



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider the maze or modified maze procedure, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery for treatment of symptomatic atrial fibrillation (AF) or flutter to be **eligible for coverage**.

When Services Are Considered Not Medically Necessary

The use of an open maze or modified maze procedure performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery for treatment of atrial fibrillation (AF) or flutter to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers minimally invasive, off-pump maze procedures (ie, modified maze procedures), including those done via mini-thoracotomy for treatment of atrial fibrillation (AF) or flutter to be **investigational**.*

Based on review of available data, the Company considers hybrid ablation (defined as a combined percutaneous and thoracoscopic approach) for the treatment of atrial fibrillation (AF) or flutter to be **investigational**.*

Based on review of available data, the Company considers the maze or modified maze procedures for any indication not listed above to be **investigational**.*

Policy Guidelines

Given the availability of less-invasive alternative approaches to treat atrial fibrillation, performing the maze procedure without concomitant cardiac surgery should rarely be needed.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

Published studies on the maze procedure have described patients with drug-resistant AF and atrial flutter as having experienced their arrhythmias for an average of 7 or more years and having had unsuccessful results with an average of 5 or more antiarrhythmic medications.

Background/Overview

ATRIAL FIBRILLATION

AF is a supraventricular tachyarrhythmia characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves the interplay between electrical triggering events that initiate AF and the myocardial substrate that permits propagation and maintenance of the aberrant electrical circuit. The most common focal trigger of AF appears to be located within the cardiac muscle that extends into the pulmonary veins. The atria are frequently abnormal in patients with AF and demonstrate enlargement or increased conduction time. Atrial flutter is a variant of AF.

Treatment

The first-line treatment for AF usually includes medications to maintain sinus rhythm and/or control the ventricular rate. Antiarrhythmic medications are only partially effective; therefore, medical treatment is not sufficient for many patients. Percutaneous catheter ablation, using endocardial ablation, is an accepted second-line treatment for patients who are not adequately controlled on medications and may also be used as first-line treatment. Catheter ablation is successful in maintaining sinus rhythm for most patients, but long-term recurrences are common and increase over time. Performed either by open surgical techniques or thoracoscopy, surgical ablation is an alternative approach to percutaneous catheter ablation.

Open Surgical Techniques

The classic Cox maze III procedure is a complex surgical procedure for patients with AF. It involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart. The procedure is also intended to preserve atrial pumping function. It is indicated for patients who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with correction of structural cardiac conditions such as valve repair or replacement. This procedure is considered the criterion standard for the surgical treatment of drug-resistant AF, with a success rate of approximately 90%.

The maze procedure entails making incisions in the heart that:

- Direct an impulse from the sinoatrial node to the atrioventricular node;
- Preserve activation of the entire atrium; and
- Block re-entrant impulses responsible for AF or atrial flutter.

The classic Cox maze procedure is performed on a nonbeating heart during cardiopulmonary bypass. Simplification of the maze procedure has evolved with the use of different ablation tools such as microwave, cryotherapy, ultrasound, and radiofrequency energy sources to create the atrial lesions instead of employing the incisional technique used in the classic maze procedure. The Cox maze IV procedure

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

involves the use of radiofrequency energy or cryoablation to create transmural lesions analogous to the lesions created by the “cut-and-sew” maze.

Minimally Invasive (Thoracoscopic) Techniques

Less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF have been developed. The evolution of these procedures involves both different surgical approaches and different lesion sets. Alternative surgical approaches include mini-thoracotomy and total thoracoscopy with video assistance. Open thoracotomy and mini-thoracotomy employ cardiopulmonary bypass and open-heart surgery, while thoracoscopic approaches are performed on the beating heart. Thoracoscopic approaches do not enter the heart and use epicardial ablation lesion sets, whereas the open approaches use either the classic “cut-and-sew” approach or endocardial ablation.

Lesion sets may vary independent of the surgical approach, with a tendency toward less extensive lesion sets targeted to areas most likely to be triggers of AF. The most limited lesion sets involve pulmonary vein isolation and exclusion of the left atrial appendage. More extensive lesion sets include linear ablations of the left and/or right atrium and ablation of ganglionic plexi. Some surgeons perform left atrial reduction in cases of left atrial enlargement.

The type of energy used for ablation also varies; radiofrequency energy is most commonly applied. Other energy sources such as cryoablation and high-intensity ultrasound have been used. For our purposes, the variations on surgical procedures for AF will be combined under the heading of “modified maze” procedures.

Hybrid Techniques

“Hybrid” ablation refers to the use of 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 a hybrid procedure is that a combination of both techniques may result in a complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines because the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized.

The hybrid approach first involves thoracoscopy with epicardial ablation. Following this procedure, an electrophysiologic study is performed percutaneously followed by endocardial ablation as directed by the results of electrophysiology. Most commonly, the electrophysiology study and endocardial ablation are done immediately after the thoracoscopy as part of a single procedure. However, some hybrid approaches perform the electrophysiology study and endocardial ablation on separate days, as directed by the electrophysiology study.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 11/01/2018

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several radiofrequency ablation systems have been cleared for marketing by the U.S. FDA through the 510(k) process for cardiac tissue ablation. Table 1 provides a select list.

Table 1. Radiofrequency Ablation Approved by the Food and Drug Administration

Device	Manufacturer	510(k) Date
Medtronic Cardioblate® System	Medtronic	Jan 2002
Cardima Ablation System	Cardima	Jan 2003
Epicor™ Medical Ablation System	Epicor Medical	Feb 2004
Isolator™ Transpolar™ Pen	AtriCure	Jun 2005
Estech COBRA® Cardiac Electrosurgical Unit	Endoscopic Technologies	Dec 2005
Coolrail™ Linear Pen	AtriCure	Mar 2008
Numeris® Guided Coagulation System with VisiTrax®	nContact Surgical	Feb 2009
EPI-Sense® Guided Coagulation System with VisiTrax®	nContact Surgical	Nov 2012

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing, including those in Table 2.

Table 2. Cryoablation Systems Approved by the Food and Drug Administration

Device	Manufacturer	510(k) Date
Cryocare® Cardiac Surgery System	Endocare	Mar 2002
SeedNet™ System	Galil Medical	May 2005
SurgiFrost® XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic	Jul 2006
Isis™ cryosurgical unit	Galil Medical	Mar 2007

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

MAZE AND RELATED PROCEDURES

Traditional Maze vs “Modified Maze” Procedures

Systematic Reviews

Khargi et al (2005) analyzed 48 studies comprising 3832 patients who received surgical treatment for AF using the classic “cut-and-sew” Cox maze III technique or an alternative source of energy. Reviewers concluded that they could not identify any significant differences in the postoperative sinus rhythm conversion rates between the classic approach and alternative sources of energy. While prospective randomized studies were lacking, the data involved a wide range of ablative patterns and their effects on atrial tissue. Topkara et al (2006) reported comparable postoperative rhythm success with both radiofrequency (RF; 121 patients) and microwave (85 patients) energy in surgical ablation of AF.

Observational Studies

Several observational studies have compared the Cox maze III procedure with other procedures (radiofrequency ablation [RFA], pulmonary vein isolation) performed at single institutions, with procedure selection guided by the surgeon. Two studies attempted to address the selection bias inherent in these studies using matching. In the first, from a U.S. university medical school wherein the maze procedure was developed, Lall et al (2007) reported on 242 patients who underwent the Cox maze procedure (154 with the classic “cut-and-sew” [Cox maze III] procedure, 88 in whom RFA replaced the incisions of the classic procedure [Cox maze IV]) were matched on their propensity for treatment assignment (a logistic regression in which the outcome is treatment assignment and the predictors are covariates that might influence which procedure is chosen by the surgeon). Fifty-eight matched pairs were studied. At 1 year, the survival rates were 94% and 89% ($p=0.19$), and freedom from AF recurrence rates were 96% and 93% ($p=0.52$) for the Cox maze III and IV groups, respectively. The authors noted that the Cox maze IV procedure was offered to higher risk patients more often than the Cox maze III procedure, which might have explained why only 58 of 88 Cox maze IV patients were matched in their analysis. The matched propensity analysis can remove measurable selection biases, but if unmeasured factors lead surgeons to choose 1 surgery over the other, these factors were not accounted for in the analysis.

In a second matched analysis, Stulak et al (2007) assessed 56 patients who underwent a Cox maze IV RFA procedure at a clinic who were matched (historical controls) to 56 patients who underwent the Cox maze III procedure. Matching factors were age, sex, New York Heart Association functional class, AF type, and concomitant mitral valve surgery. Here the Cox maze IV group had greater postoperative AF (43% vs 24%), more pacemaker requirements (25% vs 5%), greater use of antiarrhythmic drugs (75% vs 25%), and fewer patients were free from AF at late follow-up (mean 8.4 months; 62% vs 92%). Again, the Cox maze IV patients had greater underlying disease (more concomitant procedures were performed).

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

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

Subsection Summary: Traditional Maze vs “Modified Maze” Procedures

There have been numerous modifications to the original maze procedure, with variations in the surgical approach, the lesion set used, and the methods for creating lesions (eg, cut-and-sew, RFA). The evidence on comparative effectiveness of the different approaches is not high quality and is incomplete regarding addressing all of the possible comparisons. The limited available evidence from matched case series does not indicate that there are large differences in efficacy across the different approaches.

Maze and Related Procedures as an Adjunct to Open Heart Surgery

The evidence on the use of maze and related procedures in addition to on-bypass surgeries being done for other reasons (eg, mitral valve replacements) consists of several RCTs evaluating AF ablation when performed as an add-on for patients undergoing open heart surgery and systematic reviews of these trials.

Systematic Reviews

A Cochrane review by Huffman et al (2016) evaluated the evidence on concomitant AF surgery for patients undergoing cardiac surgery. Included were 22 trials that compared the effect of AF surgery with no AF surgery in adults undergoing cardiac surgery for another indication. Three trials used a “cut-and-sew” technique, 3 trials used microwave ablation, 2 trials used cryoablation, and the remainder used RFA. All trials were considered at high risk of bias. There was moderate-quality evidence that AF surgical interventions increased freedom from AF, atrial flutter, and atrial tachycardia when patients were off antiarrhythmic medications (51.0% vs 24.1%; relative risk [RR], 2.04; 95% CI, 1.63 to 2.55), but the effect on all-cause mortality was uncertain, and these procedures increased the likelihood of permanent pacemaker implantation (6% vs 4.1%; RR=1.69; 95% CI, 1.12 to 2.54).

Phan et al (2014) reported on the results of a systematic review and meta-analysis of RCTs comparing surgical ablation with no ablation among patients who had AF and were undergoing mitral valve surgery. Nine studies were selected and analyzed: 5 evaluated RFA, 2 evaluated Cox maze “cut-and-sew,” 1 evaluated cryoablation, and 1 evaluated pulmonary vein isolation and Cox maze “cut-and-sew.” In pooled analysis, the risk of 30-day all-cause mortality did not differ significantly between the ablation (4.4%) and nonablation (2.7%) groups (odds ratio, 1.45; 95% CI, 0.55 to 3.83; $p = 0.46$). The number of patients in sinus rhythm at discharge was significantly higher in the group that received mitral valve repair plus surgical ablation (67.9%) than the group that received mitral valve repair only (17.0%; odds ratio, 13.96; 95% CI,

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

6.29 to 30.99; $p < 0.001$); similarly, at 3-, 6-, 12-, and beyond 12-month follow-ups, a greater proportion of the surgical ablation group was in sinus rhythm.

In an earlier systematic review, Reston and Shuhaiber (2005) reviewed 4 RCTs and 6 comparative studies to determine whether a concurrent mitral valve surgery and maze procedure would reduce the risk of stroke or death in patients with chronic or paroxysmal AF. They found a reduction in stroke rates and a small increased risk in the need for pacemakers among patients receiving simultaneous maze procedures. Also, they noted that alternative energy sources (eg, RF) might reduce the risk of postoperative bleeding associated with classic maze incisions.

Randomized Controlled Trials

Some of the larger RCTs evaluating AF ablation in conjunction with open surgery and included in the 2016 Cochrane review are described below.

Gillinov et al (2015) published results of a large controlled trial that randomized 260 patients with persistent or long-standing AF who required mitral valve surgery to ablation (either pulmonary vein isolation or ablation with a maze lesion set) during surgery ($n=133$) or to no ablation ($n=127$). Compared with controls, significantly more patients in the ablation group were free from AF at both 6 and 12 months (63.2% vs 29.4%, $p < 0.001$). The relative success ratio (ablation group vs control group) was 2.15 (95% CI, 1.54 to 3.00) on the basis of observed data. At 1 year, mortality rates did not differ significantly between the ablation group (6.8%) and the control group (8.7%; $p=0.57$). A composite safety end point did not differ significantly between groups at 30 days, nor did serious adverse event rates at 1 year.

Budera et al (2012) reported on an RCT that randomized 224 patients from 3 clinical centers to cardiac surgery plus ablation or to cardiac surgery alone. Patients were eligible for inclusion if they had at least 2 documented episodes of AF in the last six months, as well as appropriate indications for cardiac surgery. Cardiac surgery procedures included coronary artery bypass graft (CABG), valve replacement/repair, or combined CABG and valve procedures. The primary efficacy outcome was sinus rhythm at 1 year following surgery, and the primary safety outcome was a composite outcome of death, myocardial infarction, stroke, or new-onset renal failure requiring hemodialysis at 30 days postsurgery. Sinus rhythm at 1 year was documented in 60.2% (56/93) of patients in the surgery plus ablation group compared with 35.5% (27/76) of patients in the surgery alone group. Adverse event rates were similar in both groups at 30 days and at 1-year follow-up. Secondary clinical outcomes, including mortality and New York Heart Association functional class, did not differ between groups at 1 year.

Van Breugel et al (2010) evaluated changes in quality of life (QOL) in a related patient population. One hundred fifty patients with AF who were scheduled to undergo valve surgery or CABG surgery were randomized to surgery alone or surgery plus a modified maze procedure. The primary end point was QOL, as measured by the 36-Item Short-Form Health Survey, the EuroQoL, and the Multidimensional Fatigue Inventory. A total of 132 patients had usable survey results. Both groups improved on all QOL measures, but, in general, there were no significant differences between groups. The only exception was on the

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 11/01/2018

EuroQoL pain/discomfort subscale, which showed a greater degree of worsening in the control group than in the maze group.

Nonrandomized Comparative Studies

Saint et al (2013) attempted to quantify the incremental risk conferred by adding a Cox maze IV procedure to open mitral valve repair in a comparison of 213 patients with mitral valve disease and preoperative AF who underwent mitral valve surgery only (n=109) or mitral valve surgery with a Cox maze IV procedure (n=104). The operative mortality rate for the mitral valve procedure alone was predicted for each group based on the Society of Thoracic Surgeons Risk Calculator; the risk attributed to the addition of the Cox maze IV procedure was calculated by comparing the predicted mortality rate from the isolated mitral valve procedure with the actual mortality rate. At baseline, patients who had an isolated mitral valve procedure differed significantly from those who underwent the mitral valve procedure plus a Cox maze IV procedure regarding medical comorbidities and etiology of the mitral valve disease. The observed 30-day mortality rate for patients not offered a Cox maze IV procedure was 4.6% (expected, 5.5%), yielding an observed-expected 30-day mortality ratio of 0.84 (95% CI, 0.13 to 1.54). The observed 30-day mortality rate for patients who underwent a concomitant Cox maze IV procedure and mitral valve surgery was 2.9%. The Society of Thoracic Surgeons calculator predicted the score for isolated mitral valve surgery in this group was 2.5%, yielding an observed-expected 30-day mortality ratio of 1.16 (95% CI, 0.13 to 2.44). Interpretation of this study was limited because patients who received concomitant Cox maze IV procedures with mitral valve surgery were from a select low-risk population; however, findings did suggest that, in the appropriate patient population, the Cox maze IV procedure can be added to mitral valve surgery, with limited additional short-term mortality risk.

Noncomparative Studies

Since the publication of the RCTs previously described, several noncomparative studies have reported outcomes from surgical (“cut-and-sew”) maze and modified RF maze procedures as an adjunct to planned cardiac surgery. While single-arm studies can offer useful data on some parameters, such as durability of treatment effect and adverse events, they do not offer relevant evidence on the comparative efficacy of the procedure. For example, Kim et al (2007) reported on long-term outcomes after 127 Cox maze cut-and-sew procedures in conjunction with mitral valve replacement. Patient disposition was well-documented in the analysis. Thirty percent of patients experienced late AF recurrence at a mean of 44 months. Freedom from AF was 93%, 82%, 71%, and 63% at 1, 3, 5, and 7 years, respectively, and pacemakers were implanted in 4.7% of patients. Other case series (2013, 2014) have reported success rates of the procedure in different populations, with rates of freedom from AF ranging from 53% to 79% at latest follow-up.

Section Summary: Maze and Related Procedures as an Adjunct to Open Heart Surgery

Surgical treatment of AF can be performed in conjunction with valvular surgery or CABG with little additional risk. Evidence from RCTs assessing open heart surgery plus surgical treatment of AF vs surgery alone has established 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 QOL, is currently insufficient to form conclusions.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

MAZE AND RELATED PROCEDURES AS A STAND-ALONE TREATMENT FOR AF

For maze and related procedures as stand-alone therapy, the appropriate comparison group is endocardial catheter ablation. Although freedom from AF is an important outcome following AF treatment procedures, the evaluation of stand-alone maze and related procedures also requires assessment of surgery-related complications.

The evidence on the use of maze and related procedures as stand-alone treatments for AF includes evaluations of open surgical ablation, minimally invasive surgical ablation, and “hybrid” approaches. The stand-alone procedures fall on a continuum of invasiveness, ranging from open repair with sternotomy to minimally invasive procedures done with video-assisted thoracoscopy. Hybrid approaches include concomitant epicardial and endocardial procedures and are discussed separately.

Surgical Ablation as a Stand-Alone Treatment

Systematic Reviews

A number of systematic reviews, using different inclusion criteria, have assessed the evidence on stand-alone surgical ablation.

Van Laar et al (2017) reported on a meta-analysis of stand-alone thoracoscopic maze procedures for the treatment of AF. Reviewers included 14 studies (3 RCTs, 7 prospective cohort studies, 11 observational studies; total N=1171 patients). All studies used RFA and included bilateral pulmonary vein isolation and left atrial appendage exclusion or removal. The pooled drug-free success rate at 1 year was 77% (95% CI, 72% to 83%), with a similar success rate at 2 years. Subgroup analysis of the type of AF showed the highest success rate for paroxysmal AF at 81% (95% CI, 73% to 86%). The in-hospital complication rate was 2.9% and included conversion to sternotomy, rethoracotomy due to excess bleeding, pulmonary problems, stroke, and pacemaker implantation, pneumonia, and reintubation for hypoxia.

Phan et al (2016) conducted a systematic review of studies comparing thoracoscopic surgical ablation with catheter ablation, including the Atrial Fibrillation Catheter Ablation Versus Surgical Ablation Treatment (FAST) trial. Eight comparative studies, with a total of 321 video-assisted thoracoscopic surgical ablation patients and 378 catheter ablation patients, met inclusion criteria. For the review's primary efficacy end point of freedom from AF without the use of antiarrhythmic drugs, the treatment success was significantly higher in the surgical ablation group (81%) than in the catheter ablation group (64.3%) at 6 months postprocedure (RR=1.23; 95% CI, 1.02 to 1.49; p=0.03). This difference was maintained at 12 months postprocedure. Patients treated with surgical ablation had significantly higher rates of major complications (including death, stroke, transient ischemic attack, major bleeding, pericardial effusion, cardiac tamponade, pulmonary vein stenosis, pneumothorax, hemothorax, pneumonia, myocardial infarction, conversion to complete thoracotomy) compared with catheter ablation–treated patients (28.2% vs 7.8%; RR=3.30; 95% CI, 1.73 to 6.29; p<0.001).

A systematic review of 28 single-arm studies reporting on 1051 patients who received minimally invasive surgical treatment for AF was published by La Meir et al (2013). Reviewers noted substantial differences in

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 11/01/2018

patient populations, surgical techniques, and outcome definitions across studies. At 1 year, the range of success, as defined by freedom from AF while off all medications, was 51% to 86%. Outcomes for RFA appeared superior to those using ultrasound or microwave energy sources. Reviewers also noted that success was higher for the population of patients who had paroxysmal AF compared with those who had persistent and permanent AF. Early complication rates ranged from 0% to 39%, and the most common major complications were conversion to sternotomy, bleeding, port access problems, cardiac events, cerebrovascular accidents, and pulmonary complications.

Randomized Controlled Trials

The FAST RCT, reported by Boersma et al (2012), compared stand-alone surgical ablation with percutaneous ablation. This trial enrolled 124 patients from 2 clinical centers in Europe, who had symptomatic AF for at least 1 year and had failed at least 1 antiarrhythmic medication. Patients were randomized to surgical ablation using video-assisted thoracoscopy under general anesthesia or to percutaneous catheter ablation. Both techniques used RF energy. All patients in the surgical ablation group also had their left atrial appendage removed. The primary outcome was freedom from AF while off all antiarrhythmic medications during 12 months of follow-up. Secondary outcomes were freedom from AF, including patients still on medications and adverse events. Prior unsuccessful catheter ablation had been performed in 67% of patients.

At 1 year, freedom from AF while off all antiarrhythmic drugs was achieved by 65.6% (40/61) of the surgical ablation group compared with 36.5% (23/63) of the catheter ablation group ($p=0.002$). Freedom from AF, on or off medications, was achieved by 78.7% (48/61) of the surgical ablation group compared with 42.9% (27/63) of the catheter ablation group ($p<0.001$). Serious adverse events were more common in the surgical group (23.0% [14/61]) than in the catheter ablation group (3.2% [2/63]; $p=0.001$). In each group, there was 1 episode of tamponade and stroke. Additional complications in the surgical group included 6 patients with pneumothorax, 2 who required pacemaker insertion, and 1 patient each who had hemothorax, rib fracture, pneumonia, or required sternotomy for bleeding.

In a subsequent smaller RCT, Pokushalov et al (2013) randomized patients with a prior failed first catheter ablation procedure for AF to repeat catheter ablation ($n=32$) or to surgical ablation with video-assisted thoracoscopy ($n=32$). After 12 months, a higher proportion of patients who underwent surgical ablation were free of AF and atrial tachycardia without antiarrhythmic drugs (81% vs 47%, $p=0.004$). Although the total number of adverse events did not differ significantly between groups, the number of serious adverse events was higher in the surgical ablation group (7 vs 1, $p=0.02$).

Nonrandomized Comparative Studies

Several observational studies have included a matched comparison group of patients who received alternative treatments. These case series with matched control groups offer stronger evidence for comparative efficacy than do single-arm case series.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

Stulak et al (2011) compared outcomes among patients with AF who underwent an isolated cut-and-sew Cox maze procedure or catheter ablation. Ninety-seven Cox maze patients were matched on a 1:2 basis by age, sex, and AF type with 194 patients undergoing catheter ablation. At last follow-up, 82% of patients who underwent the Cox maze procedure were free of AF and off all medications compared with 55% of patients who underwent catheter ablation ($p < 0.001$). Freedom from AF at 5 years was estimated to be 87% following Cox maze surgery compared with 28% following catheter ablation ($p < 0.001$).

Wang et al (2011) performed a retrospective matched comparison of 83 patients who underwent minimally invasive surgical ablation with 83 patients who underwent catheter ablation. All patients had long-standing persistent AF, were treated between 2006 and 2009 and were followed from 1 to 3.6 years. At last follow-up, 74.7% of patients who underwent surgical ablation were free of AF compared with 59% of patients treated by catheter ablation ($p < 0.05$). Freedom from AF while off all medications was achieved by 61.4% of the surgical group compared with 44.6% of the catheter ablation group ($p < 0.05$).

Other observational studies have reported outcomes for stand-alone AF treatment. Representative studies are described next. In a retrospective cohort study, Lawrance et al (2014) compared patients who underwent a Cox maze IV procedure either by right mini-thoracotomy ($n=104$) or sternotomy ($n=252$) at a single center from 2002 to 2014. Freedom from atrial tachyarrhythmias off antiarrhythmic drugs did not differ significantly between groups. The overall complication rate was lower in the mini-thoracotomy group (6%) than in the sternotomy group (13%; $p=0.044$).

De Maat et al (2013) published results of a retrospective observational study of minimally invasive surgical treatment for AF in 86 patients with symptomatic, drug-refractory paroxysmal or permanent AF. Patients were treated at 3 centers, via bilateral video-assisted mini-thoracotomy, from 2005 to 2007 ($n=13$ patients) and subsequently via a totally thoracoscopic approach from 2007 to 2011 ($n=73$ patients). Fifteen (17%) patients had had transcatheter ablation performed. The percentages of patients free from atrial arrhythmias without the use of antiarrhythmic drugs were 71% at 12 months, 72% at 24 months, and 69% at 36 months. Half of the 24 treatment failures underwent an additional transcatheter ablation. Major periprocedural adverse events occurred in 8%, which included 3 sternotomy or mini-thoracotomy procedures due to complications, 2 cases of late pericardial tamponade, 1 case of pericardial effusion requiring video-assisted thoracoscopic surgery, and 1 stroke.

Massimiano et al (2013) reported on outcomes for 292 consecutive patients from a single institution who underwent minimally invasive mitral valve surgery ($n=177$), surgical ablation for AF ($n=81$), or both ($n=34$). Among the 115 patients who underwent AF ablation, the percentages of patients in sinus rhythm at 6, 12, and 24 months were 93%, 93%, and 88%, respectively; the percentage of patients in sinus rhythm and not taking class I and III antiarrhythmic medications at 6, 12, and 24 months were 85%, 85%, and 77%, respectively.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

Single-Arm Studies

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

Several single-arm case series of minimally invasive epicardial ablation have reported on patients who had failed catheter ablation. These case series offer evidence that is more clinically relevant than studies of unselected patients because this population has fewer treatment options and is more likely to benefit from surgical procedures. However, these studies only offer very limited evidence of the comparative efficacy of alternatives such as catheter ablation. For example, Ad et al (2011) reported on 40 patients who had failed catheter ablation, with a mean of 2.3 prior ablations per patient. The percentages of patients maintaining sinus rhythm at 6, 12, and 24 months were 76% (29/38), 89% (23/26), and 93% (13/14), respectively. Castella et al (2010) enrolled 34 patients who had failed a mean of 2 prior catheter ablations; 17 with paroxysmal AF, 12 with persistent AF, and 5 with long-standing persistent AF. At 1-year follow-up, sinus rhythm was maintained in 82% of patients with paroxysmal AF, 60% with persistent AF, and 20% with long-standing persistent AF.

Section Summary: Maze and Related Procedures as a Stand-Alone Treatment for AF

The evidence on the role of maze and related procedures as stand-alone options consists of 2 RCTs (including the FAST study) and many case series, some with matched control groups. The RCTs have reported higher success rates in maintaining sinus rhythm at 1-year follow-up with thoracoscopic ablation but have also reported higher adverse event rates than catheter ablation. This evidence does not support the superiority of one technique over the other but suggests that other factors (eg, type of AF, prior treatments, inability to take anticoagulation, patient preference) may influence the decision for the type of procedure. Case series with matched control groups have also reported higher success rates in maintaining sinus rhythm compared with catheter ablation. The single-arm case series have corroborated the high success rates following surgical treatment, but do not provide sufficient evidence to form conclusions on the comparative efficacy of surgical treatment vs other treatments.

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

HYBRID THOROSCOPIC AND ENDOCARDIAL ABLATION PROCEDURES

Systematic Reviews

Je et al (2015) reported on results of a systematic review of 37 studies designed to compare minimally invasive AF ablation procedures, including minimally invasive endocardial Cox maze procedure, with cardiopulmonary bypass support, epicardial surgical ablation, and hybrid surgical ablation. Selected were 2 studies on minimally invasive endocardial Cox maze procedure (n=145 patients), 26 on epicardial surgical

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624
Original Effective Date: 11/01/2018
Current Effective Date: 11/01/2018

ablation (n=1382 patients), and 9 on hybrid surgical ablation (n=350 patients). No statistical analyses or meta-analyses were possible due to the heterogeneity in methodologies and data reporting. However, reviewers did report that treatment success (sinus rhythm without antiarrhythmic medications) at 12 months was 87% for the endocardial Cox maze procedure, 72% for epicardial surgical ablation, and 71% for hybrid surgical ablation.

Nonrandomized Studies

La Meir et al (2012) reported on a comparative study that enrolled 35 patients who underwent a hybrid procedure and 28 patients who underwent a standard percutaneous procedure. Approximately two-thirds (42/63) of the patients had a previous percutaneous ablation procedure. At 1 year, there were more patients in the hybrid group who were free of AF, but this difference was not statistically significant (91.4% vs 82.1%, $p=0.07$). On subgroup analysis, the success rate was higher for the hybrid group in patients with long-standing persistent AF (81.8% vs 44.4%; $p=0.001$). Significantly more patients in the hybrid group were on warfarin at 1 year (29% vs 13.4%, $p<0.001$). There was no difference between groups on the frequency of adverse events.

Observational Studies

Other relevant single-arm case series have included populations ranging from 19 to 104 patients. These series have consistently reported high success rates in maintaining sinus rhythm at 1-year follow-up, ranging from 71% to 91%. Some series have reported individual adverse events, but did so variably not systematically, resulting in an inability to accurately estimate adverse event rates.

Section Summary: Hybrid Thoracoscopic and Endocardial Ablation 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, and a systematic review of these studies. The studies have suggested that hybrid ablation procedures are associated with high rates of freedom from AF, but direct comparisons with catheter ablation are lacking. Comparative studies are needed to permit assessment of the benefits and harms of hybrid ablation procedures compared with alternatives.

SUMMARY OF EVIDENCE

For individuals who have symptomatic AF or flutter who are undergoing cardiac surgery with bypass who received a Cox maze or a modified maze procedure, the evidence includes several RCTs and nonrandomized comparative studies, along with systematic reviews of these studies. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Several small RCTs have provided most of the direct evidence confirming the benefit of a modified maze procedure for patients with AF who are undergoing mitral valve surgery. These trials have established that the addition of a modified maze procedure results in a lower incidence of atrial arrhythmias following surgery, with minimal additional risks. Observational studies have supported these RCT findings. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive minimally invasive, off-pump thoracoscopic maze procedures, the evidence includes RCTs and observational studies, some of which identify control groups. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. One RCT has provided most of the direct evidence comparing surgical AF ablation using video-assisted thoracoscopy with percutaneous catheter ablation. This trial reported higher success at maintaining sinus rhythm at 1 year of follow-up with thoracoscopic ablation but also reported higher adverse event rates compared with catheter ablation. The case series have generally reported high success rates, and a few with matched comparison groups have reported higher success rates with surgical treatment than with catheter ablation. However, this evidence does not permit definitive conclusions whether a specific approach is superior to the other. Factors, such as previous treatment, the probability of maintaining sinus rhythm, the risk of complications, contraindications to anticoagulation, and patient preference, may all affect the risk-benefit ratio for each procedure. At present, it is not possible to define a subgroup of patients who would benefit more from thoracoscopic (or other minimally invasive) surgical ablation compared with percutaneous ablation, so the risks and benefits of surgical ablation compared with catheter ablation are not well-defined. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic, drug-resistant AF or flutter who are not undergoing cardiac surgery with bypass who receive hybrid thoracoscopic and endocardial ablation procedures, the evidence includes a nonrandomized comparative study and single-arm case series. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. The studies have suggested that hybrid ablation procedures are associated with high rates of freedom from AF, but direct comparisons with catheter ablation are lacking. Comparative studies are needed to permit direct comparisons of the benefits and harms of hybrid ablation procedures with alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

1. Blue Cross and Blue Shield Association, [Medical Policy Reference Manual](#), "Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures)", 7.01.14, 5:2018.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Maze procedure for drug-resistant atrial fibrillation or flutter. *TEC Assessments*. 1994;Volume 9:Tab 19.
3. Khargi K, Hutten BA, Lemke B, et al. Surgical treatment of atrial fibrillation; a systematic review. *Eur J Cardiothorac Surg*. Feb 2005;27(2):258-265. PMID 15691679
4. Topkara VK, Williams MR, Barili F, et al. Radiofrequency and microwave energy sources in surgical ablation of atrial fibrillation: a comparative analysis. *Heart Surg Forum*. 2006;9(3):E614-617. PMID 16687343
5. Lall SC, Melby SJ, Voeller RK, et al. The effect of ablation technology on surgical outcomes after the Cox-maze procedure: a propensity analysis. *J Thorac Cardiovasc Surg*. Feb 2007;133(2):389-396. PMID 17258570
6. Stulak JM, Dearani JA, Sundt TM, 3rd, et al. Superiority of cut-and-sew technique for the Cox maze procedure: comparison with radiofrequency ablation. *J Thorac Cardiovasc Surg*. Apr 2007;133(4):1022-1027. PMID 17382646
7. Stulak JM, Suri RM, Burkhardt HM, et al. Surgical ablation for atrial fibrillation for two decades: Are the results of new techniques equivalent to the Cox maze III procedure? *J Thorac Cardiovasc Surg*. May 2014;147(5):1478-1487. PMID 24560517
8. Huffman MD, Karmali KN, Berendsen MA, et al. Concomitant atrial fibrillation surgery for people undergoing cardiac surgery. *Cochrane Database Syst Rev*. Aug 22 2016(8):CD011814. PMID 27551927

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

9. Phan K, Xie A, Tian DH, et al. Systematic review and meta-analysis of surgical ablation for atrial fibrillation during mitral valve surgery. *Ann Cardiothorac Surg.* Jan 2014;3(1):3-14. PMID 24516793
10. Reston JT, Shuhaiber JH. Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation. *Eur J Cardiothorac Surg.* Nov 2005;28(5):724-730. PMID 16143540
11. Gillinov AM, Gelijns AC, Parides MK, et al. Surgical ablation of atrial fibrillation during mitral-valve surgery. *N Engl J Med.* Apr 9 2015;372(15):1399-1409. PMID 25853744
12. Budera P, Straka Z, Osmancik P, et al. Comparison of cardiac surgery with left atrial surgical ablation vs. cardiac surgery without atrial ablation in patients with coronary and/or valvular heart disease plus atrial fibrillation: final results of the PRAGUE-12 randomized multicentre study. *Eur Heart J.* Nov 2012;33(21):2644-2652. PMID 22930458
13. Van Breugel HN, Nieman FH, Accord RE, et al. A prospective randomized multicenter comparison on health-related quality of life: the value of add-on arrhythmia surgery in patients with paroxysmal, permanent or persistent atrial fibrillation undergoing valvular and/or coronary bypass surgery. *J Cardiovasc Electrophysiol.* May 2010;21(5):511-520. PMID 19925605
14. Saint LL, Damiano RJ, Jr., Cuculich PS, et al. Incremental risk of the Cox-maze IV procedure for patients with atrial fibrillation undergoing mitral valve surgery. *J Thorac Cardiovasc Surg.* Nov 2013;146(5):1072-1077. PMID 23998785
15. Kim KC, Cho KR, Kim YJ, et al. Long-term results of the Cox-Maze III procedure for persistent atrial fibrillation associated with rheumatic mitral valve disease: 10-year experience. *Eur J Cardiothorac Surg.* Feb 2007;31(2):261-266. PMID 17158057
16. Damiano RJ, Jr., Badhwar V, Acker MA, et al. The CURE-AF trial: a prospective, multicenter trial of irrigated radiofrequency ablation for the treatment of persistent atrial fibrillation during concomitant cardiac surgery. *Heart Rhythm.* Jan 2014;11(1):39-45. PMID 24184028
17. Gaita F, Ebrille E, Scaglione M, et al. Very long-term results of surgical and transcatheter ablation of long-standing persistent atrial fibrillation. *Ann Thorac Surg.* Oct 2013;96(4):1273-1278. PMID 23915587
18. Watkins AC, Young CA, Ghoreishi M, et al. Prospective assessment of the CryoMaze procedure with continuous outpatient telemetry in 136 patients. *Ann Thorac Surg.* Apr 2014;97(4):1191-1198; discussion 1198. PMID 24582049
19. van Laar C, Kelder J, van Putte BP. The totally thoracoscopic maze procedure for the treatment of atrial fibrillation. *Interact Cardiovasc Thorac Surg.* Jan 2017;24(1):102-111. PMID 27664426
20. Phan K, Phan S, Thiagalingam A, et al. Thoracoscopic surgical ablation versus catheter ablation for atrial fibrillation. *Eur J Cardiothorac Surg.* Apr 2016;49(4):1044-1051. PMID 26003961
21. La Meir M, Gelsomino S, Luca F, et al. Minimal invasive surgery for atrial fibrillation: an updated review. *Europace.* Feb 2013;15(2):170-182. PMID 22782971
22. Boersma LV, Castella M, van Boven W, et al. Atrial fibrillation catheter ablation versus surgical ablation treatment (FAST): a 2-center randomized clinical trial. *Circulation.* Jan 3 2012;125(1):23-30. PMID 22082673
23. Pokushalov E, Romanov A, Elesin D, et al. Catheter versus surgical ablation of atrial fibrillation after a failed initial pulmonary vein isolation procedure: a randomized controlled trial. *J Cardiovasc Electrophysiol.* Dec 2013;24(12):1338-1343. PMID 24016147
24. Stulak JM, Dearani JA, Sundt TM, 3rd, et al. Ablation of atrial fibrillation: comparison of catheter-based techniques and the Cox-Maze III operation. *Ann Thorac Surg.* Jun 2011;91(6):1882-1888; discussion 1888-1889. PMID 21619987
25. Wang J, Li Y, Shi J, et al. Minimally invasive surgical versus catheter ablation for the long-lasting persistent atrial fibrillation. *PLoS One.* Jul 2011;6(7):e22122. PMID 21765943
26. Lawrance CP, Henn MC, Miller JR, et al. A minimally invasive Cox maze IV procedure is as effective as sternotomy while decreasing major morbidity and hospital stay. *J Thorac Cardiovasc Surg.* Sep 2014;148(3):955-961; discussion 962-952. PMID 25048635
27. De Maat GE, Pozzoli A, Scholten MF, et al. Surgical minimally invasive pulmonary vein isolation for lone atrial fibrillation: midterm results of a multicenter study. *Innovations (Phila).* Nov-Dec 2013;8(6):410-415. PMID 24356430
28. Massimiano PS, Yanagawa B, Henry L, et al. Minimally invasive fibrillating heart surgery: a safe and effective approach for mitral valve and surgical ablation for atrial fibrillation. *Ann Thorac Surg.* Aug 2013;96(2):520-527. PMID 23773732
29. Cui YQ, Li Y, Gao F, et al. Video-assisted minimally invasive surgery for lone atrial fibrillation: a clinical report of 81 cases. *J Thorac Cardiovasc Surg.* Feb 2010;139(2):326-332. PMID 19660413
30. Edgerton JR, Brinkman WT, Weaver T, et al. Pulmonary vein isolation and autonomic denervation for the management of paroxysmal atrial fibrillation by a minimally invasive surgical approach. *J Thorac Cardiovasc Surg.* Oct 2010;140(4):823-828. PMID 20299028

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

31. Han FT, Kasirajan V, Kowalski M, et al. Results of a minimally invasive surgical pulmonary vein isolation and ganglionic plexi ablation for atrial fibrillation: single-center experience with 12-month follow-up. *Circ Arrhythm Electrophysiol.* Aug 2009;2(4):370-377. PMID 19808492
32. Pruitt JC, Lazzara RR, Ebra G. Minimally invasive surgical ablation of atrial fibrillation: the thoracoscopic box lesion approach. *J Interv Card Electrophysiol.* Dec 2007;20(3):83-87. PMID 18214660
33. Sirak J, Jones D, Sun B, et al. Toward a definitive, totally thoracoscopic procedure for atrial fibrillation. *Ann Thorac Surg.* Dec 2008;86(6):1960-1964. PMID 19022018
34. Speziale G, Bonifazi R, Nasso G, et al. Minimally invasive radiofrequency ablation of lone atrial fibrillation by monolateral right minithoracotomy: operative and early follow-up results. *Ann Thorac Surg.* Jul 2010;90(1):161-167. PMID 20609767
35. Wudel JH, Chaudhuri P, Hiller JJ. Video-assisted epicardial ablation and left atrial appendage exclusion for atrial fibrillation: extended follow-up. *Ann Thorac Surg.* Jan 2008;85(1):34-38. PMID 18154774
36. Yilmaz A, Geuzebroek GS, Van Putte BP, et al. Completely thoracoscopic pulmonary vein isolation with ganglionic plexus ablation and left atrial appendage amputation for treatment of atrial fibrillation. *Eur J Cardiothorac Surg.* Sep 2010;38(3):356-360. PMID 20227287
37. Yilmaz A, Van Putte BP, Van Boven WJ. Completely thoracoscopic bilateral pulmonary vein isolation and left atrial appendage exclusion for atrial fibrillation. *J Thorac Cardiovasc Surg.* Aug 2008;136(2):521-522. PMID 18692667
38. Geuzebroek GS, Bentala M, Molhoek SG, et al. Totally thoracoscopic left atrial Maze: standardized, effective and safe. *Interact Cardiovasc Thorac Surg.* Mar 2016;22(3):259-264. PMID 26705300
39. Ad N, Henry L, Hunt S, et al. The outcome of the Cox Maze procedure in patients with previous percutaneous catheter ablation to treat atrial fibrillation. *Ann Thorac Surg.* May 2011;91(5):1371-1377; discussion 1377. PMID 21457939
40. Castella M, Pereda D, Mestres CA, et al. Thoracoscopic pulmonary vein isolation in patients with atrial fibrillation and failed percutaneous ablation. *J Thorac Cardiovasc Surg.* Sep 2010;140(3):633-638. PMID 20117799
41. Je HG, Shuman DJ, Ad N. A systematic review of minimally invasive surgical treatment for atrial fibrillation: a comparison of the Cox-Maze procedure, beating-heart epicardial ablation, and the hybrid procedure on safety and efficacy. *Eur J Cardiothorac Surg.* Oct 2015;48(4):531-540; discussion 540-531. PMID 25567961
42. La Meir M, Gelsomino S, Luca F, et al. Minimally invasive surgical treatment of lone atrial fibrillation: Early results of hybrid versus standard minimally invasive approach employing radiofrequency sources. *Int J Cardiol.* May 2 2012;167(4):1469-1475. PMID 22560495
43. Bisleri G, Rosati F, Bontempi L, et al. Hybrid approach for the treatment of long-standing persistent atrial fibrillation: electrophysiological findings and clinical results. *Eur J Cardiothorac Surg.* Nov 2013;44(5):919-923. PMID 23475587
44. Gehi AK, Mounsey JP, Pursell I, et al. Hybrid epicardial-endocardial ablation using a pericardioscopic technique for the treatment of atrial fibrillation. *Heart Rhythm.* Jan 2013;10(1):22-28. PMID 23064043
45. Gersak B, Pernat A, Robic B, et al. Low rate of atrial fibrillation recurrence verified by implantable loop recorder monitoring following a convergent epicardial and endocardial ablation of atrial fibrillation. *J Cardiovasc Electrophysiol.* Oct 2012;23(10):1059-1066. PMID 22587585
46. La Meir M, Gelsomino S, Lorusso R, et al. The hybrid approach for the surgical treatment of lone atrial fibrillation: one-year results employing a monopolar radiofrequency source. *J Cardiothorac Surg.* Jul 19 2012;7:71. PMID 22812613
47. Muneretto C, Bisleri G, Bontempi L, et al. Successful treatment of lone persistent atrial fibrillation by means of a hybrid thoracoscopic-transcatheter approach. *Innovations (Phila).* Jul-Aug 2012;7(4):254-258. PMID 23123991
48. Muneretto C, Bisleri G, Bontempi L, et al. Durable staged hybrid ablation with thoracoscopic and percutaneous approach for treatment of long-standing atrial fibrillation: a 30-month assessment with continuous monitoring. *J Thorac Cardiovasc Surg.* Dec 2012;144(6):1460-1465; discussion 1465. PMID 23062968
49. Pison L, La Meir M, van Opstal J, et al. Hybrid thoracoscopic surgical and transvenous catheter ablation of atrial fibrillation. *J Am Coll Cardiol.* Jul 3 2012;60(1):54-61. PMID 22742400
50. Zembala M, Filipiak K, Kowalski O, et al. Minimally invasive hybrid ablation procedure for the treatment of persistent atrial fibrillation: one year results. *Kardiol Pol.* Aug 2012;70(8):819-828. PMID 22933215
51. Gersak B, Zembala MO, Muller D, et al. European experience of the convergent atrial fibrillation procedure: multicenter outcomes in consecutive patients. *J Thorac Cardiovasc Surg.* Apr 2014;147(4):1411-1416. PMID 23988287
52. Civello KC, Smith CA, Boedefeld W. Combined endocardial and epicardial ablation for symptomatic atrial fibrillation: single center experience in 100+ consecutive patients. *J Innovations Cardiac Rhythm Manage.* 2013;August.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

53. Badhwar V, Rankin JS, Damiano RJ, Jr., et al. The Society of Thoracic Surgeons 2017 Clinical practice guidelines for the surgical treatment of atrial fibrillation. *Ann Thorac Surg.* Jan 2017;103(1):329-341. PMID 28007240
54. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* Dec 2 2014;64(21):e1-76. PMID 24685669
55. Calkins H, Kuck KH, Cappato R, et al. 2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design. *Europace.* Apr 2012;14(4):528-606. PMID 22389422
56. Pagé P, CCS Atrial Fibrillation Guidelines Committee. Canadian Cardiovascular Society atrial fibrillation guidelines 2010: surgical therapy. *Can J Cardiol.* Jan-Feb 2011;27(1):67-73. PMID 21329864
57. Skanes AC, Healey JS, Cairns JA, et al. Focused 2012 update of the Canadian Cardiovascular Society atrial fibrillation guidelines: recommendations for stroke prevention and rate/rhythm control. *Can J Cardiol.* Mar-Apr 2012;28(2):125-136. PMID 22433576

Policy History

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

08/09/2018 Medical Policy Committee review

08/15/2018 Medical Policy Implementation Committee approval. New policy

Next Scheduled Review Date: 08/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33254, 33255, 33256, 33265, 33266
HCPCS	No codes

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

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

Policy # 00624

Original Effective Date: 11/01/2018

Current Effective Date: 11/01/2018

ICD-10 Diagnosis	I48.0-I48.92
------------------	--------------

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

† Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.