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

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for the Maze procedure when it is determined to be medically necessary because the criteria shown below are met.

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

When Policy Topic is not covered
Minimally invasive, off-pump maze procedures, including those done via mini-thoracotomy, are considered investigational for treatment of drug-resistant 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.

Considerations
Given the availability of less-invasive alternative approaches in the treatment of 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 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.

Description of Procedure or Service
There are a variety of surgical approaches to treat atrial fibrillation 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 and are done via the thoracoscopic or mediastinal approach.

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 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 a majority of patients, but long-term recurrences are common and increase over time. Surgical ablation, performed either by open surgical techniques or thoracoscopically, 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 atrial fibrillation. 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 gold 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; 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.

**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 thoracotomy 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 cryoablation 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 utilizes 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, since 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.

The U.S. Food and Drug Administration (FDA) cleared for marketing (January 2002) the Medtronic Cardioblate System, which uses RF energy to ablate cardiac tissue. The Cardima SAS (Surgical Ablation System) used during mini-thoracotomy received 510(k) marketing clearance by the FDA in 2003 as substantially equivalent to the Medtronic device for performing ablation of cardiac tissue with RF energy. Another bipolar RF device cleared for use in surgical procedures is manufactured by Atricure, Inc.

Rationale

This policy was initially developed in 1995 based on a 1994 TEC Assessment, (1) and has been updated periodically with literature review. The most recent literature update includes the period of January 2012 through May 2013.

Traditional MAZE vs. “modified MAZE” procedures

Khargi and colleagues analyzed 48 studies comprising 3,832 patients who received surgical treatment of atrial fibrillation 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 ablative patterns and their effects on atrial tissue. Topkara and colleagues reported comparable postoperative rhythm success in use of either radiofrequency (RF, 121 patients) or microwave (85 patients) energy in surgical ablation of atrial fibrillation. (3)

Several observational studies compared the Cox-Maze III procedure with other procedures (radiofrequency [RF] ablation, 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 RF ablation 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 one surgery over the other, these factors are not accounted for in the analysis.

In a second matched analysis, 56 patients who underwent a CMIV RF ablation 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 atrial fibrillation (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).

Conclusions: 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,
etc.). 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. 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 atrial fibrillation (AF) who receive mitral valve surgery. 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. 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. 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 one 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 one year was documented in 60.2% (56/93) of patients in the surgery plus ablation group compared to 35.5% (27/76) patients in the surgery-alone group. Adverse events were similar in both groups at 30 days and at one-year follow-up. Secondary clinical outcomes, included mortality and NYHA functional Class, did not differ between groups at one year.

The SAFIR study 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 RF ablation 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 radiofrequency-ablation group (57% vs. 4%, respectively; p=0.004). Rates of postoperative complications and stroke were similar between groups.

Von Oppell et al. 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. compared mitral valve surgery plus a modified maze procedure to 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 15-20 months, patients in the maze group had a higher rate of freedom from atrial arrhythmias compared to the RF ablation group (82% vs. 55.2%, respectively; p<0.001). Repeat procedures were required for 15/50 patients in the radiofrequency-ablation group. Percutaneous catheter ablation was performed in 6/49 patients in the maze group for recurrent arrhythmias.

Van Breugel et al. 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 coronary artery
bypass graft (CABG) surgery were randomly assigned to surgery alone versus surgery plus a modified maze procedure. The primary endpoint was QOL, as measured by the Short Form medical outcomes (SF)-36, the EuroQoL (eQ)-5D, and the multidimensional fatigue inventory (MFI-20). 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.

A study of long-term outcomes after 127 Cox-Maze cut and sew procedures in conjunction with mitral valve replacement was identified. (12) 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.

Conclusions. Surgical treatment of atrial fibrillation 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 atrial fibrillation 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

One RCT has been completed that compares stand-alone surgical ablation versus percutaneous ablation. (13) The FAST trial enrolled 124 patients, from 2 clinical centers in Europe, who had symptomatic AF for at least one 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 one year, freedom from AF off all antiarrhythmic drugs was achieved by 65.6% (40/61) of the surgical patients compared to 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 to 42.9% (27/63) in the catheter ablation group (p=0.0001). Serious adverse events were more common in the surgical group, occurring in 23.0% (14/61) of patients compared to 3.2% (2/63) in the catheter ablation group (p=0.001). In both groups, there was one 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 one 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.

Non-randomized comparative studies. There are several observational studies that include a matched comparison group of patients who receive 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. (14) (compared 97 patients who underwent an isolated cut-and-sew Cox-Maze procedure with 194 patients who underwent catheter ablation for atrial fibrillation. Cox-Maze patients were matched according to age, gender, 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 to 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 to 28% following catheter ablation (p<0.001).
Wang et al. (15) 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 to 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 to 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 (16-24); 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.

A systematic review of 28 single-arm studies reporting on 1,051 patients who received minimally invasive surgical treatment for AF was published in 2012 by La Meir et al. (25) This review noted substantial differences in patient population, surgical techniques, and definitions of outcome across studies. At one year, the range of success, as defined by freedom from AF and off all medications, was 51-86%. Outcomes for RF ablation 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 to persistent and permanent. The early complication rate ranged from 0-39%, 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. (26). Surgical techniques varied considerably among the included studies. At one-year of follow-up, the combined estimate for single-procedure success rates off all antiarrhythmic drugs was 69% (95% confidence interval [CI]: 58-78%), and 79% (95% CI: 71-85%) success including patients still taking antiarrhythmic drugs. Mortality occurred in 0.4% of patients, and complications were reported in 12.8% of patients.

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, since 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. (27) 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. (28) 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 one-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.

Conclusions. The evidence on this question consists of one RCT (FAST study) and many case series, some with a matched control group. The RCT reports higher success at maintaining sinus rhythm at one year of follow-up with thoracoscopic ablation, but also reports higher adverse event rates compared to catheter ablation. This evidence does not clearly support the superiority of one 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 to 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.

Hybrid procedures. The evidence on hybrid ablation consists of a number of case series, one of which included a matched comparison group of patients undergoing percutaneous ablation. The study with a comparison group enrolled 35 patients who underwent a hybrid procedure and 28 patients who underwent a standard percutaneous procedure. (29) Approximately two-thirds of the patients (42/63) had undergone a previous percutaneous ablation procedure. At one year, there were more patients in the hybrid group who were free of atrial fibrillation, 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 one 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 19-101 patients. (30-37). These series consistently report high success rates in maintaining sinus rhythm at one-year follow-up, ranging from 71-91%. 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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from one physician specialty society and 3 academic medical centers (4 reviewers) for review of this policy in 2010. There was unanimous support for the policy statement regarding on-bypass maze procedure. There was mixed support for the policy statement regarding off-bypass (off-pump) maze procedure; some of those providing input indicated that, in selected patients, off-pump procedures may be useful. Several of those providing input also commented on the limited long-term data for off-pump procedures.

In response to requests, input was received from 2 physician specialty society and 6 academic medical centers (4 reviewers) for review of this policy in 2013. There was consensus agreement on the medically necessary statements. For subgroups of populations, such as those who have failed percutaneous catheter ablation, there was mixed support without a clear consensus. There was also mixed support for the use of hybrid ablation.

Summary

Several small RCTs confirm the benefit of a modified maze procedure for patients with atrial fibrillation (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, one RCT and many case series of minimally invasive surgical approaches have been published. The RCT reports higher success at maintaining sinus rhythm at one year of follow-up with thoracoscopic ablation, but also reports higher adverse event rates compared to 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 to catheter
ablation. However, this evidence does not permit definitive conclusions as to whether one 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 to 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 to alternatives. Therefore, hybrid AF ablation is considered investigational.

Ongoing clinical trials

A search of online site clinicaltrials.gov using the keywords atrial fibrillation, ablation and surgery returned 63 results. A summary of some of the relevant ongoing RCTs is given below.

- **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 2-3 years following the procedure. Estimated completion date is January 2014.
- **NCT01442182.** Minimally invasive surgical treatment versus medical management for stroke patients with atrial fibrillation. This is a randomized, cross-over trial of 30 patients with atrial fibrillation and stroke comparing medical therapy with surgical ablation. Primary outcome measure is quality of life at 6 months. Estimated completion date is April 2013.
- **NCT00662701.** Ablation or surgery for atrial fibrillation treatment. This is an RCT that randomizes 120 patients to percutaneous catheter ablation or surgical ablation. The primary outcome measures are freedom from atrial fibrillation and adverse events. Estimated completion date not provided.
- **NCT01582828.** Serial hybrid atrial fibrillation ablation. This is an RCT that randomized 162 patients to thoracoscopic surgical ablation or hybrid ablation. The primary outcome measure is freedom from atrial fibrillation. Estimated completion date is December 2014.
- **NCT00703157.** Surgical or catheter ablation of lone atrial fibrillation (AF) patients. This is an RCT that randomizes 80 patients to percutaneous catheter ablation or thoracoscopic surgical ablation. Primary outcome measure is burden of atrial fibrillation. Estimated completion date is December 2012.
- **NCT01336075.** Atrial fibrillation: Ablation or surgical treatment II: FAST II. This is an RCT that randomizes 180 patients to percutaneous ablation or thoracoscopic surgical ablation. The primary outcome measures are freedom from atrial fibrillation and quality of life. Estimated completion date is December 2013.
- **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 atrial fibrillation. Estimated completion date is February 2013.

Practice Guidelines and Position Statements

An expert consensus statement was developed by the Heart Rhythm Society (HRS), the European Heart Rhythm Association (EHRA), and the European Cardiac Arrhythmia Society (ECAS). The document was also endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). (38)
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 atrial fibrillation. (39) These guidelines state that there is a high rate of freedom from AF following surgical treatment, 70-85% at one 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 Heart Rhythm Society published guidelines in 2007 on catheter ablation and surgical ablation of atrial fibrillation. (40) The following recommendations were made regarding indications for surgical treatment of atrial fibrillation:

- 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.

References


40. 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.

**Billing Coding/Physician Documentation Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33254</td>
<td>Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)</td>
</tr>
<tr>
<td>33255</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33256</td>
<td>Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>33257</td>
<td>Operative Tissue Ablation and Reconstruction of Atria at the Time of Other Cardiac Procedure(s), Limited (List Sep)</td>
</tr>
<tr>
<td>33258</td>
<td>Operative Tissue Ablation and Reconstruction of Atria at Time of Other Procedure, Extensive, wo Bypass (List Sep)</td>
</tr>
<tr>
<td>33259</td>
<td>Operative Tissue Ablation and Reconstruction of Atria at Time of Other Procedure, Extensive, w Bypass (List Sep)</td>
</tr>
<tr>
<td>33265</td>
<td>Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33266</td>
<td>Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass</td>
</tr>
<tr>
<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
</tr>
</tbody>
</table>

The Hybrid ablation technique would be billed using the unlisted code for cardiac surgery (33999).

**Additional Policy Key Words**

- Maze procedure
- Modified maze procedure

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/08</td>
<td>New policy.</td>
</tr>
<tr>
<td>1/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>1/1/10</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>1/1/11</td>
<td>No change in policy statements. Title revised, previously titled Maze Procedures.</td>
</tr>
<tr>
<td>1/1/12</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>6/1/12</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>6/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>6/1/14</td>
<td>Investigational statement added for hybrid ablation. Updated Description to include different techniques.</td>
</tr>
</tbody>
</table>
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.