

BLUE CROSS

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MEDICAL POLICY – 7.01.587 Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)

BCBSA Ref. Policy:	7.01.14		
Effective Date:	Jun. 1, 2025	LATED MEDICAL POLICIES:	
Last Revised:	May 12, 2025	02.26 Percutaneous Left At	ial Appendage Closure Devices for Stroke
Replaces:	7.01.14	Prevention in Atrial F	ibrillation
		2.516 Catheter Ablation as	Treatment for Atrial Fibrillation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

A condition where your heartbeat is irregular, or flutters is called atrial fibrillation (AF). AF may be treated with surgery that stops the abnormal activity in the heart. One type of surgery to treat AF is called the Cox maze procedure, which is done by cutting through the chest to access the heart. This procedure was first developed to treat AF, and now is mostly done with another surgery, like valvular or coronary bypass graft surgery. A hybrid ablation is when a mini-maze procedure is performed outside of the heart without cutting into the chest, then a catheter ablation is performed on the inside of the heart by a specialist. Many other procedures to treat AF have been developed that can be done through very small cuts using special tools and techniques, removing the need for larger cuts. This policy explains when the Cox maze procedure may be considered medically necessary to treat AF or flutter.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a

Policy Coverage Criteria

Surgery	Medical Necessity
Maze or modified maze	The maze or modified maze procedure, performed on a non-
procedure with other	beating heart during cardiopulmonary bypass with
cardiac surgery (33257,	concomitant cardiac surgery is considered medically necessary
33259)	for the treatment of symptomatic atrial fibrillation or flutter.
Maze or modified maze procedure without other cardiac surgery (33254, 33256)	The use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery is considered not medically necessary for the treatment of atrial fibrillation or flutter.

Surgery	Investigational
Stand-alone minimally	Stand-alone minimally invasive, off-pump maze procedures
invasive, off-pump maze	(i.e., modified maze procedures), including those done via
procedures (33254,33255,)	mini-thoracotomy, are considered investigational for the
	treatment of atrial fibrillation or flutter.
Hybrid ablation (33254,	Hybrid ablation (defined as a combined percutaneous
33258,33265, 33266)	endocardial and thoracoscopic epicardial approach) (a.k.a.
	convergent hybrid procedure) is considered investigational for
	the treatment of atrial fibrillation or flutter.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

• Office visit notes that contain the relevant history and physical with the requested procedure (maze or modified maze) and the concomitant cardiac surgery that will be performed at the same time

Code	Description
СРТ	
33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure or hybrid ablation)
33255	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass
33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified maze procedure) (List separately in addition to code for primary procedure)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), with cardiopulmonary bypass (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
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass

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Related Information

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), 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 one Class I or III antiarrhythmic medication.

Evidence Review

Description

There are various surgical approaches to treat atrial fibrillation (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.

Background

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 individuals with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of AF.

Epidemiology

In the US, more than 3 to 6 million people have AF and it has been estimated that more than 12 million people will have AF by 2030.^{1,2,3} Age, body mass index, height, hypertension, diabetes mellitus, obstructive sleep apnea, myocardial infarction, heart failure, hyperthyroidism, chronic kidney disease, smoking, moderate to heavy alcohol consumption, and genetic predisposition are all risk factors for AF^{,3,4} Age-adjusted AF incidence and prevalence is higher among men than women, although the lifetime risk is similar at 24% for men and 22% for women⁵. AF



incidence and prevalence appear lower in individuals who are Black compared to White, despite a higher burden of comorbidities. However, this difference is likely largely explained by differential detection of AF by race/ethnicity.⁶

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 individuals. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for individuals 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 individuals, 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 individuals 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 individuals who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with the 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 non-beating 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.

Minimally Invasive (Thoracoscopic) Techniques

Less invasive, transthoracic, endoscopic, and 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 individual. 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 procedure is called "hybrid convergent" when utilizing endoscopic subxiphoid access. 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.



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.

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 individuals 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 one-year with surgical ablation but also reported significantly higher rates of serious adverse events. The remaining two 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 about whether one 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 individual preference, may all affect the risk-benefit ratio for each procedure. Additionally, the studies do not permit conclusions about harm due to



heterogeneous 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 five RCTs (sample sizes ranging from 41 to 154), comparative observational studies, single-arm case series, and systematic reviews of these studies. Evidence from randomized and nonrandomized studies found an increased rate of AF-free survival, reduced risk of cardioversion, and increased risk of periprocedural adverse events with hybrid procedures relative to standard ablation. The largest RCT (CEASE-AF) reported composite major complications at 1 year in 9% vs 6% with hybrid vs standard ablation. The surgical ablation lesion sets varied across studies and have not been standardized in practice. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03546374	Irrigated Radio Frequency Ablation to Terminate Non-Paroxysmal Atrial Fibrillation (Terminate AF Study)	160	Aug 2024
NCT06165510	Convergent Ablation Plus Left Atrial Appendage Isolation for the Treatment of Persistent Atrial Fibrillation (CLIP-AF)	48	Oct 2025
NCT03737929	Comparison of the Efficacy of Hybrid Ablative Therapy for Patients With Persistent Atrial Fibrillation Versus Conventional Catheter Ablation	228	Dec 2025
NCT05393180	Hybrid Convergent of Epicardial and Endocardial RF Ablation for the Treatment of	325	Dec 2025

Table 1. Summary of Key Trials



NCT No.	Trial Name	Planned Enrollment	Completion Date
	Symptomatic Longstanding Persistent AF: CONVERGE Post-Approval Study (PAS)		
NCT05723536	LAI-AF Trial: Hybrid Endo-epicardial Partial Left Atrial Isolation vs. Endocardial Ablation in Patients With Persistent Atrial Fibrillation (PLAI-AF)	80	Dec 2025
NCT03732794	AtriCure CryoICE Lesions for Persistent and Long-standing Persistent Atrial Fibrillation Treatment During Concomitant On-Pump Endo/Epicardial Cardiac Surgery	150	Dec 2026
NCT05411614	A Randomised Controlled Trial Comparing Hybrid Convergent Ablation to Standard Catheter Ablation in Patients With Non- Paroxysmal Atrial Fibrillation (HALT-AF)	100	Oct 2027
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 2027
NCT04715425	Thoracoscopic Surgical Versus Catheter Ablation Approaches for Primary Treatment of Persistent Atrial Fibrillation	170	Sep 2028
Unpublished			
NCT04237389	Comparative Assessment of Catheter and Thoracoscopic Approaches in Patients With Persistent and Long-standing Persistent Atrial Fibrillation	60	Aug 2022 (unknown)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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 two physician specialty societies and six academic medical centers (four reviewers) while this policy was under review in 2013. There was consensus on the medically necessary statements. For subgroups of populations (e.g., those who have failed percutaneous catheter ablation), there was mixed support without consensus. There was also mixed support for the use of hybrid ablation.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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 2023, the Society of Thoracic Surgeons published guidelines on the surgical treatment of AF.⁷⁸ Recommendations are provided in **Table 2**.

Table 2. Guidelines on Surgical Treatment of Atrial Fibrillation

Recommendation	COR	LOE
Surgical ablation for AF is recommended for first-time non-emergent concomitant mitral operations to restore sinus rhythm and improve long-term outcomes.	I	A
Surgical ablation for AF is recommended for any first-time non-emergent concomitant non- mitral operation to restore sinus rhythm and improve long-term outcomes.	I	В
Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs, catheter-based therapy or both is reasonable as a primary stand-alone procedure to restore sinus rhythm.	lla	В



Recommendation	COR	LOE
Surgical ablation for symptomatic persistent or longstanding persistent AF in the absence of	lla	В
structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV		
lesion set as the preferred procedure.		

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

American Heart Association et al

In 2023, the American Heart Association, American College of Cardiologists, American College of Clinical Pharmacy, and the Heart Rhythm Society issued joint guidelines on the diagnosis and management of individuals with AF.⁷⁹ Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in **Table 3**.

Table 3. Guidelines on the Management of Atrial Fibrillation

Recommendation	COR	LOE
For patients with AF who are undergoing cardiac surgery, concomitant surgical ablation can be beneficial to reduce the risk of recurrent AF.	2a	В
For patients with symptomatic, persistent AF refractory to antiarrhythmic drug therapy, a hybrid epicardial and endocardial ablation might be reasonable to reduce the risk of recurrent atrial arrhythmia.	2b	В

AF: atrial fibrillation; COR: class of recommendation; HF: heart failure; LOE: level of evidence.

Heart Rhythm Society et al

A 2024 expert consensus statement on catheter and surgical ablation of atrial fibrillation was developed by the Heart Rhythm Society, European Heart Rhythm Association, Asia Pacific Heart Rhythm Society, and Latin American Heart Rhythm Society.⁸⁰ Recommendations on concomitant



surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF are provided in **Table 4**.

Table 4. Guidelines on Concomitant Surgical Ablation in Patients Undergoing Cardiac Surgery^a

Recommendation	COR	LOE
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF	Advice to	META
undergoing left atrial open cardiac surgery regardless of prior antiarrhythmic drug failure or	do	
intolerance		
Concomitant surgical AF ablation is beneficial in patients with paroxysmal or persistent AF	Advice to	META
intolerant or refractory to previous antiarrhythmic drug therapy, undergoing close (non-left	do	
atrial open) cardiac surgery		
Biatrial Cox maze procedure or a minimum of PVI plus left atrial posterior wall isolation is	Advice to	RAND
beneficial in patients undergoing surgical AF ablation concomitant to left atrial open cardiac	do	
surgery		
Concomitant surgical AF ablation is reasonable in patients with paroxysmal or persistent AF	May be	META
prior to initiation of Class I or III antiarrhythmic therapy, undergoing close (non-left atrial	appropri	
open) cardiac surgery	ate to do	

META: Evidence from >1 high-quality RCT or Meta-analyses of high-quality RCTs; RAND: Evidence from 1 high-quality RCT or Evidence from >1 moderate-quality RCT or Meta-analyses of moderate-quality RCTs

The following recommendations were made on stand-alone and hybrid surgical ablation (**Table 5**).

Table 5. Guidelines on Stand-Alone and Hybrid Surgical Ablation forSymptomatic Atrial Fibrillation

Recommendation ^a	COR	LOE
Stand-alone surgical or hybrid ablation is reasonable in symptomatic patients with persistent	May be	META
AF with prior unsuccessful catheter ablation and also in those who are intolerant or refractory	appropri	
to antiarrhythmic drug therapy and prefer a surgical/hybrid approach, after careful	ate to do	
consideration of relative safety and efficacy of treatment options.		



Recommendation ^a	COR	LOE
Stand-alone surgical or hybrid ablation may be reasonable in symptomatic patients with	Area of	RAND
paroxysmal AF with prior unsuccessful catheter ablations who prefer a surgical/hybrid	uncertain	
approach, after careful consideration of relative safety and efficacy of treatment options	ty	

META: Evidence from >1 high-quality RCT or Meta-analyses of high-quality RCTs; RAND: Evidence from 1 high-quality RCT or Evidence from >1 moderate-quality RCT or Meta-analyses of moderate-quality RCTs

American Association for Thoracic Surgery

In 2017, the American Association for Thoracic Surgery published guidelines on surgical ablation for AF.⁸¹ Recommendations on concomitant surgical ablation in patients with AF are provided in **Table 6**.

Table 6. Guidelines on Concomitant Surgical Ablation in Patients withAtrial Fibrillation

Recommendation	COR	LOE
"Addition of a concomitant surgical ablation procedure for AF does not increase the incidence of perioperative morbidity."	lla	A, B-R, B-NRª
"Addition of a concomitant surgical ablation procedure for AF does not change the incidence of perioperative stroke/TIA."	lla	A
"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."	lla	A, B- NR ^b
"A surgical procedure that includes concomitant surgical ablation for AF does improve HRQL."	lla	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."	lla	C-LD
"Addition of concomitant surgical ablation for AF does improve 30-day operative mortality."	1	А
"Addition of a concomitant surgical ablation procedure for AF improves long term survival."	lla	A, B-NR ^c

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)."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several ablation systems have been approved or cleared for marketing by the US Food and Drug Administration through the 510(k) process for cardiac tissue ablation (product code OCL) or PMA process (product code OCM). **Table 7** provides a select list.

Table 7. Radiofrequency Ablation Approved by the US Food and DrugAdministration

Device	Manufacturer
EPi-Sense Guided Coagulation System	Atricure
Medtronic DiamondTemp System	Medtronic
Cobra Fusion Ablation System	AtriCure
Medtronic Cardioblate and Cardioblate Gemini Systems	Medtronic
Cardima Ablation System	Cardima
Epicor Medical Ablation System	Epicor Medical
Isolator Systems	AtriCure
Estech COBRA Cardiac Electrosurgical Unit	Endoscopic Technologies
Coolrail Linear Pen	AtriCure
Numeris Guided Coagulation System with VisiTrax	nContact Surgical
EPi-Sense Guided Coagulation System with VisiTrax	nContact Surgical

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing, including those in **Table 8**.



Table 8. Cryoablation Systems Approved or Cleared by the US Food andDrug Administration

Device	Manufacturer
Cryocare Cardiac Surgery System	Endocare
SeedNet System	Galil Medical
SurgiFrost XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic
Isis cryosurgical unit	Galil Medical
Artic Front Advance and Arctic Front Advance Pro and the Freezer Max Cardiac Cryoablation Catheters	Medtronic

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History

Date	Comments
06/01/23	New policy, approved May 9, 2023, effective for dates of service on or after September 1, 2023, following 90-day provider notification. Add to Surgery section. The maze or modified maze performed during cardiopulmonary bypass with concomitant cardiac surgery is considered medically necessary for the treatment of AF or flutter, all other variations of the procedure are considered investigational. Surgery performed without concomitant cardiac surgery is considered is considered not medically necessary.
08/01/23	Policy renumbered, approved July 11, 2023, from 7.01.14 to 7.01.587 Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures). Policy updated with literature review through March 9, 2023; references added. Policy statement unchanged.
08/03/23	Minor revision, removed the word Pharmacy from the policy header as this is a Medical-only policy.
12/01/24	Annual Review, approved November 25, 2024. Policy reviewed. References added. Policy statements unchanged.
06/01/25	Annual Review, approved May 12, 2025. Policy updated with literature review through November 19, 2024; references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit



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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

