

# Protocol

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

(70114)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/18	<b>Next Review Date:</b> 09/20
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/07, 07/08, 09/09, 03/10, 03/11, 03/12, 03/13, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18, 09/19	

### ***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With symptomatic atrial fibrillation or flutter who are undergoing cardiac surgery with bypass</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Cox maze or modified maze procedure</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medical management</li> <li>Catheter ablation</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Medication use</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Minimally invasive, off-pump thoracoscopic maze procedures</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medical management</li> <li>Catheter ablation</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Medication use</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Hybrid thoracoscopic and endocardial ablation procedures</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Medical management</li> <li>Catheter ablation</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Medication use</li> <li>Treatment-related morbidity</li> </ul>

### **DESCRIPTION**

There are various surgical approaches to treat atrial fibrillation (AF) that work by interrupting abnormal electrical activity in the atria. Open surgical procedures, such as the Cox maze procedure were first developed for this purpose and are now generally performed in conjunction with valvular or coronary artery bypass graft surgery. Surgical techniques have evolved to include minimally invasive approaches that use epicardial radiofrequency ablation, a thoracoscopic or mediastinal approach, and hybrid catheter ablations/open procedures.

### **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 randomized controlled trials (RCTs) and nonrandomized comparative studies, along with systematic reviews of these studies. The 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.

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. The 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 one 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. The 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.

## POLICY

The maze or modified maze procedure, performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery, is considered **medically necessary** for treatment of symptomatic atrial fibrillation or flutter.

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

The procedures performed on a beating heart would be off-pump and would be **investigational**.

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

The use of an open maze or modified maze procedure performed on a non-beating heart during cardio-pulmonary bypass without concomitant cardiac surgery is considered **not medically necessary** for treatment of atrial fibrillation or flutter.

## POLICY GUIDELINES

Given the availability of less-invasive alternative approaches to treat atrial fibrillation (see the Catheter Ablation as Treatment for Atrial Fibrillation Protocol) performing the maze procedure without concomitant cardiac surgery should rarely be needed.

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 seven or more years and having had unsuccessful results with an average of five or more antiarrhythmic medications.

## BACKGROUND

### ATRIAL FIBRILLATION (AF)

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 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.

## REGULATORY STATUS

Several radiofrequency ablation systems have been cleared for marketing by the U.S. Food and Drug Administration 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 20012
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

Device	Manufacturer	510(k) Date
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

## RELATED PROTOCOLS

Catheter Ablation as Treatment for Atrial Fibrillation

Percutaneous Left Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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