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

(70114)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 12/01/20</th>
<th>Next Review Date: 09/23</th>
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<tbody>
<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 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, 09/20, 09/21, 09/22</td>
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</table>

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.

RELATED PROTOCOLS

Catheter Ablation as Treatment for Atrial Fibrillation

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

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals: • With symptomatic atrial fibrillation or flutter who are undergoing cardiac surgery with bypass</td>
<td>Interventions of interest are: • Cox maze or modified maze procedure</td>
<td>Comparators of interest are: • Medical management • Catheter ablation</td>
<td>Relevant outcomes include: • Overall survival • Medication use • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass</td>
<td>Interventions of interest are: • Minimally invasive, off-pump thoracoscopic maze procedures</td>
<td>Comparators of interest are: • Medical management • Catheter ablation</td>
<td>Relevant outcomes include: • Overall survival • Medication use • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With symptomatic, drug-resistant atrial fibrillation or flutter who are not undergoing cardiac surgery with bypass</td>
<td>Interventions of interest are: • Hybrid thoracoscopic and endocardial ablation procedures</td>
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<td>Relevant outcomes include: • Overall survival • Medication use • Treatment-related morbidity</td>
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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. 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 an 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. Relevant outcomes are overall survival, medication use, and treatment-related morbidity. Two RCTs reported significantly higher rates of freedom from AF at 1-year with surgical ablation but also reported significantly higher rates of serious adverse events. The remaining 2 RCTs found no significant differences between treatment groups in rates of freedom from AF and either did not assess or did not find significant differences in serious adverse events. The comparative observational studies consistently found significantly higher rates of freedom from atrial arrhythmias but lacked assessment of serious adverse events. The noncomparative studies generally only reported short-term outcomes and did not consistently report adverse events. Therefore, this evidence does not permit definitive conclusions about 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. Additionally, the studies do not permit conclusions about harm due to heterogeneous measurement across studies, with mixed results. The evidence is insufficient to determine that the technology results in an 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 hybrid thoracoscopic and endocardial ablation procedures, the evidence includes an RCT by DeLurgio et al [2020], and nonrandomized studies that compared a ‘convergent’ hybrid approach (i.e., epicardial approach combined with endocardial ablation) to catheter ablation, and 1 observational study that compared a thoracoscopic epicardial ablation with a percutaneous trans-septal procedure hybrid approach to catheter ablation. The DeLurgio (2020) RCT (n=153) found a statistically significantly higher rate on the primary outcome of freedom from AF/atrial flutter/atrial tachycardia absent of class I/II antiarrhythmic drugs at 1-year, but with a nonstatistically significantly higher rate of major adverse events (p=.0525) between 8- and 30-days postprocedure. Major adverse events were not reported for the 1-year follow-up period. Pooled evidence from randomized and nonrandomized studies, that included the CONVERGE RCT, found an increased risk of periprocedural adverse events with the convergent hybrid procedure relative to standard ablation. An additional nonrandomized study found that the thoracoscopic epicardial ablation with a percutaneous trans-septal procedure hybrid approach was associated with an increased rate of AF-free survival and no difference in adverse events. For the ‘convergent’ hybrid approach, additional multicenter RCTs are needed with comparisons to catheter ablation that measure the freedom from AF and assess adverse events after at least 1-year of follow-up. For other types of hybrid approaches, multicenter RCTs are needed that use established techniques to control for bias and as-
sess both benefits and harms with at least 1-year of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**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.

Stand-alone 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.

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 cardiopulmonary 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**

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 (CA) 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 CA.
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 the 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, and 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 (product code OCL). Table 1 provides a select list.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>510(k)/Premarket Approval Date</th>
<th>510(k)/Premarket Approval Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPI-Sense Guided Coagulation System</td>
<td>AtriCure</td>
<td>April 2021</td>
<td>P200002</td>
</tr>
<tr>
<td>Medtronic DiamondTemp™ System</td>
<td>Medtronic</td>
<td>Jan 2021</td>
<td>P200028</td>
</tr>
<tr>
<td>Cobra Fusion Ablation System</td>
<td>AtriCure</td>
<td>Feb 2019</td>
<td>K190151</td>
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<tr>
<td>Medtronic Cardioblate® System</td>
<td>Medtronic</td>
<td>Jan 2002</td>
<td>K013392</td>
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<tr>
<td>Cardima Ablation System</td>
<td>Cardima</td>
<td>Jan 2003</td>
<td>K022008</td>
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<tr>
<td>Epicor™ Medical Ablation System</td>
<td>Epicor Medical</td>
<td>Feb 2004</td>
<td>K022894</td>
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<td>Isolator™ Transpolar™ Pen</td>
<td>AtriCure</td>
<td>Jun 2005</td>
<td>K050459</td>
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<td>Estech COBRA® Cardiac Electrosurgical Unit</td>
<td>Endoscopic Technologies</td>
<td>Jan 2006</td>
<td>K053326</td>
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<td>Coolrail™ Linear Pen</td>
<td>AtriCure</td>
<td>Mar 2008</td>
<td>K073605</td>
</tr>
<tr>
<td>Numeris® Guided Coagulation System with VisiTrax®</td>
<td>nContact Surgical</td>
<td>Feb 2009</td>
<td>K090202</td>
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<tr>
<td>EPI-Sense® Guided Coagulation System with VisiTrax®</td>
<td>nContact Surgical</td>
<td>Nov 2012</td>
<td>K120857</td>
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</table>

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 U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>510(k)/Premarket Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryocare® Cardiac Surgery System</td>
<td>Endocare</td>
<td>Mar 2002</td>
</tr>
<tr>
<td>SeedNet™ System</td>
<td>Galil Medical</td>
<td>May 2005</td>
</tr>
<tr>
<td>SurgiFrost® XL Surgical CryoAblation System</td>
<td>CryoCath Technologies; now Medtronic</td>
<td>Jul 2006</td>
</tr>
<tr>
<td>Isis™ cryosurgical unit</td>
<td>Galil Medical</td>
<td>Mar 2007</td>
</tr>
<tr>
<td>Artic Front Advance™ and Arctic Front Advance Pro™ and the Freezer Max™ Cardiac Cryoablation Catheters</td>
<td>Medtronic</td>
<td>June 2020</td>
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</table>

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

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

6. Stulak JM, Suri RM, Burkhart 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):1478-86. PMID 24560517


