Priority Health

# MEDICAL POLICY No. 91314-R14

## ELECTROPHYSIOLOGY TESTING & CATHETER ABLATION FOR CARDIAC ARRHYTHMIAS

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| **Effective Date: December 1, 2025** | **Review Dates: 1/93, 12/99, 12/01, 12/02, 2/03, 1/04, 3/04, 3/05, 2/06, 8/06, 2/07, 4/07, 4/08, 4/09, 4/10, 4/11, 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 11/18, 11/19, 11/20, 11/21, 11/22, 11/23, 11/24, 11/25** |
| **Date of Origin: November 12, 1992** | **Status: Current** |

**Summary of Changes**

Addition:

- New exclusion. Cardioneural ablation for treatment of vasovagal syncope is considered experimental, investigational or unproven.

## I. POLICY/CRITERIA

A. Electrophysiology (EP) testing does not require prior authorization.

B. Medical necessity for catheter ablation for cardiac arrhythmias is determined through InterQual® criteria.

C. Exclusions:

- High-intensity focused ultrasound (HIFU), (e.g. the Epicor™ system) as a stand-alone ablative procedure for atrial fibrillation is considered investigational.
- Use of an active esophageal cooling device (e.g. ensoETM® (Attune Medical)) during cardiac catheter ablation is considered experimental, investigational or unproven.
- Cardioneural ablation for treatment of vasovagal syncope is considered experimental, investigational or unproven.

## II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals. For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

| National Coverage Determinations (NCDs) | |
|---|---|
| None identified | |
| **Local Coverage Determinations (LCDs)** | |
| CGS Administrators, LLC | None identified |
| First Coast Service Options, Inc. | None identified |
| National Government Services, Inc. | None identified |
| Noridian Healthcare Solutions | None identified |
| Novitas Solutions, Inc. | None identified |
| Palmetto GBA | None identified |
| WPS Insurance Corporation | None identified |

## III. BACKGROUND

Atrial fibrillation (AF) is the most commonly diagnosed cardiac rhythm disturbance, with an incidence of 0.4% in the general population. AF occurs in a high percentage of patients with mitral valve (MV) disease, although it can also occur in individuals with no associated cardiac abnormalities. It is characterized by loss of normal sinoatrial electrical signal and rapid, fine, uncoordinated contraction of the atria.

Atrial fibrillation is associated with morbidity and mortality despite therapy with current antiarrhythmic drugs. Even the best available medical therapy only yields a 50-60 percent annual success rate in maintaining sinus rhythm. Side effects of these drugs can be problematic. Catheter ablation of arrhythmogenic foci can be performed using radiofrequency, microwave, and cryotherapy or ultrasound technology. The Cox-maze IV, sometimes called a mini-maze, is a closed chest, minimally-invasive endoscopic procedure that creates epicardial scar lines or lesions on the epicardium (the outside of the heart) that work to divert the abnormal electrical impulses in the heart. (The Cox-maze III is an open approach typically utilized only in conjunction with valve repair or replacement.) In the convergent procedure, upon completion of a Cox-maze IV, endocardial ablation is performed, creating any additional necessary lesions on the interior walls of the heart. High-intensity focused ultrasound (HIFU), the Epicor™ system, may also be used for ablation in conjunction with other open heart procedures.

Initial experience with catheter ablation procedures based on a creation of linear lesions in both atria was disappointing but led to the key observation that focal triggers localized in the pulmonary veins were responsible for initiation of atrial fibrillation and are thus suitable targets for catheter ablation.

Electrical isolation of all four pulmonary veins from the left atrium provides the highest cure rates for atrial fibrillation. However, the procedure is operator dependent and is associated with a small but significant risk of pulmonary vein stenosis. Given the complexity and difficulties in ablating multiple pulmonary veins, **ablation of atrial fibrillation is not considered the initial treatment of choice or the standard of care for the treatment of atrial fibrillation.**

The optimal treatment method for patients who have idiopathic paroxysmal fibrillation appears to be left atrial catheter ablation as opposed to segmental ostial catheter ablation. Patients with chronic or persistent atrial fibrillation and patients with vago-tonic type of paroxysmal atrial fibrillation pulmonary vein isolation have a low success rate. In these subgroups and in patients with paroxysmal atrial fibrillation that does not respond to pulmonary vein isolation, an approach that involves ablation within the left atrium, it is likely but not proven to yield better results.

Active Esophageal Cooling Device

One major risk of cardiac ablation is thermal injury to the esophagus, which is a consequence of the proximity of the posterior wall of the left atrium to the anterior wall of the esophagus. There are several approaches to cooling the esophagus, including open irrigation of cold liquid inside the esophagus and closed-irrigated systems (e.g., expandable esophageal balloon). These methods have been evaluated in different small clinical trials with inconsistent results, and validation of safety and efficacy is still required. Reducing intraluminal esophageal temperature via active cooling has been proposed to minimize the risk of esophageal thermal injury during RF catheter ablation. Vasoconstriction associated with cooling may predispose to ischemia or vascular compromise to the esophagus.

The FDA granted a De Novo request for classification of Class II on September 13, 2023, to ensoETM® (Attune Medical). The FDA states the device is "Intended to reduce the likelihood of ablation related esophageal injury resulting from radiofrequency cardiac ablation procedures and provide gastric decompression and suctioning." FDA identifies this generic type of device as: "Temperature regulation device for esophageal protection during cardiac ablation procedures. This device is placed in the lumen of the esophagus to reduce the likelihood of esophageal injury or a specific adverse event during cardiac ablation

procedures. The device uses temperature regulation to control the temperature of the esophagus during cardiac ablation."

The **ACC/AHA 2023 Guideline for the Diagnosis and Management of Atrial Fibrillation** (ACC/Joglar, et al., 2024) does not address esophageal cooling.

At this time, there is insufficient evidence in the peer-reviewed published literature in the form of large, well-designed randomized trials reported for the routine use of the ensoETM® esophageal cooling device to reduce ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures.

***Future Studies:***

It is expected that with further advances in technology and simplification of techniques, radio frequency ablation of atrial fibrillation will become a widespread procedure. Methods to reduce the risk of pulmonary veins stenosis are under development. These technological developments primarily focus on design of the catheter tip, including diameter of the catheter tip and method for delivering ablative energy. Balloon-based, ultra-sound catheters using laser and cryoablation are currently being designed, as are circular catheters through which either radiofrequency or cryo lesions can be delivered.

**Cardioneural Ablation for Treatment of Vasovagal Syncope**

Cardioneural ablation (CAN) is a catheter-based procedure that targets the autonomic nervous system to address functional bradyarrhythmias, such as vasovagal syncope and certain atrioventricular blocks (Li et al., 2023). CNA involves disrupting the neural pathways that cause abnormal regulation of involuntary functions, including heart rate and blood pressure (Marrese et al., 2024). During the procedure, small, flexible catheters are threaded through blood vessels to the heart, typically entering via the groin (National Heart, Lung, and Blood Institute, 2022). Electrophysiologists employ specialized mapping techniques, often guided by anatomy or electrogram analysis, to precisely locate ganglionated plexi (GPs), which are clusters of nerve cells responsible for vagal innervation near the heart. Once identified, radiofrequency energy is delivered to ablate (damage) or modify these GPs, aiming to reduce excessive vagal activity that contributes to symptoms like syncope and slow heart rate (Hayes inc., 2025)

In a multicenter US registry evaluating cardioneural ablation (CNA) for functional bradycardia and vasovagal syncope, a total of 205 patients who underwent 210 CNA procedures were included. The mean age was 47 ± 17 years, 49% were female, and baseline left ventricular ejection fraction was 60% ± 5%. The most common indication for CNA was syncope in 66.3% (VVS 61.5%, syncope related to AVB 4.9%), followed by SB in 31.2%, AVB in 1.5%, or both

SB and AVB in 0.9%. An anatomical approach to target typical ganglionated plexus locations was implemented in all cases, with high-frequency stimulation in 47% of procedures. Endocardial ablation targeting ganglionated plexuses was performed in both atria in 77%, with 697 ± 515 seconds of radiofrequency application. Vagal and sympathetic responses during ablation were observed in 52% and 73% of cases, respectively. The mean increase in heart rate immediately after ablation was 20 ± 15 beats/min. Complications were observed in 4.7% of procedures: 2 respiratory failures requiring bilevel positive airway pressure, 1 right diaphragmatic paralysis, and 4 sinus node dysfunction, with a major adverse event rate of 1.4% (2 hemopericardium, 1 death). At a mean follow-up of 14 ± 11 months, 78% of patients with syncope remained free from recurrence, with a reduction in episodes from a median of 7 (4-15) episodes to a median of 0 (0-0) episodes. Overall, 97% of the cohort remained free from pacemaker implantation. (Tung et al., 2025)

A prospective randomized trial by Piotrowski and colleagues (2023) assessed the effects of CNA vs optimal nonpharmacologic therapy on syncope recurrences in patients with vasovagal syncope (VVS). The study was designed as an open, randomized, controlled trial comparing CNA versus optimal nonpharmacologic therapy in patients with cardioinhibitory VVS. Patients were included if they had documented symptomatic cardioinhibitory or mixed VVS and positive atropine test. CNA was performed using radiofrequency ablation of the ganglionated plexi from the left and right atria. Follow-up lasted 2 years. The primary endpoint was time to first syncope recurrence. A total of 48 patients (17 male, mean age 38 ± 10 years, 24 in CNA group, 24 in control group) entered the study. The primary endpoint occurred in 2 patients (8%) from the CNA group versus 13 control patients (54%) (P = 0.0004). After CNA the mean sinus rhythm at 24-hour Holter electrocardiography was significantly faster and heart rate variability parameters significantly changed toward parasympathetic withdrawal compared with baseline values. Quality of life significantly improved in the CNA group (30 ± 10 points vs 10 ± 7 points; P = 0.0001), whereas it remained stable in control patients (31 ± 10 points vs 30 ± 10 points; P = 0.5501).

## IV. GUIDELINES / POSITION STATEMENTS

| Medical/Professional Society | Guideline |
|---|---|
| American College of Cardiology (ACC)<br>American Heart Association (AHA)<br>American College of Clinical Pharmacy (ACCP)<br>Heart Rhythm Society (HRS) | 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation |
| European Society of Cardiology (ESC)<br>European Association for Cardio-Thoracic Surgery (EACTS) | 2024 ESC Guidelines for the management of atrial fibrillation developed in collaboration with the European |

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| European Heart Rhythm Association (EHRA)<br>European Stroke Organisation (ESO) | Association for Cardio-Thoracic Surgery (EACTS): Developed by the task force for the management of atrial fibrillation of the European Society of Cardiology (ESC), with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Endorsed by the European Stroke Organisation (ESO) |
| American College of Cardiology (ACC)<br>American Heart Association (AHA)<br>European Society of Cardiology (ESC) | ACC/AHA/ESC Guidelines for the Management of Patients With Supraventricular Arrhythmias A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines |
| European Heart Rhythm Association (EHRA)<br>European Society of Cardiology (ESC)<br>Heart Rhythm Society (HRS)<br>American College of Cardiology (ACC)<br>American Heart Association (AHA) | EHRA/HRS Expert Consensus on Catheter Ablation of Ventricular Arrhythmias: Developed in a partnership with the European Heart Rhythm Association (EHRA), a Registered Branch of the European Society of Cardiology (ESC), and the Heart Rhythm Society (HRS); in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA) |

## V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

Refer to the US Food & Drug Administration Medical Device Databases for the most current information.

| Device | Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number | Notice Date |
|---|---|---|
| Epicor™ Ablation System<br>(St. Jude Medical) | K082279<br>K080292<br>K022894 | September 16, 2008<br>July 25, 2008<br>February 26, 2004 |
| ensoETM®<br>(Haemonetics®) | DEN230021 | September 13, 2023 |

## VI. CODING INFORMATION

**ICD-10 Codes** that may apply:

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| I44.30 – I44.7 | Other and unspecified atrioventricular block |
| I45.0 – I45.9 | Other conduction disorders |
| I47.0 – I47.9 | Paroxysmal tachycardia |
| I48.0 – I48.92 | Atrial fibrillation and flutter |
| I49.0 – I49.9 | Other cardiac arrhythmias |
| I97.190 – I97.191 | Other postprocedural cardiac functional disturbances following surgery |
| I97.790 – I97.791 | Other intraoperative cardiac functional disturbances during surgery |

**CPT/HCPCS Codes**

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| 93613 | Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure *(no PA required*) |
| 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 including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; 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 including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and 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 (List separately in addition to code for primary procedure) |
| 93656 | Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3- |

dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and His bundle recording, when performed

93657 Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)

33265 Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass. *(No PA required)*

33266 Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass *(No PA required)*

C1732 Catheter, Electrophysiology, diagnostic/ablation 3D or vector mapping

C1886 Catheter, extravascular tissue ablation, any modality (insertable)

**Not Covered**

93799 Unlisted cardiovascular service or procedure *(Not covered when used for High-intensity focused ultrasound (HIFU) ablation. Explanatory notes must accompany claim)*

C1889 Implantable/insertable device, not otherwise classified *[Considered Experimental/Investigational/Unproven when used to report use of an active esophageal cooling device during cardiac catheter ablation]*

## VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

## VIII. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***

- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

## IX. REFERENCES


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Cardioneural Ablation

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