I. POLICY

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.

Minimally invasive, off-pump maze procedures (i.e., modified maze procedures), including those done via mini-thoracotomy, are considered investigational for treatment of drug-resistant atrial fibrillation or flutter as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Cross-reference:
MP-2.067 Catheter Ablation for Cardiac Arrhythmias
MP-2.082 Catheter Ablation of the Pulmonary Veins as a Treatment of Atrial Fibrillation
MP-1.127 Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids [N] Indemnity
[N] PPO [N] SpecialCare
[N] HMO [N] POS
[N] SeniorBlue HMO [Y] FEP PPO*
[N] SeniorBlue PPO

*Refer to FEP Medical Policy Manual MP-7.01.14 Open and Thoracoscopic Approaches to Treat Atrial Fibrillation. The FEP Medical Policy manual can be found at: http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980

III. DESCRIPTION/BACKGROUND

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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 thorascopic 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 classic Cox maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt potential re-entrant circuits 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 atroventricular (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 energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure.

In addition, less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF 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. 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 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. Other types of energy sources such as cryoablation and high-intensity ultrasound have also been used. The U.S. Food and Drug Administration (FDA) cleared for marketing (January 2002) the Medtronic Cardioblate System, which uses radiofrequency (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.

IV. RATIONALE

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 (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% (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 RF ablation procedure at the 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).

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**

Several RCTs confirm the benefit of a modified Cox maze procedure in reducing the future incidence of AF when performed as an add-on for patients undergoing open mitral valve surgery. The SAFIR study (6) 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 radiofrequency-ablation 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. (7) 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. (8) 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. (9) 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-D, which showed a greater degree of worsening in the control group compared to the maze group.

Reston and Shuhaiber 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. (10) 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. Alternative energy sources, such as RF, may reduce the risk of postoperative bleeding associated with classic maze incisions.

A study of long-term outcomes after 127 Cox-maze cut and sew procedures in conjunction with mitral valve replacement was identified. (11) 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

There are no RCTs of stand-alone surgical procedures versus catheter ablation or medical therapy. Numerous case series report high success rates following one of these surgical
procedures (12-20), 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 23 case series using minimally invasive surgical treatment for AF was published in 2011 by Krul et al. (21). 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% 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.

Case series with matched control groups offer somewhat stronger evidence for comparative efficacy. Stulak et al. (22) 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 five years was estimated to be 87% following Cox-Maze compared to 28% following catheter ablation (p<0.001).

Wang et al. (23) 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 and were treated between 2006 and 2009, and followed ranged 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).

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 (24) 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. (25) 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 almost entirely of case series, some with a matched control group. The case series report high success rates following surgical treatment, but do not provide sufficient evidence to form conclusions on the comparative efficacy of surgical treatment of atrial fibrillation, nor do they provide sufficient evidence to accurately estimate the risk/benefit ratio of surgical treatment.

The case-series with a matched comparison group of patients undergoing catheter ablation report higher success rates following surgical treatment. However, these series are small and do not provide complete information on adverse events. Therefore it is not possible to compare the risk/benefit ratio of surgical approaches to the risk/benefit ratio of catheter ablation. Small case series that include patients who had previously failed catheter ablation also report relatively high success rates, suggesting that surgical treatment might be a reasonable option in patients who fail catheter ablation.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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. 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. 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 off-pump procedures may be useful in selected patients (such as those who cannot tolerate anticoagulation). Several of those providing input also commented on the limited long-term data for off-pump procedures.

Summary

Several small 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. One RCT that concentrated on QOL did not show a benefit for the maze procedure; however this patient population included CABG patients as well as valvular surgery patients. The available evidence is sufficient to conclude that this procedure is likely to improve outcomes by reducing symptoms and morbidity related to AF, reducing the need for antiarrhythmic medications, and potentially reducing the rate of thromboembolic events. 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, many case series of minimally invasive surgical approaches have been published, the most common approach being thoracoscopic epicardial RF ablation. These 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 conclusions on the effect of these procedures on health outcomes. The studies are small in size, retrospective, use different lesion sets for ablation, and have limited follow-up. The matched comparisons do not adequately control for selection bias between the treated populations, and the studies do not provide complete information on adverse events. Further controlled trials are needed to determine whether health outcomes are improved by surgical treatment of AF as a stand-alone procedure. Therefore, this treatment is considered investigational as a stand-alone procedure.

**Ongoing clinical trials**

The FAST II trial is an RCT of minimally invasive thoracoscopic RFA compared to percutaneous catheter ablation in patients with paroxysmal atrial fibrillation. (26) The projected enrollment for this trial is 180 participants, and the estimated completion date is December 2013. The primary outcome for this study will be freedom from AF off all antiarrhythmic drugs at 12 months’ follow-up. Secondary outcomes include reduction of AF burden, quality of life, procedural complications, and cost-effectiveness.

**Practice Guidelines and Position Statements**

The Canadian Cardiovascular Society published guidelines in 2010 on surgical therapy for atrial fibrillation. (27) 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. 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.

V. DEFINITIONS

**Atrial Flutter** is a cardiac arrhythmia marked by rapid (about three hundred beats per minute) regular atrial beating, and, usually, a regular ventricular response.

**Atrioventricular (AV) Node** is an area of specialized cardiac muscle that receives the cardiac impulse from the sinoatrial (SA) node and conducts it to the AV bundle and then to the Purkinje fibers and the walls of the ventricles. The AV node is located in the septal wall between the left and right atria.

**Atrium** is the upper chamber of each half of the heart. Atria is the plural of atrium.

**Myocardium** is the middle layer of the walls of the heart, composed of cardiac muscle.

**Sinoatrial (SA) Node** is a specialized group of cardiac muscle cells in the wall of the right atrium at the entrance to the superior vena cava. These cells depolarize spontaneously and rhythmically to initiate normal heartbeats.

**Supraventricular Tachycardia (SVT)** is any cardiac rhythm with a rate exceeding one hundred (100) beats per minute that originates above the branching part of the atrioventricular bundle, that is, in the sinus node, atria, or AV junction.

**Tachycardia** is an abnormally rapid heart rate, greater than one hundred (100) beats per minute.
VI. BENEFIT VARIATIONS
The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER
Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

28. 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.

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:
MEDICAL POLICY

POLICY TITLE | OPEN AND THORACOSCOPIC APPROACHES TO TREAT ATRIAL FIBRILLATION (MAZE AND RELATED PROCEDURES)
---|---
POLICY NUMBER | MP-2.083

CPT Codes®

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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

Investigational; therefore not covered:

CPT Codes®

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The following ICD-10 diagnosis codes will be effective October 1, 2014

ICD-10-CM Diagnosis Code*

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X. POLICY HISTORY

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