



# Louisiana

## Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 09/13/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Catheter Ablation as Treatment for Atrial Fibrillation is addressed separately in medical policy 00267.*

*Note: Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation is addressed separately in medical policy 00296.*

### When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the maze or modified maze procedure, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery for treatment of symptomatic atrial fibrillation (AF) or flutter to be **eligible for coverage**.\*\*

### When Services Are Considered Not Medically Necessary

The use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery for treatment of atrial fibrillation (AF) or flutter to be **not medically necessary**.\*\*

### When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

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Based on review of available data, the Company considers stand-alone minimally invasive, off-pump maze procedures (ie, modified maze procedures), including those done via mini-thoracotomy for treatment of atrial fibrillation (AF) or flutter to be **investigational**.\*

Based on review of available data, the Company considers hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) for the treatment of atrial fibrillation (AF) or flutter to be **investigational**.\*

Based on review of available data, the Company considers the maze or modified maze procedures for any indication not listed above to be **investigational**.\*

## **Policy Guidelines**

Given the availability of less-invasive alternative approaches to treat atrial fibrillation performing the maze procedure without concomitant cardiac surgery should rarely be needed.

Per the 2017 Expert Consensus Statement by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society (Calkins et al, 2017, referenced in the Supplemental Information section), the indication for concomitant open or closed surgical ablation, stand-alone, and hybrid surgical ablation of atrial fibrillation is symptomatic disease refractory or intolerant to at least 1 Class I or III antiarrhythmic medication.

## **Background/Overview**

### **Atrial Fibrillation**

AF is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves the interplay between electrical triggering events that initiate AF and the myocardial substrate that permits propagation and maintenance of the aberrant electrical circuit. The most common focal trigger of AF appears to be located within the cardiac muscle that extends into the pulmonary veins. The atria are frequently abnormal in patients with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of AF.

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### **Treatment**

The first-line treatment for AF usually includes medications to maintain sinus rhythm and/or control the ventricular rate. Antiarrhythmic medications are only partially effective; therefore, medical treatment is not sufficient for many patients. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for patients who are not adequately controlled on medications and may also be used as first-line treatment. Catheter ablation (CA) is successful in maintaining sinus rhythm for most patients, but long-term recurrences are common and increase over time. Performed either by open surgical techniques or thoracoscopy, surgical ablation is an alternative approach to percutaneous CA.

### **Open Surgical Techniques**

The classic Cox maze III procedure is a complex surgical procedure for patients with AF. It involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart. The procedure is also intended to preserve atrial pumping function. It is indicated for patients who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with correction of structural cardiac conditions such as valve repair or replacement. This procedure is considered the criterion standard for the surgical treatment of drug-resistant AF, with a success rate of approximately 90%.

The maze procedure entails making incisions in the heart that:

- direct an impulse from the sinoatrial node to the atrioventricular node;
- preserve activation of the entire atrium; and
- block re-entrant impulses responsible for AF or atrial flutter.

The classic Cox maze procedure is performed on a nonbeating heart during cardiopulmonary bypass. Simplification of the maze procedure has evolved with the use of different ablation tools such as microwave, cryotherapy, ultrasound, and radiofrequency energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure. The Cox maze IV procedure involves the use of radiofrequency energy or cryoablation to create transmural lesions analogous to the lesions created by the "cut-and-sew" maze.

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## **Minimally Invasive (Thoracoscopic) Techniques**

Less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF have been developed. The evolution of these procedures involves both different surgical approaches and different lesion sets. Alternative surgical approaches include mini-thoracotomy and total thoracoscopy with video assistance. Open thoracotomy and mini-thoracotomy employ cardiopulmonary bypass and open-heart surgery, while thoracoscopic approaches are performed on the beating heart. Thoracoscopic approaches do not enter the heart and use epicardial ablation lesion sets, whereas the open approaches use either the classic "cut-and-sew" approach or endocardial ablation.

Lesion sets may vary independent of the surgical approach, with a tendency toward less extensive lesion sets targeted to areas most likely to be triggers of AF. The most limited lesion sets involve pulmonary vein isolation and exclusion of the left atrial appendage. More extensive lesion sets include linear ablations of the left and/or right atrium and ablation of ganglionic plexi. Some surgeons perform left atrial reduction in cases of left atrial enlargement.

The type of energy used for ablation also varies; radiofrequency energy is most commonly applied. Other energy sources such as cryoablation and high-intensity ultrasound have been used. For our purposes, the variations on surgical procedures for AF will be combined under the heading of "modified maze" procedures.

## **Hybrid Techniques**

"Hybrid" ablation refers to the use of both thoracoscopic and percutaneous approaches in the same patient. Ablation is performed on the outer surface of the heart (epicardial) via the thoracoscopic approach, and on the inner surface of the heart (endocardial) via the percutaneous approach. The rationale for a hybrid procedure is that a combination of both techniques may result in a complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines because the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized.

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The hybrid approach first involves thoracoscopy with epicardial ablation. Following this procedure, an electrophysiologic study is performed percutaneously followed by endocardial ablation as directed by the results of electrophysiology. Most commonly, the electrophysiology study and endocardial ablation are done immediately after the thoracoscopy as part of a single procedure. However, some hybrid approaches perform the electrophysiology study and endocardial ablation on separate days, as directed by the electrophysiology study.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Several radiofrequency ablation systems have been cleared for marketing by the U.S. FDA through the 510(k) process for cardiac tissue ablation (product code OCL). Table 1 provides a select list.

**Table 1. Radiofrequency Ablation Approved by the U.S. Food and Drug Administration**

<b>Device</b>	<b>Manufacturer</b>	<b>510(k)/Premarket Approval Date</b>	<b>510(k)/Premarket Approval Number</b>
EPi-Sense Guided Coagulation System	Atricure	April 2021	P200002
Medtronic DiamondTemp™‡ System	Medtronic	Jan 2021	P200028
Cobra Fusion Ablation System	AtriCure	Feb 2019	K190151
Medtronic Cardioblate®‡ System	Medtronic	Jan 2002	K013392
Cardima Ablation System	Cardima	Jan 2003	K022008
Epicor™ Medical Ablation System	Epicor Medical	Feb 2004	K022894
Isolator™‡ Transpolar™‡ Pen	AtriCure	Jun 2005	K050459

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Estech COBRA <sup>®</sup> ‡ Cardiac Electrosurgical Unit	Endoscopic Technologies	Jan 2006	K053326
Coolrail <sup>™</sup> ‡ Linear Pen	AtriCure	Mar 2008	K073605
Numeris <sup>®</sup> ‡ Guided Coagulation System with VisiTrax <sup>®</sup>	nContact Surgical	Feb 2009	K090202
EPi-Sense <sup>®</sup> ‡ Guided Coagulation System with VisiTrax <sup>®</sup> ‡	nContact Surgical	Nov 2012	K120857

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing, including those in Table 2.

**Table 2. Cryoablation Systems Approved by the U.S. Food and Drug Administration**

Device	Manufacturer	510(k)/Premarket Approval Date
Cryocare <sup>®</sup> ‡ Cardiac Surgery System	Endocare	Mar 2002
SeedNet <sup>™</sup> ‡ System	Galil Medical	May 2005
SurgiFrost <sup>®</sup> ‡ XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic	Jul 2006
Isis <sup>™</sup> ‡ cryosurgical unit	Galil Medical	Mar 2007
Arctic Front Advance <sup>™</sup> ‡ and Arctic Front Advance Pro <sup>™</sup> ‡ and the Freezer Max <sup>™</sup> ‡ Cardiac Cryoablation Catheters	Medtronic	Jun 2020

## Rationale/Source

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There are various surgical approaches to treat AF that work by interrupting abnormal electrical activity in the atria. Open surgical procedures, such as the Cox maze procedure were first developed for this purpose and are now generally performed in conjunction with valvular or coronary artery bypass graft surgery. Surgical techniques have evolved to include minimally invasive approaches that use epicardial radiofrequency ablation, a thoracoscopic or mediastinal approach, and hybrid catheter ablations/open procedures.

### Summary of Evidence

For individuals who have symptomatic AF or flutter who are undergoing cardiac surgery with bypass who received a Cox maze or a modified maze procedure, the evidence includes several randomized controlled trials (RCTs) and nonrandomized comparative studies, along with systematic reviews of these studies. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several small RCTs have provided most of the direct evidence confirming the benefit of a modified maze procedure for patients with AF who are undergoing mitral valve surgery. These trials have established that the addition of a modified maze procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies have supported these RCT findings. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive minimally invasive, off-pump thoracoscopic maze procedures, the evidence includes RCTs and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Two RCTs reported significantly higher rates of freedom from AF at 1-year with surgical ablation, but also reported significantly higher rates of serious adverse events. The remaining 2 RCTs found no significant differences between treatment groups in rates of freedom from AF and either did not assess or did not find significant differences in serious adverse events. The comparative observational studies consistently found significantly higher rates of freedom from atrial arrhythmias, but lacked assessment of serious adverse events. The noncomparative studies generally only reported short-term outcomes and did not consistently report adverse events. Therefore, this evidence does not permit definitive conclusions whether a specific approach is superior to the other. Factors, such as previous treatment, the probability of maintaining sinus rhythm, the risk of complications, contraindications to anticoagulation, and patient preference, may all affect the risk-benefit ratio for

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each procedure. Additionally, the studies do not permit conclusions about harms due to heterogenous measurement across studies, with mixed results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive hybrid thoracoscopic and endocardial ablation procedures, the evidence includes an RCT by DeLurgio et al [2020], and 2 observational studies (Kress et al [2017] and Maclean et al [2020], N=372) that compared a ‘convergent’ hybrid approach (ie, epicardial approach combined with endocardial ablation to catheter ablation) and 1 observational study that compared a thoracoscopic epicardial ablation with a percutaneous trans-septal procedure hybrid approach to catheter ablation (LeMeir et al, 2012, n=63). The DeLurgio (2020) RCT (n=153) found a statistically significantly higher rate on the primary outcome of freedom from AF/atrial flutter/atrial tachycardia absent of class I/II antiarrhythmic drugs at 1-year, but with a nonstatistically significantly higher rate of major adverse events (p=.0525) between 8- and 30-days post procedure. Major adverse events were not reported for the 1-year follow-up period. The 2 observational studies of the convergent hybrid approach found that it was associated with an increased rate of AF-free survival, but major adverse events at 1-year were nonsignificantly more common. LeMeir et al (2012) found that the thoracoscopic epicardial ablation with a percutaneous trans-septal procedure hybrid approach was associated with an increased rate of AF-free survival and no difference in adverse events. For the ‘convergent’ hybrid approach, additional multicenter RCTs are needed with comparisons to catheter ablation that measure the freedom from AF and assess adverse events after at least 1-year of follow-up. For other types of hybrid approaches, multicenter RCTs are needed that use established techniques to control for bias and assess both benefits and harms with at least 1-year of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

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While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

## 2013 Input

In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers (4 reviewers) while this policy was under review in 2013. There was consensus on the medically necessary statements. For subgroups of populations (eg, those who have failed percutaneous catheter ablation), there was mixed support without consensus. There was also mixed support for the use of hybrid ablation.

## 2010 Input

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers (4 reviewers) while this policy was under review in 2010. There was unanimous support for the policy statement regarding with cardiopulmonary bypass maze procedure. There was mixed support for the policy statement on off-bypass (off-pump) maze procedure; some providing input indicated off-pump procedures might be useful in select patients (eg, those who cannot tolerate anticoagulation). Several providing input also commented on the limited long-term data for off-pump procedures.

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## Society of Thoracic Surgeons

In 2017, the Society of Thoracic Surgeons published guidelines on the surgical treatment of AF. Recommendations are provided in Table 3.

## Table 3. Guidelines on Surgical Treatment of Atrial Fibrillation

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Recommendation	COR	LOE
Surgical ablation for AF is recommended at the time of concomitant mitral operations to restore sinus rhythm.	I	A
Surgical ablation for AF is recommended at the time of concomitant isolated aortic valve replacement, isolated CABG surgery, and aortic valve replacement plus CABG operations to restore sinus rhythm.	I	B
Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy of both is reasonable as a primary stand-alone procedure to restore sinus rhythm.	IIa	B

AF: atrial fibrillation; CABG: coronary artery bypass graft; COR: class of recommendation; LOE: level of evidence.

### American Heart Association et al

In 2019, the American Heart Association, American College of Cardiologists, and Heart Rhythm Society issued joint guidelines in collaboration with the Society of Thoracic Surgeons on the management of patients with AF. Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in Table 4.

**Table 4. Guidelines on the Management of Atrial Fibrillation**

Recommendation	COR	LOE
"AF catheter ablation may be reasonable in selected patients with symptomatic AF and HF with reduced left ventricular (LV) ejection fraction (HFrEF) to potentially lower mortality rate and reduce hospitalization for HF (S6.3.4-1, S6.3.4-2)."	IIb	B-R

AF: atrial fibrillation; COR: class of recommendation; HF: heart failure; LOE: level of evidence.  
Heart Rhythm Society et al

A 2017 expert consensus statement was developed by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society. The statement was endorsed by 4 other cardiology associations. Recommendations on concomitant surgical ablation in patients

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undergoing cardiac surgery for other purposes and who have symptomatic AF are provided in Table 5.

**Table 5. Guidelines on Concomitant Surgical Ablation in Patients Undergoing Cardiac Surgery<sup>a</sup>**

Recommendation	COR	LOE
Paroxysmal: Surgical ablation is recommended for patients undergoing surgery for other indications	II	B-NR
Persistent: Surgical ablation is recommended for patients undergoing surgery for other indications	II	B-NR
Longstanding Persistent: Surgical ablation is recommended for patients undergoing surgery for other indications	II	NR

COR: class of recommendation; LOE: level of evidence; NR: nonrandomized. a: For patients with symptomatic AF prior to initiation of antiarrhythmic therapy with Class I or III antiarrhythmic medication and an indication for concomitant closed surgical ablation for AF, surgical ablation is reasonable for paroxysmal, persistent, and long-standing persistent disease (Class: IIa; LOE: B-NR).

The following recommendations were made on stand-alone and hybrid surgical ablation in patients with symptomatic AF refractory or intolerant to at least one class 1 or 3 antiarrhythmic medication (Table 6).

**Table 6. Guidelines on Stand-Alone and Hybrid Surgical Ablation for Symptomatic Atrial Fibrillation Refractory or Intolerant to Antiarrhythmics**

Recommendation <sup>a</sup>	COR	LOE
Paroxysmal		
Stand alone surgical ablation can be considered for patients who have not failed catheter ablation but prefer a surgical approach	Iib	B-NR

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Stand alone surgical ablation can be considered for patients who have failed one or more attempts at catheter ablation	IIb	B-NR
Persistent		
Stand alone surgical ablation is reasonable for patients who have not failed catheter ablation but prefer a surgical approach	IIa	B-NR
Stand alone surgical ablation is reasonable for patients who have failed one or more attempts at catheter ablation	IIa	B-NR
Longstanding persistent		
Stand alone surgical ablation is reasonable for patients who have not failed catheter ablation but prefer a surgical approach	IIb	B-NR
Stand alone surgical ablation is reasonable for patients who have failed one or more attempts at catheter ablation	IIb	B-NR

COR: class of recommendation; LOE: level of evidence; NR: nonrandomized. a: The recommendations noted that "it might be reasonable to apply the indication for stand-alone surgical ablation described above to patients being considered for hybrid surgical AF ablation."

### American Association for Thoracic Surgery

In 2017, the American Association for Thoracic Surgery published guidelines on surgical ablation for AF. Recommendations on concomitant surgical ablation in patients with AF are provided in Table 7.

**Table 7. Guidelines on Concomitant Surgical Ablation in Patients with Atrial Fibrillation**

Recommendation	COR	LOE
"Addition of a concomitant surgical ablation procedure for AF does not increase the incidence of perioperative morbidity."	IIa	A, B-R, B-NR <sup>a</sup>
"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of perioperative stroke/TIA."	IIa	A

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"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of late stroke/TIA, but subgroup analysis of nonrandomized controlled trials found a significant reduction in late stroke/TIA incidence."	IIa	A, B-NR <sup>b</sup>
"A surgical procedure that includes concomitant surgical ablation for AF does improve HRQL."	IIa	B-R
"Addition of concomitant surgical ablation for AF does improve AF-related symptoms, and this improvement is greater than in patients without surgical ablation for AF."	IIa	C-LD
"Addition of concomitant surgical ablation for AF does improve 30-day operative mortality."	I	A
"Addition of a concomitant surgical ablation procedure for AF improves long term survival."	IIa	A, B-NR <sup>c</sup>

AF: atrial fibrillation; COR: class of recommendation; HRQL: health-related quality of life; LOE: level of evidence ; NR: nonrandomized; R: randomized; TIA: transient ischemic attack  
a: "LOE A for deep sternal wound infection, pneumonia, reoperation for bleeding, and renal failure requiring dialysis; LOE B-R for intensive care unit length of stay and total hospital length of stay; and LOE B-NR for readmission less than 30 days and renal failure."  
b: "LOE A for no change in incidence of late stroke/ TIA (up to 1 year of follow-up after surgery) and LOE B-NR for reduction in incidence of late stroke/TIA (>1 year of follow-up after surgery)."  
c: "LOE A for no change in long-term survival (up to 1 year after surgery) and LOE B-NR for improvement in long-term survival (>1 year after surgery)."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

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Some currently ongoing and unpublished trials that might influence this review are listed in Table 8.

**Table 8. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<i>Ongoing</i>			
NCT04237389	Comparative Assessment of Catheter and Thoracoscopic Approaches in Patients With Persistent and Long-standing Persistent Atrial Fibrillation	60	Aug 2022
NCT03546374	Irrigated Radio Frequency Ablation to Terminate Non-Paroxysmal Atrial Fibrillation (Terminate AF Study)	160	May 2022
NCT03732794	AtriCure CryoICE Lesions for Persistent and Long-standing Persistent Atrial Fibrillation Treatment During Concomitant On-Pump Endo/Epicardial Cardiac Surgery	150	Jul 2024
NCT02393885	Pivotal Study Of A Dual Epicardial & Endocardial Procedure (DEEP) Approach for Treatment of Subjects With Persistent or Long Standing Persistent Atrial Fibrillation With Radiofrequency Ablation	220	Dec 2026
NCT04715425	Thoracoscopic Surgical Versus Catheter Ablation Approaches for Primary Treatment of Persistent Atrial Fibrillation	170	Sep 2028
<i>Unpublished</i>			

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NCT02047279	Left Atrium Reduction Versus no Left Atrium Reduction for Patients With Enlarged Left Atria and Persistent or Long Standing Persistent Atrial Fibrillation Undergoing Mitral Valve Surgery	120	Sep 2017 (completed)
NCT02441738	Hybrid Thoracoscopic Surgical and Transvenous Catheter Ablation Versus Transvenous Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation	41	Dec 2018 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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### **Policy History**

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08/09/2018 Medical Policy Committee review

08/15/2018 Medical Policy Implementation Committee approval. New policy

08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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08/06/2020 Medical Policy Committee review

08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/05/2021 Medical Policy Committee review

08/11/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2022

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Code Type	Code
CPT	33254, 33255, 33256, 33265, 33266
HCPCS	No codes
ICD-10 Diagnosis	I48.0-I48.92

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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