

Medical Policy



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

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With symptomatic atrial fibrillation or flutter who are undergoing cardiac surgery with bypass 	Interventions of interest are: <ul style="list-style-type: none"> Cox maze or modified maze procedure 	Comparators of interest are: <ul style="list-style-type: none"> Medical management Catheter ablation 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Medication use Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass 	Interventions of interest are: <ul style="list-style-type: none"> Minimally invasive, off-pump thoracoscopic maze procedures 	Comparators of interest are: <ul style="list-style-type: none"> Medical management Catheter ablation 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Medication use Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass 	Interventions of interest are: <ul style="list-style-type: none"> • Hybrid thoracoscopic and endocardial ablation procedures 	Comparators of interest are: <ul style="list-style-type: none"> • Medical management • Catheter ablation 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Medication use • Treatment-related morbidity

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.

OBJECTIVE

The objective of this policy is to determine whether maze or modified maze procedures improve the net health outcome when performed in patients with atrial fibrillation in combination with cardiac procedures or as a stand-alone treatment.

BACKGROUND

Atrial Fibrillation

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.

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 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 catheter ablation.

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.

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.

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.

REGULATORY STATUS

Several radiofrequency ablation systems have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for cardiac tissue ablation. Table 1 provides a select list.

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

Device	Manufacturer	510(k) Date
Medtronic Cardioblate® System	Medtronic	Jan 2002
Cardima Ablation System	Cardima	Jan 2003
Epicor™ Medical Ablation System	Epicor Medical	Feb 2004
Isolator™ Transpolar™ Pen	AtriCure	Jun 2005
Estech COBRA® Cardiac Electrosurgical Unit	Endoscopic Technologies	Dec 2005
Coolrail™ Linear Pen	AtriCure	Mar 2008
Numeris® Guided Coagulation System with VisiTrax®	nContact Surgical	Feb 2009
EPI-Sense® Guided Coagulation System with VisiTrax®	nContact Surgical	Nov 2012

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 Food and Drug Administration

Device	Manufacturer	510(k) Date
Cryocare® Cardiac Surgery System	Endocare	Mar 2002

Device	Manufacturer	510(k) Date
SeedNet™ System	Galil Medical	May 2005
SurgiFrost® XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic	Jul 2006
Isis™ cryosurgical unit	Galil Medical	Mar 2007

POLICY

- A. The maze or modified maze procedure, performed on a non–beating heart during cardiopulmonary bypass with concomitant cardiac surgery, is considered **medically necessary** for treatment of symptomatic atrial fibrillation or flutter.
- B. Minimally invasive, off-pump maze procedures (ie, modified maze procedures), including those done via mini-thoracotomy, are considered **experimental / investigational** for treatment of atrial fibrillation or flutter.
- C. Hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) is considered **experimental / investigational** for the treatment of atrial fibrillation or flutter.
- D. 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 treatment of atrial fibrillation or flutter.

Policy Guidelines

- 1. Given the availability of less-invasive alternative approaches to treat atrial fibrillation, performing the maze procedure without concomitant cardiac surgery should rarely be needed.
- 2. Published studies on the maze procedure have described patients with drug-resistant AF and atrial flutter as having experienced their arrhythmias for an average of 7 or more years and having had unsuccessful results with an average of 5 or more antiarrhythmic medications.

RATIONALE

The most recent literature update was performed through March 6, 2018. This review was informed by a TEC Assessment (1994).¹

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Maze and Related Procedures

Traditional Maze vs “Modified Maze” Procedures

Systematic Reviews

Khargi et al (2005) analyzed 48 studies comprising 3832 patients who received surgical treatment for atrial fibrillation (AF) using the classic “cut-and-sew” Cox maze III technique or an alternative source of energy.² Reviewers concluded that they could not identify any significant differences in the postoperative sinus rhythm conversion rates between the classic approach and alternative sources of energy. While prospective randomized studies were lacking, the data involved a wide range of ablative patterns and their effects on atrial tissue. Topkara et al (2006) reported comparable postoperative rhythm success with both radiofrequency (RF; 121 patients) and microwave (85 patients) energy in surgical ablation of AF.³

Observational Studies

Several observational studies have compared the Cox maze III procedure with other procedures (radiofrequency ablation [RFA], pulmonary vein isolation) performed at single institutions, with procedure selection guided by the surgeon. Two studies attempted to address the selection bias inherent in these studies using matching. In the first, from a U.S. university medical school wherein the maze procedure was developed, Lall et al (2007) reported on 242 patients who underwent the Cox maze procedure (154 with the classic “cut-and-sew” [Cox maze III] procedure, 88 in whom RFA replaced the incisions of the classic procedure [Cox maze IV]) were matched on their propensity for treatment assignment (a logistic regression in which the outcome is treatment assignment and the predictors are covariates that might influence which procedure is chosen by the surgeon).⁴ Fifty-eight matched pairs were studied. At 1 year, the survival rates were 94% and 89% ($p=0.19$), and freedom from AF recurrence rates were 96% and 93% ($p=0.52$) for the Cox maze III and IV groups, respectively. The authors noted that the Cox maze IV procedure was offered to higher risk patients more often than the Cox maze III procedure, which might have explained why only 58 of 88 Cox maze IV patients were matched in their analysis. The matched propensity analysis can remove measurable selection biases, but if unmeasured factors lead surgeons to choose 1 surgery over the other, these factors were not accounted for in the analysis.

In a second matched analysis, Stulak et al (2007) assessed 56 patients who underwent a Cox maze IV RFA procedure at a clinic who were matched (historical controls) to 56 patients who underwent the Cox maze III procedure.⁵ Matching factors were age, sex, New York Heart Association functional class, AF type, and concomitant mitral valve surgery. Here the Cox maze

IV group had greater postoperative AF (43% vs 24%), more pacemaker requirements (25% vs 5%), greater use of antiarrhythmic drugs (75% vs 25%), and fewer patients were free from AF at late follow-up (mean 8.4 months; 62% vs 92%). Again, the Cox maze IV patients had greater underlying disease (more concomitant procedures were performed).

In a second article from the same clinic, Stulak et al (2014) reported on results from an unmatched retrospective comparison of Cox maze III and IV procedures among 1540 patients who underwent surgical ablation for AF at a single institution from 1993 to 2011.⁶ Energy sources used to create lesions included “cut-and-sew” in 521 (44%), cryotherapy in 267 (22%), RF in 262 (22%), and a combination of these sources in 139 (12%) patients. On multivariate analysis, Cox maze III was independently associated with lower risk of recurrent AF over a follow-up of 1 to 5 years (hazard ratio, 0.4; 95% confidence interval [CI], 0.24 to 0.69; $p < 0.001$) and more than 5 years (hazard ratio, 0.23; 95% CI, 0.12 to 0.42; $p < 0.001$) for all patients. This study was limited by its retrospective design and lack of propensity score matching.

Subsection Summary: Traditional Maze vs “Modified Maze” Procedures

There have been numerous modifications to the original maze procedure, with variations in the surgical approach, the lesion set used, and the methods for creating lesions (eg, cut-and-sew, RFA). The evidence on comparative effectiveness of the different approaches is not high quality and is incomplete regarding addressing all of the possible comparisons. The limited available evidence from matched case series does not indicate that there are large differences in efficacy across the different approaches.

Maze and Related Procedures as an Adjunct to Open Heart Surgery

The evidence on the use of maze and related procedures in addition to on-bypass surgeries being done for other reasons (eg, mitral valve replacements) consists of several RCTs evaluating AF ablation when performed as an add-on for patients undergoing open heart surgery and systematic reviews of these trials.

Systematic Reviews

A Cochrane review by Huffman et al (2016) evaluated the evidence on concomitant AF surgery for patients undergoing cardiac surgery.⁷ Included were 22 trials that compared the effect of AF surgery with no AF surgery in adults undergoing cardiac surgery for another indication. Three trials used a “cut-and-sew” technique, 3 trials used microwave ablation, 2 trials used cryoablation, and the remainder used RFA. All trials were considered at high risk of bias. There was moderate-quality evidence that AF surgical interventions increased freedom from AF, atrial flutter, and atrial tachycardia when patients were off antiarrhythmic medications (51.0% vs 24.1%; relative risk [RR], 2.04; 95% CI, 1.63 to 2.55), but the effect on all-cause mortality was uncertain, and these procedures increased the likelihood of permanent pacemaker implantation (6% vs 4.1%; RR=1.69; 95% CI, 1.12 to 2.54).

Phan et al (2014) reported on the results of a systematic review and meta-analysis of RCTs comparing surgical ablation with no ablation among patients who had AF and were undergoing mitral valve surgery.⁸ Nine studies were selected and analyzed: 5 evaluated RFA, 2 evaluated Cox maze “cut-and-sew,” 1 evaluated cryoablation, and 1 evaluated pulmonary vein isolation and Cox maze “cut-and-sew.” In pooled analysis, the risk of 30-day all-cause mortality did not differ significantly between the ablation (4.4%) and nonablation (2.7%) groups (odds ratio, 1.45; 95%

CI, 0.55 to 3.83; $p=0.46$). The number of patients in sinus rhythm at discharge was significantly higher in the group that received mitral valve repair plus surgical ablation (67.9%) than the group that received mitral valve repair only (17.0%; odds ratio, 13.96; 95% CI, 6.29 to 30.99; $p<0.001$); similarly, at 3-, 6-, 12-, and beyond 12-month follow-ups, a greater proportion of the surgical ablation group was in sinus rhythm.

In an earlier systematic review, Reston and Shuhaiber (2005) reviewed 4 RCTs and 6 comparative studies to determine whether a concurrent mitral valve surgery and maze procedure would reduce the risk of stroke or death in patients with chronic or paroxysmal AF.⁹ They found a reduction in stroke rates and a small increased risk in the need for pacemakers among patients receiving simultaneous maze procedures. Also, they noted that alternative energy sources (eg, RF) might reduce the risk of postoperative bleeding associated with classic maze incisions.

Randomized Controlled Trials

Some of the larger RCTs evaluating AF ablation in conjunction with open surgery and included in the 2016 Cochrane review are described below.

Gillinov et al (2015) published results of a large controlled trial that randomized 260 patients with persistent or long-standing AF who required mitral valve surgery to ablation (either pulmonary vein isolation or ablation with a maze lesion set) during surgery ($n=133$) or to no ablation ($n=127$).¹⁰ Compared with controls, significantly more patients in the ablation group were free from AF at both 6 and 12 months (63.2% vs 29.4%, $p<0.001$). The relative success ratio (ablation group vs control group) was 2.15 (95% CI, 1.54 to 3.00) on the basis of observed data. At 1 year, mortality rates did not differ significantly between the ablation group (6.8%) and the control group (8.7%; $p=0.57$). A composite safety end point did not differ significantly between groups at 30 days, nor did serious adverse event rates at 1 year.

Budera et al (2012) reported on an RCT that randomized 224 patients from 3 clinical centers to cardiac surgery plus ablation or to cardiac surgery alone.¹¹ Patients were eligible for inclusion if they had at least 2 documented episodes of AF in the last six months, as well as appropriate indications for cardiac surgery. Cardiac surgery procedures included coronary artery bypass graft (CABG), valve replacement/repair, or combined CABG and valve procedures. The primary efficacy outcome was sinus rhythm at 1 year following surgery, and the primary safety outcome was a composite outcome of death, myocardial infarction, stroke, or new-onset renal failure requiring hemodialysis at 30 days postsurgery. Sinus rhythm at 1 year was documented in 60.2% (56/93) of patients in the surgery plus ablation group compared with 35.5% (27/76) of patients in the surgery alone group. Adverse event rates were similar in both groups at 30 days and at 1-year follow-up. Secondary clinical outcomes, including mortality and New York Heart Association functional class, did not differ between groups at 1 year.

Van Breugel et al (2010) evaluated changes in quality of life (QOL) in a related patient population.¹² One hundred fifty patients with AF who were scheduled to undergo valve surgery or CABG surgery were randomized to surgery alone or surgery plus a modified maze procedure. The primary end point was QOL, as measured by the 36-Item Short-Form Health Survey, the EuroQoL, and the Multidimensional Fatigue Inventory. A total of 132 patients had usable survey results. Both groups improved on all QOL measures, but, in general, there were no significant

differences between groups. The only exception was on the EuroQoL pain/discomfort subscale, which showed a greater degree of worsening in the control group than in the maze group.

Nonrandomized Comparative Studies

Saint et al (2013) attempted to quantify the incremental risk conferred by adding a Cox maze IV procedure to open mitral valve repair in a comparison of 213 patients with mitral valve disease and preoperative AF who underwent mitral valve surgery only (n=109) or mitral valve surgery with a Cox maze IV procedure (n=104).¹³ The operative mortality rate for the mitral valve procedure alone was predicted for each group based on the Society of Thoracic Surgeons Risk Calculator; the risk attributed to the addition of the Cox maze IV procedure was calculated by comparing the predicted mortality rate from the isolated mitral valve procedure with the actual mortality rate. At baseline, patients who had an isolated mitral valve procedure differed significantly from those who underwent the mitral valve procedure plus a Cox maze IV procedure regarding medical comorbidities and etiology of the mitral valve disease. The observed 30-day mortality rate for patients not offered a Cox maze IV procedure was 4.6% (expected, 5.5%), yielding an observed-expected 30-day mortality ratio of 0.84 (95% CI, 0.13 to 1.54). The observed 30-day mortality rate for patients who underwent a concomitant Cox maze IV procedure and mitral valve surgery was 2.9%. The Society of Thoracic Surgeons calculator predicted the score for isolated mitral valve surgery in this group was 2.5%, yielding an observed-expected 30-day mortality ratio of 1.16 (95% CI, 0.13 to 2.44). Interpretation of this study was limited because patients who received concomitant Cox maze IV procedures with mitral valve surgery were from a select low-risk population; however, findings did suggest that, in the appropriate patient population, the Cox maze IV procedure can be added to mitral valve surgery, with limited additional short-term mortality risk.

Noncomparative Studies

Since the publication of the RCTs previously described, several noncomparative studies have reported outcomes from surgical ("cut-and-sew") maze and modified RF maze procedures as an adjunct to planned cardiac surgery. While single-arm studies can offer useful data on some parameters, such as durability of treatment effect and adverse events, they do not offer relevant evidence on the comparative efficacy of the procedure. For example, Kim et al (2007) reported on long-term outcomes after 127 Cox maze cut-and-sew procedures in conjunction with mitral valve replacement.¹⁴ Patient disposition was well-documented in the analysis. Thirty percent of patients experienced late AF recurrence at a mean of 44 months. Freedom from AF was 93%, 82%, 71%, and 63% at 1, 3, 5, and 7 years, respectively, and pacemakers were implanted in 4.7% of patients. Other case series (2013, 2014) have reported success rates of the procedure in different populations, with rates of freedom from AF ranging from 53% to 79% at latest follow-up.¹⁵⁻¹⁷

Section Summary: Maze and Related Procedures as an Adjunct to Open Heart Surgery

Surgical treatment of AF can be performed in conjunction with valvular surgery or CABG with little additional risk. Evidence from RCTs assessing open heart surgery plus surgical treatment of AF vs surgery alone has established that there is a high rate of success in maintaining sinus rhythm and avoiding the need for antiarrhythmic medications. Evidence for a benefit in other health outcomes, such as stroke rate or QOL, is currently insufficient to form conclusions.

Maze and Related Procedures as a Stand-Alone Treatment for AF

For maze and related procedures as stand-alone therapy, the appropriate comparison group is endocardial catheter ablation. Although freedom from AF is an important outcome following AF treatment procedures, the evaluation of stand-alone maze and related procedures also requires assessment of surgery-related complications.

The evidence on the use of maze and related procedures as stand-alone treatments for AF includes evaluations of open surgical ablation, minimally invasive surgical ablation, and “hybrid” approaches. The stand-alone procedures fall on a continuum of invasiveness, ranging from open repair with sternotomy to minimally invasive procedures done with video-assisted thoracoscopy. Hybrid approaches include concomitant epicardial and endocardial procedures and are discussed separately.

Surgical Ablation as a Stand-Alone Treatment

Systematic Reviews

A number of systematic reviews, using different inclusion criteria, have assessed the evidence on stand-alone surgical ablation.

Van Laar et al (2017) reported on a meta-analysis of stand-alone thoracoscopic maze procedures for the treatment of AF.¹⁸ Reviewers included 14 studies (3 RCTs, 7 prospective cohort studies, 11 observational studies; total N=1171 patients). All studies used RFA and included bilateral pulmonary vein isolation and left atrial appendage exclusion or removal. The pooled drug-free success rate at 1 year was 77% (95% CI, 72% to 83%), with a similar success rate at 2 years. Subgroup analysis of the type of AF showed the highest success rate for paroxysmal AF at 81% (95% CI, 73% to 86%). The in-hospital complication rate was 2.9% and included conversion to sternotomy, rethoracotomy due to excess bleeding, pulmonary problems, stroke, and pacemaker implantation, pneumonia, and reintubation for hypoxia.

Phan et al (2016) conducted a systematic review of studies comparing thoracoscopic surgical ablation with catheter ablation, including the Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST) trial.¹⁹ Eight comparative studies, with a total of 321 video-assisted thoracoscopic surgical ablation patients and 378 catheter ablation patients, met inclusion criteria. For the review's primary efficacy end point of freedom from AF without the use of antiarrhythmic drugs, the treatment success was significantly higher in the surgical ablation group (81%) than in the catheter ablation group (64.3%) at 6 months postprocedure (RR=1.23; 95% CI, 1.02 to 1.49; p=0.03). This difference was maintained at 12 months postprocedure. Patients treated with surgical ablation had significantly higher rates of major complications (including death, stroke, transient ischemic attack, major bleeding, pericardial effusion, cardiac tamponade, pulmonary vein stenosis, pneumothorax, hemothorax, pneumonia, myocardial infarction, conversion to complete thoracotomy) compared with catheter ablation–treated patients (28.2% vs 7.8%; RR=3.30; 95% CI, 1.73 to 6.29; p<0.001).

A systematic review of 28 single-arm studies reporting on 1051 patients who received minimally invasive surgical treatment for AF was published by La Meir et al (2013).²⁰ Reviewers noted substantial differences in patient populations, surgical techniques, and outcome definitions across studies. At 1 year, the range of success, as defined by freedom from AF while off all medications, was 51% to 86%. Outcomes for RFA appeared superior to those using ultrasound or microwave

energy sources. Reviewers also noted that success was higher for the population of patients who had paroxysmal AF compared with those who had persistent and permanent AF. Early complication rates ranged from 0% to 39%, and the most common major complications were conversion to sternotomy, bleeding, port access problems, cardiac events, cerebrovascular accidents, and pulmonary complications.

Randomized Controlled Trials

The FAST RCT, reported by Boersma et al (2012), compared stand-alone surgical ablation with percutaneous ablation.²¹ This trial enrolled 124 patients from 2 clinical centers in Europe, who had symptomatic AF for at least 1 year and had failed at least 1 antiarrhythmic medication. Patients were randomized to surgical ablation using video-assisted thoracoscopy under general anesthesia or to percutaneous catheter ablation. Both techniques used RF energy. All patients in the surgical ablation group also had their left atrial appendage removed. The primary outcome was freedom from AF while off all antiarrhythmic medications during 12 months of follow-up. Secondary outcomes were freedom from AF, including patients still on medications and adverse events. Prior unsuccessful catheter ablation had been performed in 67% of patients.

At 1 year, freedom from AF while off all antiarrhythmic drugs was achieved by 65.6% (40/61) of the surgical ablation group compared with 36.5% (23/63) of the catheter ablation group ($p=0.002$). Freedom from AF, on or off medications, was achieved by 78.7% (48/61) of the surgical ablation group compared with 42.9% (27/63) of the catheter ablation group ($p<0.001$). Serious adverse events were more common in the surgical group (23.0% [14/61]) than in the catheter ablation group (3.2% [2/63]; $p=0.001$). In each group, there was 1 episode of tamponade and stroke. Additional complications in the surgical group included 6 patients with pneumothorax, 2 who required pacemaker insertion, and 1 patient each who had hemothorax, rib fracture, pneumonia, or required sternotomy for bleeding.

In a subsequent smaller RCT, Pokushalov et al (2013) randomized patients with a prior failed first catheter ablation procedure for AF to repeat catheter ablation ($n=32$) or to surgical ablation with video-assisted thoracoscopy ($n=32$).²² After 12 months, a higher proportion of patients who underwent surgical ablation were free of AF and atrial tachycardia without antiarrhythmic drugs (81% vs 47%, $p=0.004$). Although the total number of adverse events did not differ significantly between groups, the number of serious adverse events was higher in the surgical ablation group (7 vs 1, $p=0.02$).

Nonrandomized Comparative Studies

Several observational studies have included a matched comparison group of patients who received alternative treatments. These case series with matched control groups offer stronger evidence for comparative efficacy than do single-arm case series.

Stulak et al (2011) compared outcomes among patients with AF who underwent an isolated cut-and-sew Cox maze procedure or catheter ablation.²³ Ninety-seven Cox maze patients were matched on a 1:2 basis by age, sex, and AF type with 194 patients undergoing catheter ablation. At last follow-up, 82% of patients who underwent the Cox maze procedure were free of AF and off all medications compared with 55% of patients who underwent catheter ablation ($p<0.001$). Freedom from AF at 5 years was estimated to be 87% following Cox maze surgery compared with 28% following catheter ablation ($p<0.001$).

Wang et al (2011) performed a retrospective matched comparison of 83 patients who underwent minimally invasive surgical ablation with 83 patients who underwent catheter ablation.²⁴ All patients had long-standing persistent AF, were treated between 2006 and 2009 and were followed from 1 to 3.6 years. At last follow-up, 74.7% of patients who underwent surgical ablation were free of AF compared with 59% of patients treated by catheter ablation ($p < 0.05$). Freedom from AF while off all medications was achieved by 61.4% of the surgical group compared with 44.6% of the catheter ablation group ($p < 0.05$).

Other observational studies have reported outcomes for stand-alone AF treatment. Representative studies are described next. In a retrospective cohort study, Lawrance et al (2014) compared patients who underwent a Cox maze IV procedure either by right mini-thoracotomy ($n = 104$) or sternotomy ($n = 252$) at a single center from 2002 to 2014.²⁵ Freedom from atrial tachyarrhythmias off antiarrhythmic drugs did not differ significantly between groups. The overall complication rate was lower in the mini-thoracotomy group (6%) than in the sternotomy group (13%; $p = 0.044$).

De Maat et al (2013) published results of a retrospective observational study of minimally invasive surgical treatment for AF in 86 patients with symptomatic, drug-refractory paroxysmal or permanent AF.²⁶ Patients were treated at 3 centers, via bilateral video-assisted mini-thoracotomy, from 2005 to 2007 ($n = 13$ patients) and subsequently via a totally thoracoscopic approach from 2007 to 2011 ($n = 73$ patients). Fifteen (17%) patients had had transcatheter ablation performed. The percentages of patients free from atrial arrhythmias without the use of antiarrhythmic drugs were 71% at 12 months, 72% at 24 months, and 69% at 36 months. Half of the 24 treatment failures underwent an additional transcatheter ablation. Major periprocedural adverse events occurred in 8%, which included 3 sternotomy or mini-thoracotomy procedures due to complications, 2 cases of late pericardial tamponade, 1 case of pericardial effusion requiring video-assisted thoracoscopic surgery, and 1 stroke.

Massimiano et al (2013) reported on outcomes for 292 consecutive patients from a single institution who underwent minimally invasive mitral valve surgery ($n = 177$), surgical ablation for AF ($n = 81$), or both ($n = 34$).²⁷ Among the 115 patients who underwent AF ablation, the percentages of patients in sinus rhythm at 6, 12, and 24 months were 93%, 93%, and 88%, respectively; the percentage of patients in sinus rhythm and not taking class I and III antiarrhythmic medications at 6, 12, and 24 months were 85%, 85%, and 77%, respectively.

Single-Arm Studies

Numerous single-arm case series have reported high success rates following a minimally invasive surgical procedure; however, these case series offer limited evidence of the efficacy of the procedure itself.²⁸⁻³⁷ Most series lacked a control group, generally only reported short-term outcomes, and did not consistently report adverse events.

Several single-arm case series of minimally invasive epicardial ablation have reported on patients who had failed catheter ablation. These case series offer evidence that is more clinically relevant than studies of unselected patients because this population has fewer treatment options and is more likely to benefit from surgical procedures. However, these studies only offer very limited evidence of the comparative efficacy of alternatives such as catheter ablation. For example, Ad et al (2011) reported on 40 patients who had failed catheter ablation, with a mean of 2.3 prior

ablations per patient.³⁸ The percentages of patients maintaining sinus rhythm at 6, 12, and 24 months were 76% (29/38), 89% (23/26), and 93% (13/14), respectively. Castella et al (2010) enrolled 34 patients who had failed a mean of 2 prior catheter ablations; 17 with paroxysmal AF, 12 with persistent AF, and 5 with long-standing persistent AF.³⁹ At 1-year follow-up, sinus rhythm was maintained in 82% of patients with paroxysmal AF, 60% with persistent AF, and 20% with long-standing persistent AF.

Section Summary: Maze and Related Procedures as a Stand-Alone Treatment for AF

The evidence on the role of maze and related procedures as stand-alone options consists of 2 RCTs (including the FAST study) and many case series, some with matched control groups. The RCTs have reported higher success rates in maintaining sinus rhythm at 1-year follow-up with thoracoscopic ablation but have also reported higher adverse event rates than catheter ablation. This evidence does not support the superiority of one technique over the other but suggests that other factors (eg, type of AF, prior treatments, inability to take anticoagulation, patient preference) may influence the decision for the type of procedure. Case series with matched control groups have also reported higher success rates in maintaining sinus rhythm compared with catheter ablation. The single-arm case series have corroborated the high success rates following surgical treatment, but do not provide sufficient evidence to form conclusions on the comparative efficacy of surgical treatment vs other treatments.

Some case series and an RCT have included only patients who have failed previous catheter ablation. These studies have also reported high success rates following thoracoscopic ablation, suggesting that patients who fail catheter ablation may still benefit from thoracoscopic ablation. However, the RCT reported higher adverse event rates than catheter ablation, and the risk-benefit ratio is not well-defined.

Hybrid Thoracoscopic and Endocardial Ablation Procedures

Systematic Reviews

Je et al (2015) reported on results of a systematic review of 37 studies designed to compare minimally invasive AF ablation procedures, including minimally invasive endocardial Cox maze procedure, with cardiopulmonary bypass support, epicardial surgical ablation, and hybrid surgical ablation.⁴⁰ Selected were 2 studies on minimally invasive endocardial Cox maze procedure (n=145 patients), 26 on epicardial surgical ablation (n=1382 patients), and 9 on hybrid surgical ablation (n=350 patients). No statistical analyses or meta-analyses were possible due to the heterogeneity in methodologies and data reporting. However, reviewers did report that treatment success (sinus rhythm without antiarrhythmic medications) at 12 months was 87% for the endocardial Cox maze procedure, 72% for epicardial surgical ablation, and 71% for hybrid surgical ablation.

Nonrandomized Studies

La Meir et al (2012) reported on a comparative study that enrolled 35 patients who underwent a hybrid procedure and 28 patients who underwent a standard percutaneous procedure.⁴¹ Approximately two-thirds (42/63) of the patients had a previous percutaneous ablation procedure. At 1 year, there were more patients in the hybrid group who were free of AF, but this difference was not statistically significant (91.4% vs 82.1%, p=0.07). On subgroup analysis, the success rate was higher for the hybrid group in patients with long-standing persistent AF (81.8% vs 44.4%; p=0.001). Significantly more patients in the hybrid group were on warfarin at 1 year

(29% vs 13.4%, $p < 0.001$). There was no difference between groups on the frequency of adverse events.

Observational Studies

Other relevant single-arm case series have included populations ranging from 19 to 104 patients.⁴²⁻⁵¹ These series have consistently reported high success rates in maintaining sinus rhythm at 1-year follow-up, ranging from 71% to 91%. Some series have reported individual adverse events, but did so variably not systematically, resulting in an inability to accurately estimate adverse event rates.

Section Summary: Hybrid Thoracoscopic and Endocardial Ablation Procedures

The evidence on hybrid ablation consists of a number of case series, one of which included a matched comparison group of patients undergoing percutaneous ablation, and a systematic review of these studies. The studies have suggested that hybrid ablation procedures are associated with high rates of freedom from AF, but direct comparisons with catheter ablation are lacking. Comparative studies are needed to permit assessment of the benefits and harms of hybrid ablation procedures compared with alternatives.

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 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 a meaningful 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. One RCT has provided most of the direct evidence comparing surgical AF ablation using video-assisted thoracoscopy with percutaneous catheter ablation. This trial reported higher success at maintaining sinus rhythm at 1 year of follow-up with thoracoscopic ablation but also reported higher adverse event rates compared with catheter ablation. The case series have generally reported high success rates, and a few with matched comparison groups have reported higher success rates with surgical treatment than with catheter ablation. However, 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 each procedure. At present, it is not possible to define a subgroup of patients who would benefit more from thoracoscopic (or other minimally invasive) surgical ablation compared with percutaneous ablation, so the risks and benefits of surgical ablation compared with catheter

ablation are not well-defined. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 a nonrandomized comparative study and single-arm case series. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. The studies have suggested that hybrid ablation procedures are associated with high rates of freedom from AF, but direct comparisons with catheter ablation are lacking. Comparative studies are needed to permit direct comparisons of the benefits and harms of hybrid ablation procedures with alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT 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 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

Society of Thoracic Surgeons

The Society of Thoracic Surgeons (2017) published guidelines on the surgical treatment of atrial fibrillation (AF).⁵² Recommendations are provided in see Table 3.

Table 3. Guidelines on Surgical Treatment of AF

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

Recommendation	COR	LOE
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 recommendation.

American Heart Association et al

The American Heart Association, American College of Cardiologists, and Heart Rhythm Society issued joint guidelines (2014) on the management of patients with AF.⁵³ Recommendations on the use of surgical ablation to maintain sinus rhythm are provided in Table 4.

Table 4. Guidelines on the Management of AF

Recommendation	COR	LOE
"An AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications."	IIa	C
"A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches."	IIb	B

AF: atrial fibrillation; COR: class of recommendation; LOE: level of recommendation.

Heart Rhythm Society et al

A 2012 expert consensus statement was developed by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society.⁵⁴ The statement was endorsed by 4 other cardiology associations. Recommendations on concomitant surgical ablation in patients 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

Recommendation	COR	LOE
Paroxysmal: Surgical ablation is reasonable for patients undergoing surgery for other indications	IIa	C
Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications	IIa	C
Longstanding Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications	IIa	C

COR: class of recommendation; LOE: level of recommendation.

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

Table 6. Guidelines on Stand-Alone Surgical Ablation for Symptomatic Atrial Fibrillation Refractory to Antiarrhythmics

Recommendation	COR	LOE
Paroxysmal		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	C
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	C
Persistent		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	C
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	C

Recommendation	COR	LOE
Longstanding persistent		
Stand alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	C
Stand alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	C

COR: class of recommendation; LOE: level of recommendation.

The following recommendations were made on stand-alone surgical ablation in patients with symptomatic AF before initiation of antiarrhythmic drug therapy with a class 1 or 3 antiarrhythmic agent (see Table 7).

Table 7. Guidelines on Stand-Alone Surgical Ablation for Symptomatic AF Before Initiating Antiarrhythmics

Recommendation	COR	LOE
Paroxysmal: Stand alone surgical ablation is not recommended	III	C
Persistent: Stand alone surgical ablation is not recommended	III	C
Longstanding Persistent: Stand alone surgical ablation is not recommended	III	C

COR: class of recommendation; LOE: level of recommendation.

Canadian Cardiovascular Society

The Canadian Cardiovascular Society (2011) published guidelines on surgical therapy for AF.⁵⁵ These guidelines stated that there is a high rate of freedom from AF following surgical treatment (70%-85% at 1 year), but that surgical ablation of AF has not been shown to alter mortality rates (see Table 8).

Table 8. Guidelines on Surgical Therapy for AF

Recommendation	SOR	QOE
We recommend that a surgical AF ablation procedure be undertaken in association with mitral valve surgery in patients with AF when there is a strong desire to maintain sinus rhythm, the likelihood of success of the procedure is deemed to be high, and the additional risk is low.	Strong	Moderate
We recommend that patients with asymptomatic lone AF, in whom AF is not expected to affect cardiac outcome, should not be considered for surgical therapy for AF.	Strong	Low
In patients with AF who are undergoing aortic valve surgery or coronary artery bypass surgery, we suggest that a surgical AF ablation procedure be undertaken when there is a strong desire to maintain sinus rhythm, the success of the procedure is deemed to be high, and the additional risk low.... This recommendation recognizes that left atrial endocardial access is not routinely required for aortic or coronary surgery.	Conditional	Low
We recommend that oral anticoagulant therapy be continued following surgical AF ablation in patients with a CHADS2 score ≥ 2 .	Strong	Moderate

AF: atrial fibrillation; QOE: quality of evidence; SOR: strength of recommendation.

Although not a formal recommendation, these guidelines indicated that stand-alone surgical ablation should be considered after failure of prior attempts at catheter ablation and antiarrhythmic drugs.

The Society published a 2012 focused update to its comprehensive 2010 guidelines on AF.⁵⁶ The guidelines discussed the use of anticoagulants in the treatment of AF.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01582828	Serial Hybrid Atrial Fibrillation Ablation	162	Dec 2017
NCT02755688	Catheter Ablation Versus Thoracoscopic Surgical Ablation in Long Standing Persistent Atrial Fibrillation (CASA-AF)	120	Dec 2019
Unpublished			
NCT01319747 ^a	Video-Assisted Thoracoscopic Pulmonary Vein Isolation Versus Percutaneous Catheter Ablation in Atrial Fibrillation Trial	77	Nov 2014 (terminated)
NCT00703157 ^a	The SCALAF Success Trial	80	Nov 2016 (terminated)
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)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

- 33254 Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)
- 33255 Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass
- 33256 Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with cardiopulmonary bypass
- 33257 Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, 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 (eg, 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 (eg, 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 (eg, modified maze procedure), without cardiopulmonary bypass
- 33266 Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass

ICD-10 Diagnoses

- I48.0 Paroxysmal atrial fibrillation
- I48.1 Persistent atrial fibrillation

REVISIONS

08-08-2018	Policy added to the bcbsks.com web site on July 9, 2018, with an effective date of August 8, 2018.
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