BlueCross BlueShield of Alabama

Name of Policy:

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

Policy #: 631
Category: Surgery
Latest Review Date: June 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

Atrial Fibrillation

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves 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 atrial fibrillation.

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. Surgical ablation, performed either by open surgical techniques or thoracoscopy, 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 that 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 surgical treatment of drug-resistant AF, with an approximately 90% success rate.

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 that are responsible for AF or atrial flutter.

The classic Cox maze procedure is performed on a non–beating heart during cardiopulmonary bypass. Simplification of the maze procedure has evolved with the use of different ablation tools such as microwave, cryotherapy, ultrasound, and radiofrequency (RF) 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 RF 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 that are 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 types of energy sources such as cryoablation and high-intensity ultrasound have also 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 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.

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, as directed by the electrophysiology study, on a separate day.

Policy:

Effective for dates of service on and after May 15, 2017:

The maze or modified MAZE procedure, performed on a non-beating heart during cardiopulmonary bypass **with concomitant cardiac surgery**, **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **for symptomatic, atrial fibrillation or atrial flutter. (CPT codes 33257 or 33259)**

The maze or modified MAZE procedure performed on a non-beating heart during cardiopulmonary bypass **without concomitant cardiac surgery does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **for atrial fibrillation or atrial flutter and is considered investigational. (CPT codes 33254 and 33256)**

Minimally invasive, off-pump maze procedures (i.e., modified MAZE procedures), including those done via mini-thoracotomy, do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**. **(CPT codes 33265 and 33266)**

Hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

The MAZE or modified MAZE procedure performed without cardiopulmonary bypass does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational. (CPT codes 33255 and 33258)**

For alternative approaches for the treatment of atrial fibrillation, see medical policies #493 - *Catheter Ablation for Cardiac Arrhythmias* and #283 - *Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as a Treatment of Atrial Fibrillation*.

Effective for dates of service prior to May 15, 2017:

The maze or modified MAZE procedure, performed on a non-beating heart during cardiopulmonary bypass **with concomitant cardiac surgery**, **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **for symptomatic, drug resistant atrial fibrillation or atrial flutter.**

The maze or modified MAZE procedure performed on a non-beating heart during cardiopulmonary bypass **without concomitant cardiac surgery, does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **for symptomatic, drug resistant atrial fibrillation or atrial flutter.**

Minimally invasive, off-pump maze procedures (i.e., modified MAZE procedures), including those done via mini-thoracotomy, do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review is through March 6, 2018.

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 versus "Modified Maze" Procedures

Khargi et al analyzed 48 studies comprising 3832 patients who received surgical treatment of atrial fibrillation (AF) using the classic "cut-and-sew" Cox maze III technique or an alternative source of energy. 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 are lacking, the data involve a wide range of ablative patterns and their effects on atrial tissue. Topkara et al (2006) reported comparable postoperative rhythm success in use of either radiofrequency (RF; 121 patients) or microwave (85 patients) energy in surgical ablation of AF.

Observational Studies
Several observational studies 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 [CMIII] procedure, and 88 in whom RFA replaced the incisions of the classic procedure [CMIV]) 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). Fifty-eight matched pairs were studied. At 1 year, survival was 94% and 89%, respectively (p=0.19), and freedom from AF recurrence was 96% and 93% (p=0.52) for the CMIII and CMIV groups, respectively. The authors note that the CMIV procedure was offered to higher risk patients than the CMIII procedure, which may explain why only 58 of 88 CMIV patients were able to be matched in their analysis. The matched propensity analysis can remove measureable selection biases, but if unmeasured factors lead surgeons to choose 1 surgery over the other, these factors are not accounted for in the analysis.

In a second matched analysis, Stulk et al (2007) assessed 56 patients who underwent a CMIV RFA procedure at a clinic who were matched (historical controls) to 56 patients who underwent the CMIII procedure. Matching factors were age, sex, New York Heart Association (NYHA) functional class, AF type, and concomitant mitral valve surgery. Here the CMIV 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 with freedom from AF at late follow-up (mean 8.4 months; 62% vs 92%). Again, the CMIV patients had greater underlying disease (more concomitant procedures were performed).

In a second article reporting results from the same clinic, Stulak et al (2014) reported results from an unmatched retrospective comparison of CMIII and CMIV among 1540 patients who underwent surgical ablation for AF at a single institution from 1993 to 2011. Energy sources used to create lesions included cut and sew in 521 (44%), cryothermy in 267 (22%), RF in 262 (22%), and a combination of these sources in 139 patients (12%). On multivariate analysis, CMIII was independently associated with less risk of recurrent AF at a follow-up period of 1 to 5 years (hazard ratio [HR], 0.4; 95% confidence interval [CI], 0.24 to 0.69; p<0.001) and more than 5 years (HR=0.23; 95% CI, 0.12 to 0.42; p<0.001) for all patients. This study is limited by its retrospective design and lack of propensity score matching.

<u>Subsection Summary: Traditional Maze versus “Modified Maze” Procedures</u>
There have been numerous modifications on the original maze procedure, with variations in the surgical approach, the lesion set used, and the methods for creating lesions (e.g., cut-and-sew, RFA). The evidence on comparative effectiveness of the different approaches is not of high quality and is incomplete in terms of addressing all of the possible comparisons. The limited available evidence from matched case series does not indicate that there are large differences in efficacy among 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 (e.g., mitral valve replacements) consists of several randomized controlled trials (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 2016 Cochrane review by Huffman et al evaluated the evidence on concomitant AF surgery for people undergoing cardiac surgery. Included were 22 trials that evaluated the effect of AF surgery compared to no AF surgery in adults who were 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 to have a high risk of bias. There was moderate-quality evidence that the interventions increased freedom from atrial fibrillation/flutter/tachycardia when off antiarrhythmic medications (51.0% vs 24.1%); relative risk, 2.04; 95% Cl, 1.63 to 2.55), but the effect on all-cause mortality was uncertain and the procedures increased the risk of permanent pacemaker implantation (6% vs 4.1%; RR=1.69; 95% Cl, 1.12 to 2.54).

In 2014, Phan et al reported results of a systematic review and meta-analysis of RCTs comparing surgical ablation with no ablation among patients with AF undergoing mitral valve surgery. Nine studies were included in the analysis: 5 that evaluated RFA, 2 that evaluated Cox maze cut-and-sew, 1 that evaluated cryoablation, and 1 that 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 and non-ablation groups (4.4% vs 2.7%, respectively; odds ratio [OR], 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 receiving mitral valve repair plus surgical ablation compared with the group receiving mitral valve repair only (67.9% vs 17.0%; OR=13.96; 95% CI, 6.29 to 30.99; p<0.001); similarly, at 3-, 6-, 12-, and greater than 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. They found a reduction in stroke rates and a small increased risk in the need for pacemakers among patients receiving simultaneous maze procedures. In addition, they noted that alternative energy sources, such as RF, may 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 Cochran review are described below.

In 2015, Gillinov et al published results of a large RCT that randomized 260 patients with persistent or long-standing AF who required mitral valve surgery to either ablation (either pulmonary vein isolation or ablation with a maze lesion set) during surgery (n=133) or no ablation (n=127). 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: control group) was 2.15 (95% CI, 1.54 to 3.00) on the basis of observed data. At 1 year, mortality did not differ significantly between the ablation group and the control group (6.8% vs 8.7%, respectively, p=0.57). A composite safety endpoint did not differ significantly between groups at 30 days, and serious adverse event rates did not differ significantly between groups at 1 year.

Budera et al (2012) published an RCT in 2012, which randomized 224 patients from 3 clinical centers to cardiac surgery plus ablation versus cardiac surgery alone. Patients were eligible for inclusion if they had at least 2 episodes of documented AF in the last 6 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 following surgery. 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 events were similar in both groups at 30 days and at 1-year follow-up. Secondary clinical outcomes, including mortality and NYHA 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. One hundred fifty patients with AF who were scheduled to undergo either valve surgery or CABG surgery were randomly assigned 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 (EQ-5D), 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 Pain/Discomfort subscale of the EQ-5D, which showed a greater degree of worsening in the control group compared with 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). The operative mortality for the mitral valve procedure alone was predicted for each group based on Society of Thoracic Surgeons (STS) perioperative risk calculator; the risk attributed to the addition of the Cox maze IV procedure was calculated by comparing the predicted mortality 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 in terms of medical comorbidities and etiology of the mitral valve disease. The observed 30-day mortality 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 for patients who underwent a concomitant Cox maze IV procedure with mitral valve surgery was 2.9%. The STS predicted 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 is limited by the fact that patients who received

concomitant Cox maze IV procedures with mitral valve surgery were a selected low-risk population; however, it suggests that in the appropriate patient population, the Cox maze IV procedure can been 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 long-term outcomes after 127 Cox maze cut-and-sew procedures in conjunction with mitral valve replacement. 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.

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 surgery with little additional risk. Evidence from RCTs of open heart surgery plus surgical treatment of AF versus surgery alone establishes 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 quality of life, 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 requires assessment of surgery-related complications.

The evidence related to 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/endocardial procedures and are discussed separately.

Surgical Ablation as a Stand-Alone Treatment
Systematic Reviews
A number of systematic reviews that have used different inclusion criteria have assessed the evidence on stand-alone surgical ablation.

In 2017, van Laar et al reported a meta-analysis of totally thoracoscopic maze procedures for the treatment of AF. 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 let atrial appendage exclusion or removal. The pooled drug-free success rate at1 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.

In 2016, Phan et al reported results of a systematic review of studies comparing thoracoscopic surgical ablation with catheter ablation, including the FAST trial. Eight comparative studies, with a total of 321 video-assisted thoracoscopic surgical ablation patients and 378 catheter ablation patients, met the inclusion criteria. For the study's primary efficacy end point of freedom from AF off antiarrhythmic drugs, the treatment success was significantly higher in the surgical ablation group compared with the catheter ablation group at 6 months post procedure (81% vs 64.3%; risk ratio [RR], 1.23; 95% CI, 1.02 to 1.49; p=0.03). This difference was maintained at 12 months post procedure. 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 in 2013 by La Meir et al. This review noted substantial differences in patient populations, surgical techniques, and definitions of outcome across studies. At 1 year, the range of success, as defined by freedom from AF and off all medications, was 51% to 86%. Outcomes for RFA appeared superior to those using ultrasound or microwave energy sources. The authors also noted that success was higher for the population of patients who had paroxysmal AF compared with those having persistent and permanent AF. The early complication rate 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. 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 removal of the left atrial appendage. The primary outcome was freedom from AF 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 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, occurring in 23.0% (14/61) of patients compared with 3.2% (2/63) in the catheter ablation group (p=0.001). In both groups, there was 1 episode each of tamponade and stroke. Additional complications in the surgical group were 6 patients who had pneumothorax, 2 patients 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 receive either repeat catheter ablation (n=32) or surgical ablation with video assisted thoracoscopy (n=32). After 12 months, a higher proportion of patients who underwent surgical ablation were free of AF or 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 that include a matched comparison group of patients who received alternate 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. 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 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. All patients had longstanding 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 with catheter ablation (p<0.05). Freedom from AF off all medications was 61.4% in the surgical group compared with 44.6% in the catheter ablation group (p<0.05).

Other observational studies report outcomes for stand-alone AF treatment. Representative studies are described next. Lawrance et al conducted a retrospective cohort study comparing patients who underwent a Cox maze IV procedure either by right minithoracotomy (n=104) or sternotomy (n=252) at a single center from 2002 to 2014. Freedom from atrial tachyarrhythmias off antiarrhythmic drugs was not significantly different between groups. The overall complication rate was lower in the minithoracotomy 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. 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 previous transcatheter ablation performed. The percentage of patients free from atrial arrhythmias without the use of antiarrhythmic drugs was 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 minithoracotomy due to complications, 2 cases of late pericardial tamponade, 1 pericardial effusion requiring video-assisted thoracoscopic surgery, and 1 stroke.

Massimiano et al (2013) reported 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). Among the 115 patients who underwent AF ablation, the percentage of patients in sinus rhythm at 6, 12, and 24 months was 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 was 85%, 85%, and 77%, respectively.

Single-Arm Studies

Numerous single-arm case series report high success rates following a minimally invasive surgical procedures; however, these case series offer limited evidence regarding the efficacy of the procedure itself. Most of the case series are limited by a lack of control group, generally only report short-term outcomes, and do not consistently report adverse events.

Several single-arm case series of minimally invasive epicardial ablation report on the population of 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 more limited treatment options and is more likely to benefit from surgical procedures. However, these studies only offer very limited evidence about comparative efficacy with alternatives such as catheter ablation. Ad et al (2011) reported on 40 patients who had failed catheter ablation, with a mean of 2.3 prior ablations per patient. The percentages of patients maintaining sinus rhythm at 6, 12, and 24 months was 76% (29/38), 89% (23/26), and 93% (13/14), respectively. Castella et al (2010) enrolled 34 patients who had failed a mean of 2.0 prior catheter ablations; 17 with paroxysmal AF, 12 with persistent AF, and 5 with long-standing persistent AF. 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 procedures consists of 2 RCTs (FAST study) and many case series, some with matched control groups. The RCTs report higher success at maintaining sinus rhythm at 1-year follow-up with thoracoscopic ablation, but also report higher adverse event rates than catheter ablation. This evidence does not support the superiority of 1 technique over the other, but suggests that other factors such as type of AF, prior treatments, inability to take anticoagulation, and patient preference may influence the decision for type of procedure. Case series with matched control groups also report higher success rates in

maintaining sinus rhythm compared with catheter ablation. The single-arm case series corroborated the high success rates following surgical treatment, but do not provide sufficient evidence to form conclusions on the comparative efficacy of surgical treatment versus other treatments.

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

Hybrid Thorascopic/ Endocardial Ablation Procedures

Systematic Reviews

Je et al (2015) reported 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. The studies included were 2 on minimally invasive endocardial Cox maze procedure (total sample size, 145 patients), 26 on epicardial surgical ablation (1382 patients), and 9 on hybrid surgical ablation (350 patients). No statistical analyses or meta-analyses were possible due to the heterogeneity in methodology and data reporting. However, the authors do 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 Comparative Studies

In 2012, La Meir reported a study with a comparison group that enrolled 35 patients who underwent a hybrid procedure and 28 patients who underwent a standard percutaneous procedure. Approximately two-thirds (42/63) of the patients had undergone 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 been published that include populations of 19 to 104 patients. These series consistently report high success rates in maintaining sinus rhythm at 1-year follow-up, ranging from 71% to 91%. Some of these series report individual adverse events, but reporting on adverse events is variable and not systematic in these case series, resulting in an inability to accurately estimate rates of adverse events.

Section Summary: Hybrid Thorascopic/Endocardial Ablation Procedures

The evidence on hybrid ablation consists of a number of case series, 1 of which included a matched comparison group of patients undergoing percutaneous ablation, and a systematic review of these studies. The studies suggest 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, atrial fibrillation (AF) or flutter who are undergoing cardiac surgery with bypass who received a Cox maze procedure or modified MAZE procedure, the evidence includes several randomized controlled trials (RCTs) and nonrandomized comparative studies, along with systematic reviews of these studies. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several small RCTs have provided most of the direct evidence confirming the benefit of a modified MAZE procedure for patients with AF who are undergoing mitral valve surgery. These trials establish that the addition of a modified MAZE procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies support the 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 generally report high success rates, and the few case series with matched comparison groups report higher success rates with surgical treatment compared with catheter ablation. However, this evidence does not permit definitive conclusions whether 1 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 will 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/endocardial ablation procedures, the evidence includes 1 nonrandomized comparative study and single-arm case series. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. The studies suggest 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 allow direct comparisons of the benefits and harms of hybrid ablation procedures compared with alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

Society of Thoracic Surgeons

In 2017, the Society of Thoracic Surgeons published guidelines for the surgical treatment of atrial fibrillation. Recommendations include the following (see Table 1).

Table 1: Guidelines on Surgical Treatment of Atrial Fibrillation

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

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

American Heart Association, American College of Cardiologists, and Heart Rhythm Society

In 2014, the American Heart Association, American College of Cardiologists, and Heart Rhythm Society (HRS) issued guidelines on the management of patients with atrial fibrillation (AF). The guideline provides the following recommendations related to the use of surgical ablation to maintain sinus rhythm (see Table 2):

Table 2: Guidelines on the Management of Atrial Fibrillation

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.

HRS, European Heart Rhythm Association, and European Cardiac Arrhythmia Society

A 2012 expert consensus statement was developed by the HRS, European Heart Rhythm Association, and European Cardiac Arrhythmia Society. The document was also endorsed by the American College of Cardiology, American Heart Association, Asia Pacific Heart Rhythm Society, and Society of Thoracic Surgeons.

The following recommendations were made regarding concomitant surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF: (see Table 3).

Table 3: 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 regarding stand-alone surgical ablation in patients with symptomatic AF refractory or intolerant to at least one class 1 or 3 antiarrhythmic medication (see Table 4).

Table 4: Guidelines on Stand-Alone Surgical Ablation with Symptomatic AF Refractory

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
Paroxysmal: 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
Persistent: Stand-alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation	IIb	C
Longstanding Persistent: Stand-alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach	IIb	C
Longstanding Persistent: 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 regarding stand-alone surgical ablation in patients with symptomatic AF prior to initiation of antiarrhythmic drug therapy with a class 1 or 3 antiarrhythmic agent:

> "Paroxysmal: Standalone surgical ablation is not recommended (Class III, Level C)
>
> Persistent: Standalone surgical ablation is not recommended (Class III, Level C)
>
> Longstanding Persistent: Standalone surgical ablation is not recommended (Class III, Level C)"

<u>Canadian Cardiovascular Society</u>

The Canadian Cardiovascular Society (CVS) published guidelines in 2011 on surgical therapy for AF. These guidelines state that there is a high rate of freedom from AF following surgical treatment, 70% to 85% at 1 year, but that surgical ablation of AF has not been shown to alter mortality. The following recommendations were made:

> "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 Recommendation, Moderate-Quality Evidence).
>
> 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 Recommendation, Low-Quality Evidence).
>
> 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 (Conditional Recommendation, Low-Quality Evidence)…. This recommendation recognizes that left atrial endocardial access is not routinely required for aortic or coronary surgery.

We recommend that oral anticoagulant therapy be continued following surgical AF ablation in patients with a CHADS2 score ≥2 (Strong Recommendation, Moderate-Quality Evidence)."

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

CVS published a 2012 focused update to their comprehensive 2010 guidelines on AF. The 2012 focused guidelines discuss the use of anticoagulants in the treatment of AF.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Maze procedure, hybrid maze procedure, mini-maze, mini maze, surgical ablation, hybrid, cardiac ablation, atrial fibrillation, minimally invasive technique, thorascopic, hybrid ablation, mini-thorascopic, modified MAZE, Cardioblate®, Cardima Ablation System, Epicor™, Isolator ™ Transpolar™ Pen,Estech COBRA®, Coolrail™, Numeris®, Epi-Sense®, Cryocare® Cardiac Surgery System, SeedNet™, SurgiFrost® XL , Isis™ cryosurgical unit

Approved by Governing Bodies:

Several RFA systems used for cardiac tissue ablation have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. They include:

- The Medtronic Cardioblate® System (Medtronic, Minneapolis, MN; cleared for marketing in January 2002);
- The Cardima Ablation System (Cardima, San Carlos, CA; cleared for marketing in January 2003);
- The Epicor™ Medical Ablation System (Epicor Medical , Sunnyvale, CA); cleared for marketing February 2004);
- The Isolator™ Transpolar™ Pen (AtriCure, West Chester, OH; cleared for marketing in June 2005);
- The Estech COBRA® Cardiac Electrosurgical Unit (Endoscopic Technologies, Danville, CA; cleared for marketing in December 2005);
- The Coolrail™ Linear Pen (AtriCure, West Chester, OH; cleared for marketing in March 2008).
- The Numeris® Guided Coagulation System with VisiTrax® (nContact Surgical, Morrisville, NC; cleared for marketing in February 2009).

- The EPi-Sense® Guided Coagulation System with VisiTrax® (nContact Surgical, Morrisville, NC; cleared for marketing in November 2012).

A number of cryoablation systems which may be used on cardiac ablation procedures have also been cleared for marketing, including:

- The Cryocare® Cardiac Surgery System (Endocare, Irvine, CA; cleared for marketing in March 2002);
- The SeedNet™ System (Galil Medical; cleared for marketing in May 2005);
- SurgiFrost® XL Surgical CryoAblation System (CryoCath Technologies, Kirkland, QC, acquired by Medtronic; cleared for marketing in July 2006);
- The Isis™ cryosurgical unit (Galil Medical; cleared for marketing in March 2007).

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified MAZE procedure)
33255	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass
33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified MAZE procedure) (List separately in addition to code for primary procedure.)
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified MAZE procedure), without cardiopulmonary bypass

33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass.
33999	Unlisted procedure, cardiac surgery

References:

1. Ad N, Henry L, Hunt S, et al. The outcome of the Cox Maze procedure in patients with previous percutaneous catheter ablation to treat atrial fibrillation. Ann Thorac Surg. May 2011; 91(5):1371-1377; discussion 1377.
2. Badhwar V, Rankin JS, Damiano RJ, Jr., et al. The Society of Thoracic Surgeons 2017 Clinical practice guidelines for the surgical treatment of atrial fibrillation. Ann Thorac Surg. Jan 2017; 103(1):329-341.
3. Bisleri G, Rosati F, Bontempi L, et al. Hybrid approach for the treatment of long-standing persistent atrial fibrillation: electrophysiological findings and clinical results. Eur J Cardiothorac Surg. Nov 2013; 44(5):919-923.
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Maze procedure for drug-resistant atrial fibrillation or flutter. TEC Assessments. 1994; Volume 9, Tab 19.
5. Boersma LV, Castella M, van Boven W, et al. Atrial fibrillation catheter ablation versus surgical ablation treatment (FAST) a 2-center randomized clinical trial. Circulation. 2012 Jan3; 125(1):23-30.
6. Budera P, Straka Z, Osmancik P, et al. Comparison of cardiac surgery with left atrial surgical ablation vs. cardiac surgery without atrial ablation in patients with coronary and/or valvular heart disease plus atrial fibrillation: final results of the PRAGUE-12 randomized multicentre study. Eur Heart J. Nov 2012; 33(21):2644-2652.
7. Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. Europace. Apr 2012; 14(4):528-606.
8. Castella M, Pereda D, Mestres CA, et al. Thoracoscopic pulmonary vein isolation in patients with atrial fibrillation and failed percutaneous ablation. J Thorac Cardiovasc Surg. Sep 2010; 140(3):633-638.
9. Chernyavskiy A, Kareva Y, Pak I, et al. Quality of Life after Surgical Ablation of Persistent Atrial Fibrillation: A Prospective Evaluation. Heart Lung Circ. Apr 2016; 25(4):378-383.
10. Chevalier P, Leizorovicz A, Maureira P, et al. Left atrial radiofrequency ablation during mitral valve surgery: a prospective randomized multicentre study (SAFIR). Arch Cardiovasc Dis. Nov 2009; 102(11):769-775.
11. Civello KC, Smith CA, Boedefeld W. Combined endocardial and epicardial ablation for symptomatic atrial fibrillation: single center experience in 100+ consecutive patients. J Innovations Cardiac Rhythm Manage. 2013; August.
12. Cui YQ, Li Y, Gao F, et al. Video-assisted minimally invasive surgery for lone atrial fibrillation: a clinical report of 81 cases. J Thorac Cardiovasc Surg. Feb 2010; 139(2):326-332.

13. Damiano RJ, Jr., Badhwar V, Acker MA, 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. Jan 2014; 11(1):39-45.
14. De Maat GE, Pozzoli A, Scholten MF, et al. Surgical minimally invasive pulmonary vein isolation for lone atrial fibrillation: midterm results of a multicenter study. Innovations (Phila). Nov-Dec 2013; 8(6):410-415.
15. Edgerton JR, Brinkman WT, Weaver T, et al. Pulmonary vein isolation and autonomic denervation for the management of paroxysmal atrial fibrillation by a minimally invasive surgical approach. J Thorac Cardiovasc Surg. Oct 2010; 140(4):823-828.
16. Gaita F, Ebrille E, Scaglione M, et al. Very long-term results of surgical and transcatheter ablation of longstanding persistent atrial fibrillation. Ann Thorac Surg. Oct 2013; 96(4):1273-1278.
17. Gehi AK, Mounsey JP, Pursell I, et al. Hybrid epicardial-endocardial ablation using a pericardioscopic technique for the treatment of atrial fibrillation. Heart Rhythm. Jan 2013; 10(1):22-28.
18. Gersak B, Pernat A, Robic B, et al. Low rate of atrial fibrillation recurrence verified by implantable loop recorder monitoring following a convergent epicardial and endocardial ablation of atrial fibrillation. J Cardiovasc Electrophysiol. Oct 2012; 23(10):1059-1066.
19. Gersak B, Zembala MO, Muller D, et al. European experience of the convergent atrial fibrillation procedure: multicenter outcomes in consecutive patients. J Thorac Cardiovasc Surg. Apr 2014; 147(4):1411-1416.
20. Geuzebroek GS, Bentala M, Molhoek SG, et al. Totally thoracoscopic left atrial Maze: standardized, effective and safe. Interact Cardiovasc Thorac Surg. Mar 2016; 22(3):259-264.
21. Gillinov AM, Gelijns AC, Parides MK, et al. Surgical ablation of atrial fibrillation during mitral-valve surgery. N Engl J Med. Apr 9 2015; 372(15):1399-1409.
22. Han FT, Kasirajan V, Kowalski M, et al. Results of a minimally invasive surgical pulmonary vein isolation and ganglionic plexi ablation for atrial fibrillation: single-center experience with 12-month follow-up. Circ Arrhythm Electrophysiol. Aug 2009; 2(4):370-377.
23. Huffman MD, Karmali KN, Berendsen MA, et al. Concomitant atrial fibrillation surgery for people undergoing cardiac surgery. Cochrane Database Syst Rev. Aug 22 2016(8):CD011814.
24. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. Dec 2 2014; 64(21):e1-76.
25. Je HG, Shuman DJ, Ad N. 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.
26. Khargi K, Hutten BA, Lemke B, et al. Surgical treatment of atrial fibrillation; a systematic review. Eur J Cardiothorac Surg. Feb 2005; 27(2):258-265.
27. Kim KC, Cho KR, Kim YJ, et al. Long-term results of the Cox-Maze III procedure for persistent atrial fibrillation associated with rheumatic mitral valve disease: 10-year experience. Eur J Cardiothorac Surg. Feb 2007; 31(2):261-266.

28. Krul SP, Driessen AH, Zwinderman AH, et al. Navigating the mini-maze: Systematic review of the first results and progress of minimally-invasive surgery in the treatment of atrial fibrillation. Int J Cardiol. 2013 Jun5; 166(1): 132-40.
29. Lall SC, Melby SJ, Voeller RK, et al. The effect of ablation technology on surgical outcomes after the Cox-maze procedure: a propensity analysis. J Thorac Cardiovasc Surg. Feb 2007; 133(2):389-396.
30. La Meir M, Gelsomino S, Lorusso R, et al. The hybrid approach for the surgical treatment of lone atrial fibrillation: one-year results employing a monopolar radiofrequency source. J Cardiothorac Surg. 2012; 7:71.
31. La Meir M, Gelsomino S, Luca F, et al. Minimal invasive surgery for atrial fibrillation: an updated review. Europace. Feb 2013; 15(2):170-182.
32. La Meir M, Gelsomino S, Luca F, et al. Minimally invasive surgical treatment of lone atrial fibrillation: Early results of hybrid versus standard minimally invasive approach employing radiofrequency sources. Int J Cardiol. May 2 2012; 167(4):1469-1475.
33. Lawrance CP, Henn MC, Miller JR, et al. A minimally invasive Cox maze IV procedure is as effective as sternotomy while decreasing major morbidity and hospital stay. J Thorac Cardiovasc Surg. Sep 2014; 148(3):955- 961; discussion 962-952.
34. Liu X, Tan HW, Wang XH, et al. Efficacy of catheter ablation and surgical CryoMaze procedure in patients with long-lasting persistent atrial fibrillation and rheumatic heart disease: a randomized trial. Eur Heart J. Nov 2010; 31(21):2633-2641.
35. Massimiano PS, Yanagawa B, Henry L, et al. Minimally invasive fibrillating heart surgery: a safe and effective approach for mitral valve and surgical ablation for atrial fibrillation. Ann Thorac Surg. Aug 2013; 96(2):520-527.
36. Muneretto C, Bisleri G, Bontempi L, et al. Durable staged hybrid ablation with thoracoscopic and percutaneous approach for treatment of long-standing atrial fibrillation: a 30-month assessment with continuous monitoring. J Thorac Cardiovasc Surg. Dec 2012; 144(6):1460-1465; discussion 1465.
37. Muneretto C, Bisleri G, Bontempi L, et al. Successful treatment of lone persistent atrial fibrillation by means of a hybrid thoracoscopic-transcatheter approach. Innovations (Phila). Jul-Aug 2012; 7(4):254-258.
38. Page P, C. C. S. Atrial Fibrillation Guidelines Committee. Canadian Cardiovascular Society atrial fibrillation guidelines 2010: surgical therapy. Can J Cardiol. Jan-Feb 2011; 27(1):67-73.
39. Phan K, Phan S, Thiagalingam A, et al. Thoracoscopic surgical ablation versus catheter ablation for atrial fibrillation. Eur J Cardiothorac Surg. Apr 2016; 49(4):1044-1051.
40. Phan K, Xie A, Tian DH, et al. Systematic review and meta-analysis of surgical ablation for atrial fibrillation during mitral valve surgery. Ann Cardiothorac Surg. Jan 2014; 3(1):3-14.
41. Pison L, La Meir M, van Opstal J, et al. Hybrid thoracoscopic surgical and transvenous catheter ablation of atrial fibrillation. J Am Coll Cardiol. Jul 3 2012; 60(1):54-61.
42. Pokushalov E, Romanov A, Elesin D, et al. Catheter versus surgical ablation of atrial fibrillation after a failed initial pulmonary vein isolation procedure: a randomized controlled trial. J Cardiovasc Electrophysiol. Dec 2013; 24(12):1338-1343.
43. Pruitt JC, Lazzara RR, Ebra G. Minimally invasive surgical ablation of atrial fibrillation: the thoracoscopic box lesion approach. J Interv Card Electrophysiol. Dec 2007; 20(3):83-87.

44. Reston JT, Shuhaiber JH. Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation. Eur J Cardiothorac Surg. Nov 2005; 28(5):724-730.
45. Saint LL, Damiano RJ, Jr., Cuculich PS, et al. Incremental risk of the Cox-maze IV procedure for patients with atrial fibrillation undergoing mitral valve surgery. J Thorac Cardiovasc Surg. Nov 2013; 146(5):1072-1077.
46. Sirak J, Jones D, Sun B, et al. Toward a definitive, totally thoracoscopic procedure for atrial fibrillation. Ann Thorac Surg. Dec 2008;86(6):1960-1964.
47. Skanes AC, Healey JS, Cairns JA, et al. Focused 2012 update of the Canadian Cardiovascular Society atrial fibrillation guidelines: recommendations for stroke prevention and rate/rhythm control. Can J Cardiol. Mar-Apr 2012; 28(2):125-136.
48. Speziale G, Bonifazi R, Nasso G, et al. Minimally invasive radiofrequency ablation of lone atrial fibrillation by monolateral right minithoracotomy: operative and early follow-up results. Ann Thorac Surg. Jul 2010; 90(1):161- 167.
49. Stulak JM, Dearani JA, Sundt TM, 3rd, et al. Ablation of atrial fibrillation: comparison of catheter-based techniques and the Cox-Maze III operation. Ann Thorac Surg. Jun 2011; 91(6):1882-1888; discussion 1888-1889.
50. Stulak JM, Dearani JA, Sundt TM, 3rd, et al. Superiority of cut-and-sew technique for the Cox maze procedure: comparison with radiofrequency ablation. J Thorac Cardiovasc Surg. Apr 2007; 133(4):1022-1027.
51. Stulak JM, Suri RM, Burkhart HM, et al. Surgical ablation for atrial fibrillation for two decades: Are the results of new techniques equivalent to the Cox maze III procedure? J Thorac Cardiovasc Surg. May 2014; 147(5):1478- 1487.
52. Topkara VK, Williams MR, Barili F, et al. Radiofrequency and microwave energy sources in surgical ablation of atrial fibrillation: a comparative analysis. Heart Surg Forum. 2006; 9(3):E614-617.
53. Van Breugel HN, Nieman FH, Accord RE, et al. A prospective randomized multicenter comparison on healthrelated quality of life: the value of add-on arrhythmia surgery in patients with paroxysmal, permanent or persistent atrial fibrillation undergoing valvular and/or coronary bypass surgery. J Cardiovasc Electrophysiol. May 2010; 21(5):511-520.
54. van Laar C, Kelder J, van Putte BP. The totally thoracoscopic maze procedure for the treatment of atrial fibrillation. Interact Cardiovasc Thorac Surg. Jan 2017; 24(1):102-111.
55. von Oppell UO, Masani N, O'Callaghan P, et al. Mitral valve surgery plus concomitant atrial fibrillation ablation is superior to mitral valve surgery alone with an intensive rhythm control strategy. Eur J Cardiothorac Surg. Apr 2009; 35(4):641-650.
56. Wang J, Li Y, Shi J, et al. Minimally invasive surgical versus catheter ablation for the long-lasting persistent atrial fibrillation. PLoS One. 2011; 6(7):e22122.
57. Watkins AC, Young CA, Ghoreishi M, et al. Prospective assessment of the CryoMaze procedure with continuous outpatient telemetry in 136 patients. Ann Thorac Surg. Apr 2014; 97(4):1191-1198; discussion 1198.
58. Wudel JH, Chaudhuri P, Hiller JJ. Video-assisted epicardial ablation and left atrial appendage exclusion for atrial fibrillation: extended follow-up. Ann Thorac Surg. Jan 2008; 85(1):34-38.
59. Yilmaz A, Geuzebroek GS, Van Putte BP, et al. Completely thoracoscopic pulmonary vein isolation with ganglionic plexus ablation and left atrial appendage amputation for treatment of atrial fibrillation. Eur J Cardiothorac Surg. Sep 2010; 38(3):356-360.

60. Yilmaz A, Van Putte BP, Van Boven WJ. Completely thoracoscopic bilateral pulmonary vein isolation and left atrial appendage exclusion for atrial fibrillation. J Thorac Cardiovasc Surg. Aug 2008; 136(2):521-522.
61. Zembala M, Filipiak K, Kowalski O, et al. Minimally invasive hybrid ablation procedure for the treatment of persistent atrial fibrillation: one year results. Kardiol Pol. 2012; 70(8):819-828.

Policy History:

Medical Policy Panel, May 2016
Medical Policy Group, January 2017 **(4):** Newly adopted policy
Medical Policy Administration Committee, February 2017
Available for comment February 1 through March 17, 2017
Medical Policy Panel, May 2017
Medical Policy Group, May 2017 **(4):** Updates to Description, Key Points, Key Words, Approved by Governing Bodies, and References. Removed "drug resistant" from the policy statement regarding coverage of maze procedure. Drug resistant afib is not required when having concomitant cardiac surgery.
Medical Policy Administration Committee, May 2017
Available for comment May 15 through June 29, 2017
Medical Policy Panel June 2017
Medical Policy Group, June 2017 **(4):** Updates to Medical Policy Title, Policy, and Key Points
Medical Policy Group, July 2017 **(4):** Updates to Policy section. Added "and is considered investigational" to statement and added CPT codes to coverage statement.
Medical Policy Panel, May 2018
Medical Policy Group, June 2018 **(4):** Updates to Description and Key Points. No change to policy statement.