

# MEDICAL POLICY



<b>Medical Policy Title</b>	<b>Maze Procedures for Atrial Fibrillation and Flutter</b>
<b>Policy Number</b>	<b>7.01.27</b>
<b>Current Effective Date</b>	June 26, 2025
<b>Next Review Date</b>	June 2026

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## POLICY STATEMENT(S)

- I. Maze procedures performed on a non-beating heart during cardiopulmonary bypass are considered **medically appropriate** for the treatment of medically refractory, chronic, symptomatic atrial fibrillation or flutter, with or without concurrent cardiac surgery.
- II. Minimally invasive, off-pump Maze procedures (e.g., mini thoracotomy); including Hybrid or convergent ablation procedures (defined as a combined percutaneous catheter and thoroscopic surgical ablation approach), are considered **investigational** as a treatment of atrial fibrillation or flutter.

This policy does not address percutaneous transcatheter ablation procedures for the treatment of cardiac arrhythmias.

## RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

Not Applicable

## DESCRIPTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a prevalence estimated at 0.4% of the population, increasing with age. AF is a supraventricular tachyarrhythmia, characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves an interplay between electrical triggering events 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. Atrial flutter is considered a variant of AF. Due to the necessity of long-term drug therapy and its associated potential toxicity in patients with AF, surgical techniques have been developed as part of the armamentarium of alternative non-pharmacological treatments. Literature describes patients with drug-resistant AF and flutter as having experienced their arrhythmias for an average of seven years or more and having unsuccessful results with an average of five or more antiarrhythmic medications.

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The classic Cox Maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt potential re-entrant circuits, which interrupts the aberrant atrial conduction pathways in the heart in cases of AF. 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 conditions of the heart, such as valve repair or replacement. The procedure has become the gold standard technique for the surgical treatment of drug-resistant AF. This procedure is performed on a non-beating heart during cardiopulmonary bypass.

The Maze procedure entails making incisions in the heart that:

- I. guide an impulse from the sinoatrial (SA) node to the atrioventricular (AV) node;
- II. preserve activation of the entire atrium; and
- III. block re-entrant impulses that are responsible for AF or atrial flutter (AFI).

Despite its high success rate, the traditional “cut and sew” Maze procedure has not been widely utilized other than for those patients who also require concomitant cardiac surgery necessitating the need for cardiopulmonary bypass. Therefore, simplification of the Maze procedure, sometimes referred to as the Cox-Maze IV procedure, has evolved with the use of different ablation tools, such as microwave, cryotherapy, ultrasonography and radiofrequency energy sources to create atrial ablative lesions instead of employing the incisional technique used in the traditional Maze procedure.

Due to the complexity and technical difficulty, associated with the Cox-Maze procedure, less invasive, trans-thoracic, endoscopic, off-pump procedures to treat refractory AF are also being developed and evaluated. Examples of these minimally invasive, off-pump surgical techniques include the thoracoscopic Wolf Mini-Maze and the Ex-Maze which use a paracardioscopic approach.

Studies are also starting to emerge investigating a hybrid approach that combines off- pump surgical and endocardial percutaneous catheter ablation. Hybrid ablation or convergent procedure refers to a procedure that uses 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 doing a hybrid procedure is that a combination of both techniques may result in more 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. This convergent ablation procedure has been proposed for highly symptomatic patients with persistent AF and long-standing persistent AF for whom stand-alone surgical or endocardial ablation procedures have provided unsatisfactory outcomes.

### **SUPPORTIVE LITERATURE**

#### **MAZE Procedure**

Sakurai et al. (2025) reported long-term survival outcomes from a systematic review and meta-analysis of 38 studies (n=41,678) comparing surgical ablation with no surgical ablation during cardiac

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surgery. The analysis included 9 RCTs and 15 comparative observational studies. The median follow-up was 62 months. Surgical ablation was associated with decreased risk of mortality (HR=0.78; 95% CI, 0.71 to 0.84), stroke (HR=0.60; 95% CI, 0.48 to 0.76), heart failure rehospitalization (HR=0.92; 95% CI, 0.87 to 0.96) and freedom from AF (RR=1.93; 95% CI, 1.50 to 2.49). Surgical ablation was also associated with higher risk of permanent pacemaker implantation (HR=1.35; 95% CI, 1.03 to 1.77).

The Catheter Ablation (CA) Versus Thoracoscopic Surgical Ablation (SA) in Long Standing Persistent Atrial Fibrillation (LSPAF) CASA-AF trial (Haldar 2020), is the first RCT that evaluated the efficacy and safety of thoracoscopic surgical ablation versus CA as the index procedure in 120 patients with long-standing persistent AF. A reduction in AF burden of  $\geq 75\%$  was seen in 67% in the surgical ablation group versus 77% in the CA group (OR, 1.13; 95% CI, 0.67 to 4.08;  $p=.3$ ). Improvements in AF symptoms were increased following CA; surgical ablation was more expensive and was associated with fewer quality-adjusted life years ( $p=.02$ ) compared with CA. Long-term (up to 3 years) outcomes of the CASA-AF trial were reported by Boyalla, et al. (2024). One hundred and four (104) participants (90%) completed 36-month follow-up (CA,  $n=57$  vs SA,  $n=47$ ). 7 participants (12%) in the CA group and 5 (11%) in the surgical ablation group were free from atrial fibrillation/tachycardia (AF/AT) $\geq 30$  seconds at 36 months (HR=1.2; 95% CI, 0.81 to 1.83;  $p=.41$ ). 33 patients (58%) in the CA group versus 26 (55%) in the surgical ablation group had their AF/AT burden reduced by  $\geq 75\%$  (HR=1.04; 95% CI, 0.57 to 1.88;  $p=.91$ ). The mean quality-adjusted life years, calculated as the area under the EuroQol 5 Dimension 5 Level questionnaire index score, were 2.5 (95% CI, 2.3 to 2.6) for CA versus 2.3 (95% CI, 2.1 to 2.5) for surgical ablation. The authors concluded this long term study showed in symptomatic LSPAF, CA and SA were equally effective at achieving arrhythmia outcomes (freedom from AF/ AT  $\geq 30$  seconds and  $\geq 75\%$  burden reduction) after a single procedure without antiarrhythmic drugs. However, SA is significantly more costly than CA.

Evidence from a number of prospective and retrospective studies conclude that the Maze procedure is effective in restoring sinus rhythm in up to 90% of patients with medically refractory, chronic, symptomatic AF. In addition, there is evidence that, when performed in conjunction with valve repair or replacement, the Maze procedure may reduce the risk of stroke, compared with valve replacement alone (e.g., Reston 2005, Lim 2010, Budera 2012, and Ad 2013).

Some case series investigating minimally invasive, off-pump procedures include only patients who have failed previous catheter ablation. These studies report high success rates following thoracoscopic ablation, suggesting that patients who fail catheter ablation may still benefit from thoracoscopic ablation. However, these series are small and do not provide complete information on comparative efficacy or adverse events (e.g., Okada 2013).

### Hybrid MAZE Procedure

The CONVERGE trial (Delurgio 2020) was a prospective, multi-center, randomized controlled clinical trial, longitudinal study performed from December 2013 to August 2018 to compare the effectiveness of Hybrid Convergent procedure to endocardial catheter ablation (CA) and to demonstrate its safety for treatment of symptomatic persistent and long-standing persistent AF. The trial enrolled 153 patients at 27 locations (25 in the USA and two in the UK). Patients were randomized at a rate of 2:1 and received either the hybrid Convergent procedure or an endocardial catheter ablation alone. Of

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149 evaluated patients at 12 months post-procedure, primary effectiveness was achieved in 67.7 percent (67/99) patients with Hybrid Convergent and 50.0 percent (25/50) with CA ( $p=0.036$ ) on/off previously failed AADs and in 53.5 percent (53/99) versus 32.0 percent (16/50) ( $p=0.0128$ ) respectively off AADs. At 18-months using a 7-day Holter monitor, 74.0 percent (53/72) Hybrid Convergent and 55 percent (23/42) CA patients experienced >90 percent AF burden reduction. There were no deaths, cardiac perforations or atrio-esophageal fistulas reported in the trial. The major adverse events (MAEs) rate through 30-days post intervention (primarily reported as inflammatory pericardial effusions) was 7.8 percent in the treatment arm, which was lower than the protocol pre-specified performance goal of 12 percent. There was also no long-lasting safety events observed in the trial. The clinical trial data showed a greater than 23 percent advantage for the Convergent arm over the control arm.

There is limited literature related to the use of the hybrid approach in the treatment of AF. While short-term outcomes appear promising, further studies are necessary to determine whether the hybrid approach is effective, especially in patients with persistent lone or long-standing persistent, drug-resistant AF (LaMeir 2012, Pison 2012, Bisleri 2013, Gehi 2013). Recent studies and reviews focusing on the convergent ablation procedure include Delurgio and colleagues (2020); Larson and colleagues (2020) and Makati and colleagues (2020). Large population studies are needed as well as comparative studies to include direct comparisons of the hybrid ablation procedures with alternative treatment options.

Eranki et al. (2023) reported results of a systematic review of mid-term (at least 2 year) outcomes of hybrid ablation. The review included 1,242 individuals from 15 retrospective cohort studies and 1 RCT (Jan, et al, 2018) with sample sizes ranging from 24 to 451. Mean follow-up was 32 (SD=8) months. The mean age of patients was 62 (SD=10) years. 73% of patients were men. 5 studies included patients with paroxysmal AF; the majority of the studies included patients with persistent and long-standing AF. Overall, the mid-term freedom from AF was 75% (95% CI, 67 to 82). Freedom from AF at years 1, 2 and 3 was 78%, 74% and 74%, respectively. There were 12 deaths (0.97%) overall following the hybrid procedure; 10 occurred within 30 days of the procedure. 4 deaths were due to a direct mechanical complication of the procedure (atrio-esophageal fistulae) and 2 patients died of stroke. The pooled complication rate was 5.5% (95% CI, 3 to 9). The authors concluded the study shows Hybrid AF ablation offers promising mid-term freedom from AF reported at a mean follow-up of 31.5 months. The overall complication rate remains low.

Mhanna et al. (2021) conducted a systematic review and meta-analysis of 8 controlled studies (including the DeLurgio 2020 RCT and the Kress 2016 and Maclean 2020 nonrandomized studies) of 797 patients with AF undergoing hybrid epicardial/endocardial (convergent) ablation ( $n=366$ ) or standard endocardial ablation ( $n=431$ ). Across the studies, the mean age of study participants was 61 years, 77% were male, 93% had persistent AF, and 18% had undergone a previous ablation. The included studies were all assessed as having low to moderate risk of bias. Based on pooled analyses, hybrid ablation was associated with greater freedom from atrial arrhythmia, but also an increased risk of adverse events that included bleeding, pericardial effusion, and cardiac tamponade. The study authors noted that across studies 5 deaths were reported among hybrid ablation patients while no endocardial ablation patients died, but no risk estimate was reported. The authors concluded the

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meta-analysis showed that although hybrid ablation was associated with a higher success rate, this should be judged for increased periprocedural adverse events and extended hospital stay.

Eranki et al. (2022) conducted a systematic review and meta-analysis of 4 RCTs and propensity score-matched studies (N=422) of hybrid convergent ablation. Hybrid convergent participants had significantly higher rates of freedom from AF than endocardial ablation participants (OR=2.8; 95% CI, 1.8 to 4.2;  $p<.01$ ). Major post-operative complications were also significantly higher in hybrid convergent participants (OR=5.1; 95% CI; 1.7 to 15.5;  $p<.01$ ). One death was reported in the hybrid convergent participants; no deaths were reported in the in the endocardial ablation participants.

Doll et al. (2023) reported results of the Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation versus Repeated Catheter Ablation in Patients with Persistent and Longstanding Persistent Atrial Fibrillation (CEASE-AF, NCT02695277) RCT. CEASE-AF is a multicenter RCT comparing hybrid combined epicardial and endocardial ablation to standard endocardial CA in 9 hospitals in Germany, Netherlands, United Kingdom, Czech Republic, and Poland between 2015 and 2020 including 154 participants (102 hybrid ablation; 52 standard ablation) with symptomatic, drug refractory persistent AF and left atrial diameter > 4.0 cm or longstanding persistent AF. Participants and study physicians were not blinded to treatment assignment; the core rhythm monitoring laboratory was blinded. In the hybrid CA group, pulmonary veins and left posterior atrial wall were isolated with thoracoscopic epicardial ablation including left atrial appendage exclusion and endocardial touch-up ablation was performed 91 to 180 days afterwards. In the standard CA group, endocardial PV isolation and optional substrate ablation were performed. The primary outcome was freedom from AF, atrial flutter, or atrial tachycardia lasting >30 seconds through 12 months without class I/III anti-arrhythmic drugs except those not exceeding previously failed doses. Rhythm status was assessed with 48-hour Holter monitoring during scheduled visits and symptom-driven monitoring during unscheduled visits. 81% of participants had persistent AF. 75% were male and the mean age was 61 (SD=8) years. Race/ethnicity was not reported. Total procedure duration was significantly longer in the hybrid group (336 minutes, SD=97) compared to the CA group (252 minutes, SD=114,  $p < 0.001$ ). Through 12-months follow-up, 72% (68/95) in the hybrid group were free from AF versus 39% (20/51) in the CA group (absolute risk difference = 32% (95% CI, 14 to 48;  $p < 0.001$ ). In persistent AF subgroup, freedom from AF was 73% (56/77) in the hybrid group versus 42% (18/43) in the CA group (absolute risk difference=31% (95% CI, 10 to 48). In the longstanding persistent AF subgroup, freedom from AF was 67% (12/18) in the hybrid group compared to 25% (2/8) in the CA group (absolute risk difference=42% (95% CI, 4 to 73). Composite major complication rates within 30 days after the index procedure and 30 days after the second stage hybrid ablation or repeat standard ablation were 8% (8/102) and 6% (3/52) in the hybrid versus CA groups ( $p = 0.751$ ). Through 12-months post-index procedure, composite major complications occurred in 9% (9/102) in the hybrid group versus 6% (3/52) in the CA group ( $p = 0.752$ ). There was one death (myocardial infarction) in the hybrid group at 93 days post-index procedure. By the 12-month follow-up visit, 4% (4/95) in the hybrid group and 35% (18/51) in the CA group had additional ablation ( $p < 0.001$ ). Cardioversions (pharmaceutical and electrical) were performed in 12% (11/95) in the hybrid group and 26% (13/51) in the CA group during this time frame ( $p = 0.037$ ). The authors concluded the study showed hybrid epicardial-endocardial ablation had superior effectiveness compared to catheter ablation/repeat catheter ablation in persistent atrial fibrillation

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and longstanding persistent atrial fibrillation without significant procedural risk increase. This study was sponsored by AtriCure, Inc.

Lee et al. (2022) reported results of the Epicardial Approach in Recurred Atrial Fibrillation (EPIREAF; NCT02979847) RCT comparing a combined epicardial and endocardial ablation approach (n=50) with a conventional endocardial ablation approach (n=50). In the combined approach, subxiphoid epicardial access was obtained under fluoroscopic guidance (hybrid convergent). Participants had symptomatic, persistent AF refractory or intolerant to antiarrhythmic drugs and prior endocardial ablation. EPIREAF was a single-center, open-label, unblinded trial enrolling participants from June 2016 to November 2019. Rhythm monitoring occurred via 12-lead ECG and 24 hour Holter monitoring at 1, 3, 6, 9, and 12 months after the procedure and then every 6 months thereafter. The primary efficacy outcome was time to recurrence of sustained (>30 seconds) AF or atrial tachycardia following the 90-day blanking period within 12 months of the procedure. The reported safety outcome was occurrence of procedure-related complications within 24 hours after the procedure. Complications included death, any event requiring emergent surgery, severe bradycardia requiring cardiac pacing, pericardial effusion with tamponade or requiring transfusion, ischemic stroke, and procedure-related hematoma or vessel injury. The median age of participants was 59 years and 16% were women. Race/ethnicity of participants was not reported. The median CHA2DS2-VASc score was 1 and the median number of prior ablations was 1. The median procedure time was 232.5 minutes in the hybrid convergent group and 226 minutes in the CA group. 93 (93%) completed the trial. Events relevant to the primary outcome occurred in 16 patients in the treatment group and in 21 patients in the control group {Kaplan-Meier estimator percentages, 32 vs. 42%; hazard ratio, 0.71 [95% confidence interval (CI): 0.37-1.37]}. The periprocedural complication rate was lower in the treatment group [2 vs. 16%; odds ratio, 0.11 (95% CI: 0.00-0.87)] with similar achievement of the procedural endpoint in the two groups. In the redo procedure for persistent atrial fibrillation, the combined approach had no significant difference of recurrence-free survival, and a lower procedural complication rate compared with the conventional approach.

van der Heijden et al. (2023) reported results of the Hybrid Versus Catheter Ablation in Persistent AF (HARTCAP-AF; NCT02441738) RCT. HARTCAP-AF was a single-center, open-label, unblinded trial randomizing 41 ablation-naïve adults with symptomatic, long-standing persistent AF to either hybrid ablation (n=19) or CA (n=22) between October 2016 and December 2018. All randomized participants received their allocated treatment. The hybrid ablation was performed by an experienced surgeon and electrophysiologist in a single-stage procedure. Rhythm observation was performed with a 12-lead ECG and 24-hour-Holter monitor at 3 and 6 months or following report of symptoms. A 7-day-Holter was collected at 12 months. The primary efficacy outcome was freedom from any atrial tachyarrhythmia (lasting >5 minutes) off antiarrhythmic drugs after the 3-month blanking period until 12 months. The primary safety outcome was a composite of major adverse events and complications occurring within 12 months of follow-up. Major adverse event included death, stroke, bleeding requiring transfusion and/or reoperation, cardiac tamponade or pericardial effusion requiring intervention, empyema, myocardial infarction, pericarditis requiring pericardiocentesis or (prolongation of) (re)hospitalization, pneumothorax requiring intervention (after removal of chest tubes), gastroparesis, symptomatic pulmonary vein stenosis >70%, or (persistent) diaphragmatic paresis. The median age of participants was approximately 65 years; approximately 90% of

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participants had persistent but not long-standing AF and approximately 10% had persistent, long-standing AF. Several baseline characteristics were not balanced between the 2 treatment groups: women (5% in hybrid vs 18% in CA); median AF duration (22 months in hybrid vs 33 months in CA); CHA2DS2-VASc score >3 (53% in hybrid vs 27% in CA); and congestive heart failure (5% in hybrid vs 27% in CA). Race/ethnicity of participants was not reported. Median procedure time (4 hours 16 minutes vs 2 hours 53 minutes;  $p < .001$ ) and length of hospital stay (4 days vs 2 days;  $p < .001$ ) were significantly longer in the hybrid group. Radiation dose (31 cGycm<sup>2</sup> vs 67 cGycm<sup>2</sup>;  $p = .004$ ) and radiation exposure time (23 minutes vs 1 hour 54 minutes;  $p < .001$ ) were significantly higher in the CA group. After 12 months, the freedom of atrial tachyarrhythmias off antiarrhythmic drugs was higher in the HA group compared with the CA group (89% vs 41%,  $P = 0.002$ ). There was 1 pericarditis requiring pericardiocentesis and 1 femoral arteriovenous fistula in the HA group. In the CA arm, 1 bleeding from the femoral artery occurred. There were no deaths, strokes, need for pacemaker implantation, or conversions to sternotomy, and the number of (serious) adverse events was comparable between groups (21% vs 14%,  $P = 0.685$ ). The authors concluded the study showed Hybrid AF ablation is an efficacious and safe procedure and results in better outcomes than catheter ablation for the treatment of patients with persistent AF. The study was funded by AtriCure, Inc.

Pannone et al. (2023) published results from a study to assess the long-term outcomes of hybrid ablation in a large cohort of patients after both an initial and as a redo procedure. All consecutive patients undergoing hybrid AF ablation at UZ Brussel from 2010 to 2020 were retrospectively evaluated. Hybrid AF ablation was performed in a one-step procedure: (i) thoracoscopic ablation followed by (ii) endocardial mapping and eventual ablation. All patients received PVI and posterior wall isolation. Additional lesions were performed based on clinical indication and physician judgement. Primary endpoint was freedom from atrial tachyarrhythmias (ATas). A total of 120 consecutive patients were included, 85 patients (70.8%) underwent hybrid AF ablation as first procedure (non-paroxysmal AF 100%), 20 patients (16.7%) as second procedure (non-paroxysmal AF 30%), and 15 patients (12.5%) as third procedure (non-paroxysmal AF 33.3%). After a mean follow-up of 62.3 months  $\pm$  20.3, a total of 63 patients (52.5%) experienced ATas recurrence. Complications occurred in 12.5% of patients. There was no difference in ATas between patients undergoing hybrid as first vs. redo procedure ( $P = 0.53$ ). Left atrial volume index and recurrence during blanking period were independent predictors of ATas recurrence. In a large cohort of patients undergoing hybrid AF ablation, the survival from ATas recurrence was 47.5% at  $\approx$ 5 years follow-up. There was no difference in clinical outcomes between patients undergoing hybrid AF ablation as first procedure or as a redo.

### **PROFESSIONAL GUIDELINE(S)**

The Heart Rhythm Society (HRS) (2017) has stated that a hybrid approach could hold significant promise for those patients with persistent lone or long-standing persistent, drug-resistant AF, offering improved results over minimal-access surgical ablation or catheter ablation alone. It might be reasonable to apply the indications for stand-alone surgical ablation described above to patients being considered for hybrid surgical ablation (Class IIb, LOE C).

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The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos 2024.) state the gold standard of surgical ablation has remained the Cox maze procedure and its iteration, based on the original work of Dr. Cox. Given stronger longitudinal evidence of efficacy and longitudinal freedom from atrial fibrillation, antiarrhythmic drugs, as well as oral anticoagulation following a full biatrial Cox Maze, the field awaits more Journal Pre-proof homogeneous or randomized evidence on hybrid or epicardial ablation procedures that adhere to the concept of the Cox Maze lesion set. Epicardial ablation with atypical lesions remains exploratory until more robust evidence becomes available.

In 2023, updated American College of Cardiology (ACC) /American Heart Association (AHA) /American College of Clinical Pharmacy (ACCP)/ Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation were released (Joglar 2024). These updated guidelines state a hybrid procedure might be reasonable to reduce the risk of recurrent atrial arrhythmia citing a weak level of evidence 2B recommendation and the Level of Evidence (LOE) was B-R (moderate-quality evidence from 1 or more RCTs; meta-analyses of moderate-quality RCTs).

**REGULATORY STATUS**

Several ablation systems have been approved or cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for cardiac tissue ablation (product code OCL) or PMA process (product code OCM).

**Radiofrequency Ablation Approved or Cleared by the U.S. Food and Drug Administration**

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



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

### **Cryoablation Systems Approved or Cleared by the U.S. Food and Drug Administration**

<b>Device</b>	<b>Manufacturer</b>
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 Freezor Max Cardiac Cryoablation Catheters	Medtronic

### **CODE(S)**

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### **CPT Codes**

<b>Code</b>	<b>Description</b>
33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure)
33255 (E/I)	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 (E/I)	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)

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Code	Description
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 (E/I)	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass
33266 (E/I)	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass

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### HCPCS Codes

Code	Description
Not Applicable	

### ICD10 Codes

Code	Description
I48.0-I48.92	Atrial fibrillation and flutter (code range)

### REFERENCES

Abreu Filho CA, et al. Effectiveness of the maze procedure using cooled-tip radiofrequency ablation in patients with permanent atrial fibrillation and rheumatic mitral valve disease. *Circ.* 2005 Aug 30;112(9 Suppl):I20-5.

Ad N, et al. The outcome of the Cox maze procedure in patients with previous percutaneous catheter ablation to treat atrial fibrillation. *Ann Thorac Surg.* 2011 May;91(5):1371-7.

Barnett SD, AD N. Surgical ablation as treatment for the elimination of atrial fibrillation: a meta-analysis. *J Thorac Cardiovasc Surg.* 2006 May;131(5):1029-35.

Ballaux PK, et al. Freedom from atrial arrhythmias after classic maze III surgery: a 10-year experience. *J Thorac Cardiovasc Surg.* 2006 Dec;132(6):1433-40; comment pg.1253.

Beukema WP, et al. Intermediate to long-term results of radiofrequency modified maze procedure as an adjunct to open-heart surgery. *Ann Thorac Surg.* 2008 Nov;86(5):1409-14.

Boyalla V, et al.; CASA-AF Investigators. Long-term clinical outcomes and cost-effectiveness of catheter vs thoracoscopic surgical ablation in long-standing persistent atrial fibrillation using continuous cardiac monitoring: CASA-AF randomized controlled trial. *Heart Rhythm.* 2024 Sep;21(9):1562-1569.

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Bulava A, et al.; SURHYB Trial Investigators. Sequential hybrid ablation vs. surgical CryoMaze alone for treatment of atrial fibrillation: results of multicenter randomized controlled trial. *Europace*. 2024 Feb;26(2):euae040.

Budera P, et al. Two-staged hybrid ablation of non-paroxysmal atrial fibrillation: clinical outcomes and functional improvements after 1 year. *Interact Cardiovasc Thorac Surg*. 2018 Jan 1;26(1):77-83.

Cox JL, et al. A hybrid Maze procedure for long-standing persistent atrial fibrillation. *Ann Thor Surg*. 2019 Feb;107(2):610-618.

Damiano RJ Jr, et al. The CURE-AF trial: a prospective, multicenter trial of irrigated radiofrequency ablation for the treatment of persistent atrial fibrillation during concomitant cardiac surgery. *Heart Rhythm*. 2014 Jan;11(1):39-45.

DeLurgio DB, et al. Hybrid convergent procedure for the treatment of persistent and long-standing persistent atrial fibrillation: results of CONVERGE clinical trial. *Circulation: Arrhythmia and Electrophysiology*. 2020 Dec;13(12).

Doll N, et al. Efficacy and safety of hybrid epicardial and endocardial ablation versus endocardial ablation in patients with persistent and longstanding persistent atrial fibrillation: a randomised, controlled trial. *EClinicalMedicine*. 2023 Jun 22;61:102052.

Dunnington GH, et al. A heart-team hybrid approach for atrial fibrillation: a single-centre long-term clinical outcome cohort study. *European Journal of Cardio-Thoracic Surgery*. 2021; 60:1343-1350.

Eranki A, et al. Mid-term freedom from atrial fibrillation following hybrid ablation, a systematic review and meta-analysis. *J Cardiothorac Surg*. 2023 Apr 19; 18(1): 155.

Eranki A, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: a systematic review and meta-analysis of randomised control trials and propensity matched studies. *J Cardiothorac Surg*. 2022 Aug 13;17(1):181.

Fuster V, et al. ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association. *Circulation*. 2006 Aug 15;114(7):e257-354.

Gaynor SL, et al. A prospective, single-center clinical trial of a modified Cox maze procedure with bipolar radiofrequency ablation. *J Thorac Cardiovasc Surg*. 2004 Oct;128(4):535-42.

Gaynor SL, et al. Surgical treatment of atrial fibrillation: predictors of late recurrence. *J Thorac Cardiovasc Surg*. 2005 Jan;129(1):104-11.

Haldar S, et al. Catheter ablation vs. thoracoscopic surgical ablation in long-standing persistent atrial fibrillation: CASA-AF randomized controlled trial. *Eur Heart J*. 2020 Dec 14;41(47):4471-4480.

Haywood GA, et al. European multicentre experience of staged hybrid atrial fibrillation ablation for the treatment of persistent and longstanding persistent atrial fibrillation. *IJC Heart & Vasculature*. 2020;26:100459.

Hindricks G, et al. ESC Scientific Document Group. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-

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Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J*. 2021 Feb 1;42(5):373-498.

Hwang SK, et al. Long-term outcomes of the maze procedure combined with mitral valve repair: risk of thromboembolism without anticoagulation therapy. *Ann Thorac Surg* 2015 Sep;100(3):840-3.

Je HG, et al. A systematic review of minimally invasive surgical treatment for atrial fibrillation: a comparison of the Cox-Maze procedure, beating-heart epicardial ablation, and the hybrid procedure on safety and efficacy. *Eur J Cardiothorac Surg*. 2015 Oct;48(4):531-40.

Joglar JA, et al; Peer Review Committee Members. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024 Jan;149(1):e1-e156.

Kim JB, et al. Long-term outcomes of mechanical valve replacement in patients with atrial fibrillation. Impact of the maze procedure. *Circulation*. 2012 May;125(5):2071-80.

Larson J, et al. Outcomes of convergent atrial fibrillation ablation with continuous rhythm monitoring. *J Cardiovasc Electrophysiol*. 2020;31:1270–1276.

Maclean E, et al. The convergent procedure versus catheter ablation alone in longstanding persistent atrial fibrillation: A single centre, propensity-matched cohort study. *International Journal of Cardiology*. 2020;303:49–53.

Makati KJ, et al. Combined epicardial and endocardial ablation for atrial fibrillation: best practices and guide to hybrid convergent procedures. *Heart Rhythm*. 2021 Feb;18(2):303-312.

Mhanna M, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: A systematic review and meta-analysis. *Journal of Arrhythmia*. 2021;37:1459-1467.

Nakajima H, et al. The effect of cryo-maze procedure on early and intermediate term outcome in mitral valve disease: case matched study. *Circ*. 2002 Sep 24;106(12 Suppl 1):I46-50.

Pannone L, et al. Hybrid atrial fibrillation ablation: long-term outcomes from a single-centre 10-year experience. *Europace*. 2023 May 19;25(5):euad114.

Sakurai Y, et al. Late survival benefits of concomitant surgical ablation for atrial fibrillation during cardiac surgery: a systematic review and meta-analysis. *Am J Cardiol*. 2025 Jan 15;235:16-29.

Shrestha S, et al. Hybrid Convergent ablation for atrial fibrillation: A systematic review and meta-analysis. *Heart Rhythm O2*. 2022 May;3(4):396-404.

van der Heijden CAJ, et al. Hybrid ablation versus repeated catheter ablation in persistent atrial fibrillation: a randomized controlled trial. *JACC Clin Electrophysiol*. 2023 Jul;9 (7 Pt 2):1013-1023.

Wyler von Ballmoos MC, et al. The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation. *Ann Thorac Surg*. 2024 Jan:S0003-4975(24)00057-2.

## Medical Policy: Maze Procedures for Atrial Fibrillation and Flutter

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Yonas E, et al. Comparison between surgical and catheter-based ablation in atrial fibrillation, should surgical based ablation be implemented as first line? A meta-analysis of studies. Indian Pacing and Electrophysiology Journal. 2020;20: 14-20.

### SEARCH TERMS

Atrial fibrillation (AF), Atrial Flutter, MAZE, Convergent procedure, COX-III, Epicardial Maze, Ex-Maze, Hybrid, MiniMaze, Thoracoscopic off-pump surgical ablation (TOPS).

### CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon our review, the Maze procedure as treatment for atrial fibrillation is not addressed in National or Regional Medicare coverage determinations or policies.

### PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

### POLICY HISTORY/REVISION

#### Committee Approval Dates

10/18/01, 02/21/02, 10/20/05, 07/20/06, 05/17/07, 05/14/08, 05/28/09, 04/22/10, 06/16/11, 05/24/12, 06/20/13, 05/22/14, 04/16/15, 03/17/16, 03/16/17, 01/18/18, 04/18/19, 04/16/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 06/26/25

Date	Summary of Changes
06/26/25	<ul style="list-style-type: none"><li>• Annual review, policy intent unchanged.</li></ul>
01/01/25	<ul style="list-style-type: none"><li>• Summary of changes tracking implemented.</li></ul>
10/18/01	<ul style="list-style-type: none"><li>• Original effective date</li></ul>