Medical Policy

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

Section 7.0 Surgery  
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Description

There are a variety of 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 (CABG) surgery. Minimally invasive surgical techniques employ epicardial radiofrequency ablation (RFA) and are done via the thoracoscopic or mediastinal approach.

Related Policies

- Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as Treatment for Atrial Fibrillation

Policy

The maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass with or without concomitant cardiac surgery may be considered medically necessary for treatment of symptomatic, drug-resistant atrial fibrillation or flutter.

Minimally invasive, off-pump maze procedures (i.e., modified maze procedures), including those done via mini-thoracotomy, are considered investigational for treatment of atrial fibrillation or flutter.

Hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) is considered investigational for the treatment of atrial fibrillation or flutter.

Policy Guidelines

Given the availability of less-invasive alternative approaches in the treatment of atrial fibrillation (See Transcatheter Ablation of Arrhythmogenic Foci in the Pulmonary Veins as Treatment for Atrial Fibrillation), performing the maze procedure without concomitant cardiac surgery should rarely be needed.

Published studies on the maze procedure describe patients with drug-resistant atrial fibrillation (AF) and atrial flutter as having experienced their arrhythmias for an average of 7 or more years and having unsuccessful results with an average of 5 or more antiarrhythmic medications.
Coding
CPT code 33253 was replaced with the following 5 CPT codes specific to the various open and endoscopic maze procedures:

- **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
- **33265**: Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass
- **33266**: Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass.

There are new CPT add-on codes for when the maze procedure is performed at the time of other cardiac procedures:

- **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)

Benefit Application
Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

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. 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 that involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart for patients with AF. 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 (SA) node to the atrioventricular (AV) node
- Preserve activation of the entire atrium
- Block re-entrant impulses that are 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 (RF) energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure.

Minimally Invasive (Thoracoscopic) Techniques

In addition, 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; RF energy is most commonly applied. Other types of energy sources such as cryoaulation and high-intensity ultrasound have also been used. For the purposes of this policy statement, 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, endocardial 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.

Regulatory Status

Several radiofrequency ablation (RFA) systems that are used for cardiac tissue ablation have been cleared for marketing by the United States Food and Drug Administration (FDA) based on substantial equivalence to predicate devices. These include the Medtronic Cardioblate® System (Medtronic Inc., Minneapolis, MN; cleared for marketing in January 2002), the Cardima Ablation System (Cardima Inc., San Carlos, CA; cleared for marketing in January 2003), the Epicor™ Medical Ablation System (Epicor Medical Inc., Sunnyvale, CA; cleared for marketing in February 2004), the Isolator™ Transpolar™ Pen (AtriCure Inc., West Chester, OH; cleared for marketing in June 2005), the Estech COBRA® Cardiac Electrosurgical Unit (Endoscopic Technologies Inc., Danville, CA; cleared for marketing in December 2005), and the Coolrail™ Linear Pen (AtriCure Inc., West Chester, OH; cleared for marketing in March 2008).

A number of cryoaulation systems which may be used on cardiac ablation procedures have also been cleared for marketing, including the Cryocare® Cardiac Surgery System (Endocare Inc., Irvine, CA; cleared for marketing in March 2002), the SeedNet™ System (Galil Medical Ltd.; cleared for marketing in May 2005), SurgiFrost® XL Surgical CryoAblation System (CryoCath Technologies Inc., Kirkland, Quebec; cleared for marketing in July 2006), the Isis™ cryosurgical unit (Galil Medical Ltd.; cleared for marketing in March 2007).

FDA Product Code: OCL

Literature Review

Traditional Maze versus “Modified Maze” Procedures
Khargi et al analyzed 48 studies comprising 3832 patients who received surgical treatment of AF using the classic “cut-and-sew” Cox-Maze III technique or an alternative source of energy. (2) They concluded that they could not identify any significant differences in the postoperative sinus rhythm conversion rates between the classical approach and alternative sources of energy. While prospective randomized studies are lacking, the data involve a wide range of ablation patterns and their effects on atrial tissue. Topkara et al reported comparable postoperative rhythm success in use of either RF (121 patients) or microwave (85 patients) energy in surgical ablation of AF. (3)

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 by matching. In the first, from the Washington University School of Medicine, wherein the maze procedure was developed, the 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). (4) 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 is partly why only 58 of 88 CMIV patients were able to be matched in their analysis. The matched propensity analysis is able to remove measurable 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, 56 patients who underwent a CMIV RFA procedure at Mayo Clinic were matched (historical controls) to 56 patients who underwent the CMIII procedure. (5) Matching factors were age, gender, New York Heart Association (NYHA) 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%), more antiarrhythmic drug use (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 Mayo Clinic, Stulak et al 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. (6) Energy sources included cut and sew in 521 (44%), cryothermy in 267 (22%), RF in 262 (22%), and a combination 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.

**Section Summary**

There are 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 this question consists of several RCTs evaluating AF ablation when performed as an add-on for patients undergoing open mitral valve surgery, and systematic reviews of these trials.

Systematic Reviews

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. (7) Nine studies were included in the analysis, 4 that evaluated RFA, 1 that evaluated RFA with port access, 3 that evaluated Cox-Maze cut-and-sew, 1 that evaluated cryoablation, and 1 that evaluated pulmonary vein isolation. In pooled analysis, the risk of 30-day all-cause mortality did not differ significantly between the mitral valve repair plus AFA and the mitral valve repair only 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 mitral valve repair plus AF ablation group compared with the mitral valve repair only group (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 mitral valve repair plus AFA was in sinus rhythm.

In an earlier systematic review, Reston et al reviewed 4 randomized controlled trials (RCTs) and 6 comparative studies to determine whether a simultaneous maze procedure reduces the risk of stroke or death in patients with chronic or paroxysmal AF who receive mitral valve surgery. (8) They concluded that the studies support a reduction in stroke rates and a small increased risk in need for pacemakers among patients receiving simultaneous maze procedures. The authors also conclude that alternative energy sources, such as RF, may reduce the risk of postoperative bleeding associated with classic maze incisions.

Randomized Controlled Trials

Several additional RCTs evaluating AF ablation in conjunction with open surgery that were not included in the systematic reviews have been published.

Budera et al published the largest RCT in 2012, which was not included in the systematic review by Reston et al. This study randomized 224 patients from 3 clinical centers to cardiac surgery plus ablation versus cardiac surgery alone. (9) 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) patients in the surgery-alone group (p<0.005). Adverse events were similar in both groups at 30 days and at 1-year follow-up. Secondary clinical outcomes, included mortality and NYHA functional class, did not differ between groups at 1 year.

The SAFIR study (10) was a multicenter, double-blind, RCT conducted at 4 university hospitals. This trial randomly assigned 43 patients with mitral valve disease and long-standing persistent AF to mitral surgery alone versus surgery plus RFA of the left atrium. At 12 months, 95% of patients in the RFA group were in sinus rhythm compared with 33.3% of patients in the surgery-alone group (p<0.005). The primary endpoint of sinus rhythm at 12
months without recurrence of any atrial arrhythmias was reached by a significantly
greater percent of patients in the RFA group (57% vs. 4%, respectively; p = 0.004). Rates of
postoperative complications and stroke were similar between groups.

Von Oppell et al (11) randomly assigned 49 patients with AF of greater than 6 months
who were scheduled for mitral valve surgery to a modified RF maze procedure versus
valve surgery alone. At 12 months of follow-up, more patients in the maze group
remained in sinus rhythm (75% vs. 39%, respectively; p = 0.03). There was also a significant
decrease in amiodarone use for the maze group and no difference in the use of
warfarin.

Liu et al (12) compared mitral valve surgery plus a modified maze procedure with mitral
valve surgery alone followed by RF catheter ablation 6 months later in 99 patients with
rheumatic heart disease. After a mean follow-up of 15 to 20 months, patients in the maze
group had a higher rate of freedom from atrial arrhythmias compared with the RFA
group (82% vs. 55.2%, respectively; p < 0.001). Repeat procedures were required for 15/50
patients in the RFA group. Percutaneous catheter ablation was performed in 6/49
patients in the maze group for recurrent arrhythmias.

Van Breugel et al (13) 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 versus 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 to the maze group.

Nonrandomized Comparative Studies

Saint et al attempted to quantify the incremental risk conferred by adding a Cox-Maze
IV procedure to open mitral 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). (14) 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 Cox-Maze
IV procedure addition 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). 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 can
been added on to mitral 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, a study of long-term outcomes after 127 Cox-Maze cut-and-sew procedures in conjunction with mitral valve replacement was identified. (15) Patient disposition was well-documented in the analysis. Thirty percent of patients experienced late AF recurrence at a mean of 44±27 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 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. (16-18)

Section Summary

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 Atrial Fibrillation

The evidence related to the use of maze and related procedures as stand-alone treatments for atrial fibrillation (AF) includes evaluations of open surgical ablation, minimally invasive surgical ablation, and “hybrid” approaches.

Surgical Ablation as a Stand-Alone Treatment

One RCT has been completed that compares stand-alone surgical ablation versus percutaneous ablation. (19) The FAST 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 group also had surgical 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 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 patients compared with 36.5% (23/63) of the catheter ablation patients (p=0.002). Freedom from AF, on or off medications, was achieved by 78.7% (48/61) in the surgical group compared with 42.9% (27/63) in 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 the catheter ablation group, 6.3% (4/63) of patients had a groin hematoma, which was considered a minor complication.

Nonrandomized Comparative Studies

There are several observational studies that include a matched comparison group of patients who received alternate treatments. These case series with matched control
groups offer somewhat stronger evidence for comparative efficacy than do single-arm case series.

Stulak et al (20) compared 97 patients who underwent an isolated cut-and-sew Cox-Maze procedure with 194 patients who underwent catheter ablation for AF. Cox-Maze patients were matched according to age, sex, and AF type on a 1:2 basis with patients undergoing catheter ablation. At last follow-up, 82% of patients who underwent the Cox-Maze were free of AF off all meds compared with 55% of patients who underwent catheter ablation (p<0.001). By life table analysis, 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 (21) performed a retrospective matched comparison of 83 patients who underwent minimally invasive surgical ablation with 83 patients who underwent catheter ablation. All patients had long-standing persistent AF, were treated between 2006 and 2009, and followed up ranging from 1 to 3.6 years. At last follow-up, 74.7% of patients who underwent surgical ablation were free of AF compared with 59.0% of the patients treated with catheter ablation (p<0.05). Freedom from AF off all drugs was 61.4% in the surgical group compared with 44.6% in the catheter ablation group (p<0.05).

Single-arm Studies

Numerous single-arm case series report high success rates following one of these surgical procedures (22-30); however, these case series offer limited evidence regarding the efficacy of the procedure. 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.

Minimally Invasive Surgical Ablation as a Stand-Alone Treatment

A systematic review of 28 single-arm studies reporting on 1051 patients who received minimally invasive surgical treatment for AF was published in 2012 by La Meir et al. (31) This review noted substantial differences in patient population, 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 paroxysmal AF compared with persistent and permanent. 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.

An earlier, similar systematic review of 23 case series using minimally invasive surgical treatment for AF was published in 2011 by Krul et al. (32) Surgical techniques varied considerably among the included studies. At 1-year follow-up, the combined estimate for single-procedure success rates off all antiarrhythmic drugs was 69% (95% CI: 58% to 78%), and 79% (95% CI: 71% to 85%) success including patients still taking antiarrhythmic drugs. Mortality occurred in 0.4% of patients, and complications were reported in 12.8% of patients.

Since publication of the Krul et al and La Meir et al systematic reviews, De Maat et al 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. (33) Patients were treated by 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 patients (17%) had previous transcatheter ablation performed. The percentage of the 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 requirements for stentomy or mini-thoracotomy due to complications, 2 cases of late pericardial tamponade, and 1 pericardial effusion requiring video-assisted thoracoscopic surgery, and 1 stroke.

Massimiano et al reported outcomes for 292 consecutive patients who underwent minimally invasive surgery for mitral valve surgery (n=177), surgical ablation for AF (n=81), or both (n=34) at a single institution. 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.

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 (35) reported on 40 patients who had failed catheter ablation, with a mean of 2.3 prior ablations per patient. Maintenance of sinus rhythm at 6, 12, and 24 months was 76% (29/38), 89% (23/26), and 93% (13/14) respectively. Castella et al (36) 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.

Hybrid procedures as a stand-alone treatment. 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. The study with a comparison group enrolled 35 patients who underwent a hybrid procedure and 28 patients who underwent a standard percutaneous procedure. Approximately two-thirds of the patients (42/63) 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 did not reach statistical significance (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). 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.

Other single-arm case series have been published that include populations of 19 to 101 patients (38-45). 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

The evidence on the role of Maze and related procedures as stand-alone procedures consists of 1 RCT (FAST study) and many case series, some with matched control groups. The RCT reports higher success at maintaining sinus rhythm at 1 year of follow-up with thoracoscopic ablation, but also reports higher adverse event rates compared with
catheter ablation. This evidence does not clearly 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 in maintaining sinus rhythm compared with catheter ablation. The single-arm case series corroborate 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 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, these series are small and do not provide complete information on comparative efficacy or adverse events.

Summary

Surgical approaches to treating atrial fibrillation (AF) function by interrupting abnormal electrical activity in the atria. This may be accomplished in an open surgical procedure, the Cox-Maze III procedure, either in isolation or, more frequently, in conjunction with other cardiac 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.

Several small randomized controlled trials (RCTs) confirm 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. Therefore, surgical treatment of AF, by the modified maze or related procedures, may be considered medically necessary for patients with AF undergoing open heart surgery for other indications.

As a stand-alone procedure to treat AF, 1 RCT and many case series of minimally invasive surgical approaches have been published. The RCT reports higher success at maintaining sinus rhythm at 1 year of follow-up with thoracoscopic ablation, but also reports 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. However, at the present time, it is not possible to define a subgroup of patients who will benefit more from thoracoscopic ablation compared with percutaneous ablation; therefore, thoracoscopic AF ablation is considered investigational as a stand-alone procedure.

Hybrid ablation, which combines both thoracoscopic and percutaneous approaches, is another option for AF ablation. There is limited evidence on this technique, consisting of only case series. This evidence is insufficient to determine the comparative efficacy and safety of hybrid ablation compared with alternatives. Therefore, hybrid AF ablation is considered investigational.
Ongoing Clinical Trials
A search of online database ClinicalTrials.gov using the keywords “atrial fibrillation,” “ablation” and “surgery” identified the following ongoing RCTs evaluating surgical approaches to treating AF:

- NCT01298986 – Atrial Fibrillation Ablation - The Hybrid Approach Versus Traditional Management. This is an RCT that randomizes 152 patients to hybrid ablation or standard percutaneous ablation. The primary outcome measure is maintenance of sinus rhythm at 2 to 3 years following the procedure. The estimated completion date is January 2014.

- NCT01442181 – Minimally Invasive Surgical Treatment Versus Medical Management for Stroke Patients with Atrial Fibrillation. This is a randomized, crossover trial of 30 patients with AF and stroke comparing medical therapy with surgical ablation. The primary outcome measure is quality of life at 6 months. The estimated completion date is November 2014.

- NCT01582828 – Serial Hybrid Atrial Fibrillation Ablation. This is an RCT that will randomize 162 patients to thoracoscopic surgical ablation or hybrid ablation. The primary outcome measure is freedom from AF. The estimated completion date is December 2014.

- NCT00703157 – Surgical or Catheter Ablation of Lone Atrial Fibrillation (AF) Patients (SALAF). This is an RCT that randomizes 80 patients to percutaneous catheter ablation or thoracoscopic surgical ablation for AF. The primary outcome measure is burden of AF. The estimated completion date is December 2012.

- NCT01319747 – Video-Assisted Thoracoscopic Pulmonary Vein Isolation Versus Percutaneous Catheter Ablation in Atrial Fibrillation Trial. This RCT randomizes 160 patients to thoracoscopic surgical ablation or percutaneous catheter ablation. The primary outcome measure is recurrence of AF. The estimated completion date was February 2013, but no results have been posted.

- NCT02047279 – Ablation and Left Atrium Reduction During Mitral Valve Surgery for Atrial Fibrillation (ALARM-vs.-AF). This a randomized, single-blinded trial to compare maze performed with RFA to maze plus left atrial reduction for the treatment of AF during mitral valve surgery. Enrollment is planned for 100 subjects; the estimated study completion date is February 2015.

- NCT01891825 – Persistent Atrial Fibrillation Ablation Trial (PAAT). This is a randomized, open label trial to compare minimally-invasive thoracoscopic surgical with percutaneous ablation for AF. Enrollment is planned for 50 subjects; the estimated study completion date is September 2015.

- NCT01649544 – Comparison of Treatment of Atrial Fibrillation (AF) Between Surgical Ultrasonic Technology or Drug Therapy for Patients With AF Requiring Mitral Valve Surgery (EPICAF). This is a randomized, open-label trial comparing an ultrasonic cardiac ablation system with medical management for patients with AF who undergo mitral valve surgery. Enrollment is planned for 110 subjects; the estimated study completion date is May 2015.

Practice Guidelines and Position Statements
In 2014, the American Heart Association, American College of Cardiologists, and the Heart Rhythm Society (HRS) issued guidelines on the management of patients with AF.(46) The guideline provides the following recommendations related to the use of surgical ablation to maintain sinus rhythm:
• Class IIa recommendations: An AF surgical ablation procedure is reasonable for selected patients with AF undergoing cardiac surgery for other indications. (Level of Evidence: C)

• Class IIb recommendations: A stand-alone AF surgical ablation procedure may be reasonable for selected patients with highly symptomatic AF not well managed with other approaches. (Level of Evidence: B)

A 2012 expert consensus statement was developed by HRS, the European Heart Rhythm Association, and the European Cardiac Arrhythmia Society. The document was also endorsed by the American College of Cardiology, the American Heart Association, the Asia Pacific Heart Rhythm Society, and the Society of Thoracic Surgeons. (47)

The following recommendations were made regarding concomitant surgical ablation in patients undergoing cardiac surgery for other purposes and who have symptomatic AF:

• Paroxysmal: Surgical ablation is reasonable for patients undergoing surgery for other indications (IIa recommendations, level of evidence C)

• Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications (IIa recommendations, level of evidence C)

• Longstanding Persistent: Surgical ablation is reasonable for patients undergoing surgery for other indications (IIa recommendation, level of evidence C)

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:

• Paroxysmal: Stand-alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (IIb recommendation, level of evidence C)

• Paroxysmal: Stand-alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (IIb recommendation, level of evidence C)

• Persistent: Stand-alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (IIb recommendation, level of evidence C)

• Persistent: Stand-alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (IIb recommendation, level of evidence C)

• Longstanding Persistent: Stand-alone surgical ablation may be considered for patients who have not failed catheter ablation but prefer a surgical approach (IIb recommendation, level of evidence C)

• Longstanding Persistent: Stand-alone surgical ablation may be considered for patients who have failed one or more attempts at catheter ablation (IIb recommendation, level of evidence C)

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: Stand-alone surgical ablation is not recommended (III recommendation, level of evidence C)
• Persistent: Stand-alone surgical ablation is not recommended (III recommendation, level of evidence C)
• Longstanding Persistent: Stand-alone surgical ablation is not recommended (III recommendation, level of evidence C)

The Canadian Cardiovascular Society published guidelines in 2010 on surgical therapy for AF. (48) 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:

• Surgical ablation should be undertaken in association with valve surgery and/or CABG in patients with AF when there is a strong desire to maintain sinus, the likelihood of success is high, and the additional risk is low.
• Patients with asymptomatic lone AF, in whom AF is not expected to affect cardiac outcome, should not undergo surgical ablation.
• Closure of the left atrial appendage should be undertaken as part of surgical ablation associated with valve surgery and/or CABG.
• Oral anticoagulant therapy should be continued following surgical ablation in patients with a CHADS2 score of 2 or greater.

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

The Canadian Cardiovascular Society published a 2012 focused update to their comprehensive 2010 guidelines on AF. (49) The 2012 focused guidelines discuss the use of anticoagulants in the treatment of AF.

The HRS published guidelines in 2007 on catheter ablation and surgical ablation of AF. (50) The following recommendations were made regarding indications for surgical treatment of AF:

• Symptomatic AF patients undergoing other cardiac surgical procedures,
• Selected asymptomatic AF patients undergoing cardiac surgery in whom the ablation can be performed with minimal risk,
• Stand-alone AF surgery should be considered for symptomatic AF patients who prefer a surgical approach, have failed one or more attempts at catheter ablation, or are not candidates for catheter ablation.

U.S. Preventive Services Task Force Recommendations
Maze and related procedures are not preventive services.

References


50. Calkins H, Brugada J, Packer DL et al. HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation developed in partnership with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS); in collaboration with the American College of Cardiology (ACC), American Heart
Association (AHA), and the Society of Thoracic Surgeons (STS). Endorsed and approved by the governing bodies of the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. Europace 2007; 9(6):335-79.


**Documentation Required for Clinical Review**

- History and physical and/or consultation notes including:
  - Procedure performed
  - Previous treatment(s) and response to treatment(s) for atrial fibrillation or flutter
- EKG
- Cardiac operative report

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT®</td>
<td>33254</td>
<td>Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure)</td>
</tr>
<tr>
<td></td>
<td>33255</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass</td>
</tr>
<tr>
<td></td>
<td>33256</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass</td>
</tr>
<tr>
<td></td>
<td>33257</td>
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<td>Procedure Code</td>
<td>Description</td>
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<tr>
<td>33258</td>
<td>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)</td>
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<tr>
<td>37.33</td>
<td>Excision or destruction of other lesion or tissue of heart, open approach</td>
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<tr>
<td>37.34</td>
<td>Excision or destruction of other lesion or tissue of heart, endovascular approach</td>
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<tr>
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<td>02560ZZ</td>
<td>Destruction of Right Atrium, Open Approach</td>
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<tr>
<td>02563ZZ</td>
<td>Destruction of Right Atrium, Percutaneous Approach</td>
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<td>02564ZZ</td>
<td>Destruction of Right Atrium, Percutaneous Endoscopic Approach</td>
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<td>02570ZZ</td>
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<td>025K0ZZ</td>
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Medical Policy

For dates of service on or after 10/01/2015

<table>
<thead>
<tr>
<th>ICD-9 Diagnosis</th>
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<tbody>
<tr>
<td>ICD-10 Diagnosis</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
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<th>Reason</th>
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<tr>
<td>12/7/2006</td>
<td>BCBSA Medical Policy adoption</td>
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<tr>
<td>7/2/2010</td>
<td>Policy Revision with position change</td>
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<td>7/1/2011</td>
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<td>11/26/2014</td>
<td>Policy title change from Maze Procedure Policy revision without position change</td>
<td>Medical Policy Committee</td>
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</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is
not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements**

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.