves inserting catheters into the heart to measure electrical signals and to diagnose and treat various cardiac arrhythmias (abnormal heart rhythms).

EPS for the evaluation of manifest high-grade atrioventricular (AV) block is recommended when conduction disease is suspected and non-invasive testing does not reveal the location of the AV block. EPS can identify infranodal conduction disease, which can determine if a patient requires permanent pacing. While EPS can be used to evaluate AV nodal function, the study is typically part of a comprehensive EPS for other arrhythmias, especially when symptoms suggest ventricular arrhythmias.

There is no specific indication for EPS to evaluate sinus node dysfunction. However, EPS may be considered when conduction disease is suspected and when non-invasive testing does not reveal an AV block. While there are maneuvers during an EPS that can evaluate sinus node recovery, the study is typically part of a comprehensive EPS for other arrhythmias. This includes atrial fibrillation (AF) or flutter, which can be associated with sinus node dysfunction in tachy-brady syndrome.

Catheter ablation is an acceptable first-line therapy for the treatment of supraventricular tachycardia (SVT). It can be used prior to medication due to its high success and low complication rate. Depending on location, the arrhythmia substrate can be approached using radiofrequency or cryothermal energy. Cryoablation has dramatically reduced the probability of inadvertent AV block during ablation procedures.² EPS describes the diagnostic studies performed to evaluate the cardiac electrical system, usually prior to catheter ablation during the same procedure. Occasionally, diagnostic EPS is used to assess the risk for life-threatening arrhythmias, especially in the decision-making process for an implantable cardioverter defibrillator (ICD) implant.³

EPS for the syncope evaluation depends on the presence of another cardiac disease. In the absence of known cardiac disease, the diagnostic yield of EPS was approximately 10% in patients without; the yield was 50% in patients with structural heart disease. EPS is recommended if clinical arrhythmias are detected during ambulatory monitoring and could benefit from interventions such as ICD implantation, ablation, or permanent pacemaker insertion. Furthermore, EPS may be warranted if conduction abnormalities are suspected, particularly if non-invasive testing fails to identify an AV block. Particular techniques employed during an EPS can assess the recovery of the sinus node. These maneuvers are commonly integrated into a thorough EPS designed to address arrhythmias like AF or flutter, which may correlate with sinus node dysfunction in tachy-brady syndrome. EPS may be indicated when a patient presents with syncope and displays a Brugada pattern on ECG; however, the findings are controversial.

EPS is utilized for patients with congenital heart disease, including preoperative screening for an Ebstein's anomaly to determine the presence of accessory pathways and those with Tetralogy of Fallot (TOF) for inducible ventricular arrhythmias. Some procedures may lead to ablation of the arrhythmogenic substrate (or cause of the arrhythmia) or lead to a decision to implant a defibrillator, especially when hemodynamic risk factors are present that could increase the risk of sudden cardiac death.⁶

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of electrophysiological studies. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Procedure-related complications. Horowitz et al (1987) conducted a
 prospective analysis of 1000 consecutive patients who underwent EPS.
 While a low rate overall, complications may include thrombophlebitis,
 arterial injury, pulmonary embolism, cardiac perforation, and systemic
 arterial embolism. In addition, one death was reported. Cardioversion
 for sustained ventricular tachycardia was also reported.²
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Low complication rate. Al-Khatib et al (2016) cite a low risk of complications in a registry study of 2169 patients (0.09% to 1%). This included pneumothorax and access site complications.⁸
- Risk stratification. There is the benefit of EPS for patients with asymptomatic pre-excitation. In addition, patients who are considered high-risk for future arrhythmias may benefit from accessory-pathway ablation.⁸
- To evaluate conduction disorders. EPS is beneficial for the diagnosis of a conduction order as well as for determining cardiac device implantation indications and utilization of catheter ablation procedures.⁹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- → An **electrophysiological study (EPS)** is considered appropriate if **ANY** of the following is **TRUE**:
 - Symptomatic or significant bradycardia (sinus node dysfunction, atrioventricular [AV] block, etc.) with inconclusive 30 days of non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing)¹; OR
 - Focal atrial tachycardia, which is the likely etiology of new cardiomyopathy; OR
 - ◆ Supraventricular tachycardia (SVT) with ANY of the following:
 - The patient has Ebstein anomaly (with or without pre-excitation or SVT) and no prior surgical intervention on the tricuspid valve^{6,10}; OR
 - The patient has symptomatic or sustained SVT11; OR
 - For risk stratification of Brugada Syndrome with spontaneous or induced type 1 ECG pattern¹²; OR
 - ◆ Wolff-Parkinson-White (WPW) pattern with syncope and **ANY** of the following related to ventricular pre-excitation¹³:
 - The patient's employment would be impacted (e.g., pilots, military service)⁹; OR
 - The patient is asymptomatic and EPS is needed to determine ANY of the following:
 - Inducibility of atrioventricular reentrant tachycardia (AVRT); OR
 - The rapidity of antegrade conduction is a risk factor for sudden cardiac arrest; OR

- ◆ **ANY** of the following related to syncope:
 - Evaluation following myocardial infarction if 30 days of non-invasive monitoring is unrevealing; OR
 - Unexplained syncope with 30 days of inconclusive non-invasive evaluation(s) (e.g., extended ECG monitoring, stress testing) with ANY of the following¹⁴:
 - Asymptomatic sinus node dysfunction is suspected;
 OR
 - o Bifascicular block suspected¹⁵; **OR**
 - Ventricular arrhythmia suspected; OR
- Congenital heart disease (CHD) with ANY of the following:
 - Complex CHD with non-sustained ventricular tachycardia³;
 OR
 - Complex CHD with unexplained syncope³; OR
 - ALL of the following:
 - All evaluations were inconclusive, including comprehensive ECG monitoring and stress testing;
 AND
 - ANY of the following symptoms of significant rhythm abnormalities:
 - ◆ Palpitations; **OR**
 - Shortness of breath; OR
 - ◆ Syncope; OR
- ◆ Ischemic cardiomyopathy with **ALL** of the following¹⁶:
 - Ejection fraction (EF) greater than 35% AND
 - Non-sustained ventricular tachycardia (NSVT) to determine inducibility of sustained VT or ventricular fibrillation.

Non-Indications

- → An electrophysiological study (EPS) is not considered appropriate if ANY of the following is TRUE:
 - Non-sustained, asymptomatic supraventricular tachycardia; OR
 - Risk assessment for an implantable cardioverter defibrillator (ICD) indication and the patient has heart failure with an ejection fraction (EF) less than or equal to 35%; OR
 - Any clinical scenario or documented arrhythmia that is a class I or class II indication for pacemaker or ICD implantation.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	
93600	Bundle of His recording	
93602	Intra-atrial recording	
93603	Right ventricular recording	
93610	Intra-atrial pacing	
93612	Intraventricular pacing	
93618	Induction of arrhythmia by electrical pacing	
93619	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording	
93620	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, right ventricular pacing and recording, and His bundle recording	
93623	Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)	
93624	Electrophysiologic follow-up study with pacing and recording to test effectiveness of therapy with attempted induction of arrhythmia	
93631	Intra-operative epicardial and endocardial pacing and mapping to localize the site of tachycardia or zone of slow conduction for surgical correction	
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode	

	catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with treatment of supraventricular tachycardia by ablation	
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, with attempted induction of arrhythmia, with right atrial pacing and recording, with focus of ventricular ectopy	
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	
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation	
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture	

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Waldmann et al (2023) conducted a prospective multicenter study to systematically evaluate electrophysiological studies (EPS) using programmed ventricular stimulation in tetralogy of Fallot (TOF) patients undergoing assessment for PVR between January 2020 and December 2021. A uniform stimulation protocol was implemented across all participating centers. A cohort included 120 patients (mean age of 39.2±14.5 years; 53.3% males). Sustained ventricular tachycardia (SVT) was induced in 27 (22.5%) patients. The critical isthmus most frequently implicated (90.0%) was identified between the ventricular septal defect patch and pulmonary annulus. Factors independently associated with inducible ventricular tachycardia included a history of atrial arrhythmia and pulmonary annulus diameter greater than 26 mm. EPS findings prompted significant management alterations in 23 (19.2%) cases, including catheter ablation (CA) in 18 (15.0%), surgical cryoablation during pulmonary valve replacement (PVR) in 3 (2.5%), and defibrillator implantation in 9 (7.5%) cases. During a follow-up period of 13 (6.1-20.1) months, no patients experienced sustained ventricular arrhythmias. The authors conclude that the systematic performance of programmed ventricular stimulation in TOF patients undergoing evaluation for PVR reveals a notable rate of inducible ventricular tachycardia and holds the potential to influence treatment strategies. Further research is warranted to ascertain whether adopting a standardized treatment approach based on EPS outcomes will translate into improved clinical outcomes. (ClinicalTrials.gov identifier: NCT04205461).18

Oliveira et al (2023) performed a retrospective study to identify predictors associated with the lack of referral for CA as the initial treatment option in SVT patients. Various clinical and demographic factors were treated as independent variables, while non-referral for CA as the primary treatment was considered the dependent variable in a stepwise logistic regression analysis. Out of 350 patients, 20 clinical-demographic variables were examined, with 10 initially included in the logistic regression analysis: age, gender, presence of pre-excitation on ECG, palpitations, dyspnea, chest discomfort, number of antiarrhythmic drugs prior to ablation, number of concomitant symptoms, duration of symptoms, and emergency room visits due to SVT. Following multivariable-adjusted analysis, age, chest discomfort during SVT, and the number of antiarrhythmic drugs administered before

ablation emerged as independent predictors positively associated with the lack of referral for CA as the first-line treatment for SVT. Overall, the study suggests that certain independent predictors contribute to the underutilization of catheter ablation as the initial treatment option for SVT.¹⁹

Adhaduk et al (2022) conducted a meta-analysis and systematic review of 52 articles and 8 studies to evaluate the role of electrophysiology study in risk stratification of patients with cardiac sarcoidosis (CS). The studies included 298 patients - most studies did not include patients with coronary artery disease (CAD). Use of immunosuppression ranged from 35.8–88%; the mean left ventricle ejection fraction (LVEF) was 34–66.3%. Limitations of the analysis included heterogeneity due to differing diagnostic criteria for CS, including patients with VT. Also, some studies did not include patients with systolic heart failure. The authors concluded that the high sensitivity and specificity of EPS make it a valuable risk stratification tool for patients with CS.²⁰

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