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Medical Policy Manual

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

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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.

First-line treatment for AF usually includes medications to maintain sinus rhythm and/or control ventricular rate. Percutaneous endocardial catheter ablation (e.g., transcatheter pulmonary vein isolation) is an accepted second-line treatment for patients who are not adequately controlled with medications. While catheter ablation is successful in maintaining sinus rhythm for a majority of patients, long-term recurrences are common and increase over time. Epicardial surgical ablation may also be performed, either by open surgical techniques or via thoracoscopy.

There are a variety of surgical approaches to treat AF that work by interrupting abnormal electrical activity in the atria. The classic Cox maze III procedure is a complex open surgical procedure performed on a non-beating heart during cardiopulmonary bypass. This technique involves the creation of a “maze” of sequential atriotomy incisions (lesion set) that interrupt the aberrant atrial conduction pathways in the heart for patients with atrial fibrillation. The procedure is also intended to preserve atrial function (pumping). 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 about 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.

Simplification of the maze procedure has evolved with the use of ablation tools such as microwave, cryotherapy, high-intensity focused ultrasound, and radiofrequency (RF) energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure. This ablation technique may be referred to as the Cox maze IV procedure.

In addition, less invasive, off-pump procedures performed via the thoracoscopic or mediastinal approach are being developed and evaluated. 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. 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 towards 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 lesions sets include linear ablations of the left and/or right atrium, and ablation of ganglionic plexi. Some surgeons perform left-atrial reduction in cases of left-atrial enlargement. The type of energy used for ablation also varies; radiofrequency energy is most commonly applied.

Also being investigated is a “hybrid” technique in which epicardial ablation via the thoracoscopic approach and endocardial ablation via the percutaneous approach are performed in the same patient. The thoracoscopic epicardial ablation is performed first, followed by a percutaneous electrophysiologic study (EPS). Endocardial ablation is then performed as directed by the results of the EPS. The hybrid procedure is most commonly performed in a single operative session, but the EPS and endocardial ablation may be performed on a separate day. The rationale for performing a hybrid procedure is that the 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.

Minimally invasive procedures may be referred to as “mini-maze” procedures. However, the 2012 consensus statement from the Heart Rhythm Society recommends that the term “maze” procedure only be used when referring to “the biatrial lesion set of the Cox maze operation. Less extensive lesions sets should not be referred to as a “Maze” procedure, but rather as a surgical AF ablation procedure. In general, surgical ablation procedures for AF can be grouped into three different groups: (1) a full Cox-Maze procedure, (2) PVI alone, and (3) PVI combined with left atrial lesion sets.”[1]

Regulatory Status

The U.S. Food and Drug Administration (FDA) cleared for marketing (January 2002) the Medtronic Cardioblate System, which uses radiofrequency 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, the Isolator Synergy Dual Electrode Clamp (AtriCure®, Inc.), has also received FDA 510k clearance.

MEDICAL POLICY CRITERIA

I. The maze procedure performed on a non-beating heart during cardiopulmonary bypass is considered **medically necessary** when one of the following criteria (I.A. or B.) are met:

A. When performed for atrial fibrillation or flutter *with* concomitant cardiac surgery

B. When performed alone, *without* concomitant cardiac surgery, and both of the following criteria (I.B.1 and 2) are met:

1. The patient has symptomatic atrial fibrillation or flutter

   Symptomatic is defined as impaired ability to complete activities of daily living or essential job related activities due to atrial fibrillation despite treatment to control rate. This also includes patients who have required repeated electrical cardioversion or other nonpharmacologic interventions (e.g., transcatheter endocardial ablation or pulmonary vein isolation).

2. Antiarrhythmic medications have failed to control symptoms or could not be tolerated by the patient

II. Off-pump maze procedures, for all indications, including but not limited to treatment of symptomatic, drug-resistant atrial fibrillation or flutter, are considered **investigational**, including but not limited to the following:

A. Minimally invasive maze or mini-maze procedures, including but not limited to those performed via mini-thoracotomy

B. Hybrid ablation, defined as combined percutaneous endocardial ablation and thoracoscopic epicardial ablation

SCIENTIFIC EVIDENCE

Recommendations for outcome assessment in trials of atrial fibrillation (AF) treatment were included in the American College of Cardiology/American Heart Association practice guidelines for the treatment of atrial fibrillation.[2] These guidelines pointed out that, ideally, controlled clinical trials would report a range of outcomes (including quality of life) and complications in homogeneous patient groups and compared with treatment alternatives.

The principle outcomes for the treatment of AF are:
- Mortality and morbidity (e.g., cardiovascular mortality, stroke, and congestive heart failure)
- Quality of life (e.g., symptoms such as reduced exercise tolerance or hypotension that significantly reduce the patient's daily functional levels)
- Recurrence of AF

Assessment of the efficacy of minimally invasive techniques performed on the beating heart for treatment of drug-refractory AF requires comparison against the existing standard of care of conventional on-pump Cox maze procedures or percutaneous catheter ablation.

Literature Appraisal

Cox Maze Procedure Performed on the Non-Beating Heart ("On Pump")

Systematic Reviews

- Mitral valve surgery with versus without simultaneous maze procedure

  Reston and colleagues reviewed 4 randomized controlled trials 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 who receive mitral valve surgery. [3] They concluded that the studies supported a reduction in stroke rates and a small increased risk in need for pacemakers among patients receiving simultaneous maze procedures. Alternative energy sources, such as radiofrequency (RF), may reduce the risk of postoperative bleeding associated with classic maze incisions.

- Cox maze III by various techniques

  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.[4] The authors reported that they could not identify any significant differences in the postoperative sinus rhythm conversion rates between the classical approach and alternative sources of energy.

Randomized Controlled Trials (RCTs)

- Since publication of the systematic reviews, several randomized controlled trials (RCTs) have confirmed the benefit of the Cox maze procedure in reducing the future incidence of AF when performed as an add-on for patients undergoing open mitral valve surgery.[5-9]
- No RCTs were found for stand-alone on-pump surgical procedures versus catheter ablation or medical therapy.

Nonrandomized Comparative Studies

- Mitral valve surgery with versus without simultaneous maze procedure

  One retrospective controlled trial was identified that compared 66 patients undergoing mitral valve surgery alone with 37 patients undergoing mitral valve surgery plus the maze III procedure for patients with mitral valve pathology and persistent AF.[10] Selection for either procedure was not described. Clinical characteristics did not differ between groups on most preoperative measures reported, however, the maze group had a higher EuroScore cardiac operative risk (17.4 vs. 12.0, p=0.09) while the surgery-alone group had a higher percent of patients receiving anticoagulation (65.2% vs. 43.2%, p=0.03). Five-year follow-up revealed superior outcomes for the surgery plus maze group. An estimated 91% of patients in the maze group remained in sinus rhythm compared to 33% in the surgery alone group (p<0.001). Overall survival was significantly improved for the maze group (89% vs. 60%, p=0.008). After multivariate adjustment for preoperative variables in a Cox regression analysis, addition of the maze procedure remained an independent predictor of survival (p=0.019).

- Comparison of various Cox maze techniques

  Several observational studies compared the Cox maze III procedure with other procedures [radiofrequency ablation (RFA), pulmonary vein isolation (PVI)] performed at single institutions, with procedure selection guided by the surgeon. The two studies summarized below attempted to address the selection bias inherent in these studies by matching. This evidence from matched case series, though limited, does not indicate that there are large differences in efficacy among the different approaches.

  - In the first, from the Washington University School of Medicine, where 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 where radiofrequency ablation replaced the incisions of the classic procedure [Cox maze IV or CMIV]) were matched on their propensity for treatment assignment (a logistic regression where the outcome is treatment assignment and the predictors are covariates that might influence which procedure is chosen by the surgeon). [11] Fifty-eight matched pairs were studied. At 1 year, survival was 94% and 89% (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 measureable 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 radiofrequency ablation procedure at the Mayo Clinic were matched (historical controls) to 56 patients who underwent the CMIII procedure. [12] Matching factors were age, gender, 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).
  - Other nonrandomized case series reported similar outcomes when various energy sources for on-pump CMIV were compared. For example, Kim et al compared cryoablation (n=244) with microwave ablation (n=96).[13] These CMIV procedures were all performed simultaneously with mitral valvuloplasty. The only significant between-group difference was the longer aortic clamping time in the microwave group (n=0.005).
  - Similarly, Topkara et al. reported comparable postoperative rhythm success in use of either radiofrequency (RF, 121 patients) or microwave (85 patients) energy in surgical ablation of atrial fibrillation. [14]

Other Nonrandomized Studies

The study with the longest follow-up was a case series on 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 atrial fibrillation (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.

<u>Minimally Invasive Epicardial Ablation Performed on the Beating Heart ("Off-Pump")</u>

Technology Assessment

A 2013 Comparative Effectiveness Review performed by Duke Evidence-based Practice Center for the Agency for Healthcare Research and Quality (AHRQ) reported a significantly higher procedure-related adverse event rate for minimally invasive epicardial ablation than for catheter ablation (23% vs. 3.2%,

respectively; p= 0.001).[16] This was based on the single RCT[17] that compared these 2 techniques; this RCT is summarized in detail below. The Report concluded did not make any specific conclusions for minimally invasive maze procedures, but made a general conclusion that there is insufficient data on the effect of pulmonary vein isolation or surgical maze procedures to determine their effect on rhythm control and final health outcomes.

Systematic Reviews

- A systematic review of 23 case series using minimally invasive surgical treatment for AF was published in 2011 by Krul et al.[18] Surgical techniques varied considerably among the included studies. At one-year follow-up, the combined estimate for single-procedure success rates were 69% (95% CI 58-78%) in patients who were off all antiarrhythmic drugs (AADs), and 79% (95% CI 71-85%) in patients still taking AADs. Mortality occurred in 0.4% of patients, and complications were reported in 12.8% of patients. The authors concluded that, while promising, these minimally invasive surgical techniques continue to evolve. Additional studies are needed to validate these first combined results. In addition, further study is needed to determine the value of additional left atrial ablation lines (ALAL) and ganglion plexus ablation.
- A 2013 systematic review of 28 single-arm studies reporting on 1051 patients who received minimally invasive surgical treatment for AF was published in 2013 by La Meir et al.[19] 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 bipolar RFA were superior to those using high focused ultrasound or microwave energy sources, which were described as suboptimal. Ganglionated plexi ablation and left atrial appendage removal did not appear to influence AF recurrence or postoperative thromboembolic events. The authors also noted that success was higher for the population of paroxysmal AF compared to persistent and permanent AF. 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. The authors concluded that, while satisfactory 1-year outcomes were achieved with bipolar RFA, the relatively high complication rate suggested the need for further refinement. Early outcomes using the hybrid approach appear promising, but require additional study.

Randomized Controlled Trials (RCTs)

A 2-center randomized controlled trial was found comparing surgical ablation (SA) via thoracoscopic epicardial pulmonary vein isolation using a bipolar radiofrequency clamp plus left atrial (LA) appendage removal (n=61) with percutaneous catheter ablation (CA) (n=63).[17] Most patients had undergone a prior unsuccessful CA. Sixty-seven percent of patients had paroxysmal AF and 33% had continuous persistent AF. Variations in technique were allowed between the two centers in the number and location of ablation lines and ablation of ganglionic plexi of the atrium. At 6 and 12 months follow-up, overall freedom from LA arrhythmia was significantly greater in the in the SA group with and without antiarrhythmia drugs. However, when the two centers were analyzed separately the between group difference was not significant. Procedure-related adverse events were significantly higher in the SA group compared with the CA group (23% and 3.2%, respectively p=0.001). The rate of other adverse events during the 12-month follow-up period did not differ significantly between the two groups. No significant effect of AF type was observed; however, the authors noted that the study may have been underpowered for this factor. Nor was the study powered adequately to study the effect of procedural differences between the two centers. The authors concluded that minimally invasive SA was superior to CA in achieving freedom from atrial arrhythmias at one year, but the adverse event rate was significantly higher in the SA group. Larger, longer-term randomized trials are needed to validate these findings, determine the durability of any beneficial treatment effects, and to determine which patients are most likely to benefit from these procedures.

Nonrandomized Studies

The remaining evidence for epicardial ablation on the beating heart is limited to numerous uncontrolled case series and retrospective reviews.[20-33] The approach used was thoracoscopic RF ablation in nearly all cases, although there was substantial variability in the specific ablation lines performed and in other technical aspects of the procedure. Freedom from recurrent AF was the primary outcome, with most reporting on this outcome at 12 months. Complications were variably reported in these studies; reported complications included bleeding requiring conversion to open surgery, stroke, acute heart failure, and prolonged intubation. The rate of these adverse events cannot be reliably estimated from the available data.

In addition, single-arm case series of minimally invasive epicardial ablation have reported on the population of patients who had failed catheter ablation.[34,35] These case series may 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.

The evidence from these case series and retrospective reviews does not permit conclusions due to the following methodological limitations:

- Lack of randomized treatment allocation to control for potential bias
- Lack of appropriate control groups for comparison of health outcomes between minimally invasive and conventional surgical techniques
- Small study populations limit the ability to rule out the role of chance as an explanation of study findings
- Short-term follow-up does not permit conclusions about the durability of treatment effects
- Lack of consistent reporting of adverse effects of treatment

Hybrid Ablation Procedures Performed on the Beating Heart ("Off-Pump")

The evidence on hybrid ablation is limited to a number of preliminary case series, one of which included a matched comparison group of patients undergoing percutaneous ablation. This nonrandomized study compared 35 patients who underwent the hybrid procedure with a matched group of 28 patients who underwent percutaneous ablation.[36] 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 AF, but this difference did not reach statistical significance (91.4% vs. 82.1%, p=0.07). 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. 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).

Other single-arm case series have been published that included populations of 19-101 patients.[37-44] These series consistently reported high success rates in maintaining sinus rhythm at one year follow-up, ranging from 71-91%. Some of these series reported individual adverse events, but reporting on adverse events was variable and not systematic in these case series, resulting in an inability to accurately estimate rates of adverse events. For the reasons noted above, this case series evidence does not permit conclusions on the effectiveness or the rate of adverse events and reoperations compared with stand-alone percutaneous endocardial or thoracoscopic epicardial ablation techniques.

Clinical Practice Guidelines and Position Statements

Current clinical practice guidelines are limited to the following opinion-based consensus statements:

Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society (HRS/EHRA/ECAS)

The 2012 updated consensus statement on catheter ablation and surgical ablation for AF from the Heart Rhythm Society[1] provided recommendations for which the level of evidence was ranked as Level C, defined as consensus opinion based on case series and/or clinical experience. The document was also endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS).

- Class I recommendations, defined as benefit markedly exceeds risks and AF ablation should be performed

  There were no Class I recommendations for surgical ablation for AF

- Class IIa recommendations, defined as benefit exceeds risks and AF ablation is reasonable

  Concomitant surgical ablation at the time of other cardiac surgery in patients with:

  - symptomatic paroxysmal, persistent, or long-standing persistent AF refractory to or intolerant of at least one Class 1 or 3 antiarrhythmic medication
  - symptomatic paroxysmal or persistent AF prior to initiation of antiarrhythmic drug therapy in patients

- Class IIb recommendations, defined as benefit greater or equal to the risks and AF ablation may be considered

  - Concomitant surgical ablation at the time of other cardiac surgery in patients with symptomatic long-standing persistent AF prior to initiation of antiarrhythmic drug therapy in patients undergoing surgery for other indications.
  - Stand-alone, minimally invasive ablation techniques

    "Currently the limitations of the energy delivery devices and the attempt to deploy them through minimal access incisions or ports place constraints on the location and number of ablation lesions that can be performed. The impact of these alternative lesion patterns and the less invasive surgical approaches on results requires further observational prospective analysis and randomized trials." This summary includes the following indications in patients with symptomatic paroxysmal, persistent, and longstanding persistent AF refractory to or intolerant of at least one Class 1 or 3 antiarrhythmic medication:

    - In patients who have not failed catheter ablation but prefer a surgical approach
    - In patients with paroxysmal AF who have failed one or more catheter ablation attempts

- Class III recommendations, defined as no proven benefit and is not recommended

  Stand-alone surgical ablation in all patients prior to initiation of antiarrhythmic drug therapy with a Class 1 or 3 antiarrhythmic agent.

American College of Cardiology Foundation/American Heart Association/European Society of Cardiology (ACCF/AHA/ESC)

The ACCF/AHA practice guideline[45] published in 2013 was a compilation of the 2006 ACC/AHA/ESC consensus-based practice guidelines for management of AF[2] and the 2011 joint ACCF/AHA/Heart Rhythm Society (HRS) focused update.[46] This compilation did not include an updated review of the published literature. The guidelines focused mainly on medication and cardioversion. Surgical treatments were briefly described but were not included in the recommendations.

Summary

Despite the variety of techniques used in studies of conventional Cox maze procedures performed in conjunction with other cardiac surgery while the patient is on cardiopulmonary bypass, the current evidence from randomized controlled trials is sufficient to confirm the benefit of the Cox maze procedure in reducing the future incidence of atrial fibrillation (AF). Therefore, these techniques may be medically necessary for selected symptomatic AF patients who did not achieve adequate AF control with antiarrhythmic medication or were unable to tolerate medication.

The current evidence is insufficient to determine the effectiveness, rate of adverse events, and reoperation rate of atrial fibrillation (AF) treatment using minimally invasive surgical techniques on the beating heart compared with standard catheter ablation techniques. In addition, there are no evidence-based clinical practice guidelines from US professional societies that recommend the use of minimally invasive techniques. Therefore, minimally invasive AF procedures, including those done via mini-thoracotomy or thoracoscopy, and hybrid procedures, are considered investigational.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure) [without concurrent procedure that requires median sternotomy or cardiopulmonary bypass.]
	33255	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass
	33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass
	33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified maze procedure) (List separately in addition to code for primary procedure)
	33258	Operative tissue ablation and reconstruction of atria, performed at the time of other

CODES	NUMBER	DESCRIPTION
		cardiac procedure(s), extensive (e.g., maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)
	33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)
	33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass
	33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass
	33999	Unlisted procedure, cardiac surgery
HCPCS	None	