

(70114)

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

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required for the medically necessary indications listed in the guidelines.** 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.*

### Description

There are a variety of 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 (CABG) surgery. Minimally invasive surgical techniques employ epicardial radiofrequency ablation and are done via the thoracoscopic or mediastinal approach.

#### Background

Atrial fibrillation (AF) is a supraventricular tachyarrhythmia, characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves interplay between electrical triggering events 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 atrial fibrillation.

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. Catheter ablation is successful in maintaining sinus rhythm for a majority of patients, but long-term recurrences are common and increase over time. Surgical ablation, performed either by open surgical techniques or thoracoscopy, is an alternative approach to percutaneous catheter ablation.

Open surgical techniques. The classic Cox-Maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt the aberrant atrial conduction pathways in the heart for patients with atrial fibrillation. 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 gold standard for surgical treatment of drug-resistant AF with an approximately 90% success rate.

The maze procedure entails making incisions in the heart that:

- direct an impulse from the sinoatrial (SA) node to the atrioventricular (AV) node;
- preserve activation of the entire atrium; and

- block re-entrant impulses that are responsible for AF or atrial flutter.

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

Minimally invasive (thoracoscopic) techniques. In addition, 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 that are most likely to be triggers of AF. The most limited lesion sets involve pulmonary vein isolation and exclusion of the left atrial appendage. More extensive 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; RF energy is most commonly applied. Other types of energy sources such as cryoablation and high-intensity ultrasound have also been used. For the purposes of this Protocol statement, the variations on surgical procedures for AF will be combined under the heading of “modified maze” procedures.

Hybrid techniques. “Hybrid” ablation refers to a procedure that utilizes 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 doing a hybrid procedure is that a combination of both techniques may result in more complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines, since the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. 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, as directed by the electrophysiology study, on a separate day.

The U.S. Food and Drug Administration (FDA) cleared for marketing (January 2002) the Medtronic Cardioblate System, which uses RF energy to ablate cardiac tissue. The Cardima SAS (Surgical Ablation System) used during mini-thoracotomy received 510(k) marketing clearance by the FDA in 2003 as substantially equivalent to the Medtronic device for performing ablation of cardiac tissue with RF energy. Another bipolar RF device cleared for use in surgical procedures is manufactured by Atricure, Inc.

*Related Protocols:*

Catheter Ablation of the Pulmonary Veins as Treatment for Atrial Fibrillation

Catheter Ablation for Cardiac Arrhythmias

### Corporate Medical Guideline

The maze or modified maze procedure, performed on a non-beating heart during cardiopulmonary bypass with or without concomitant cardiac surgery, is considered **medically necessary** for treatment of symptomatic, drug-resistant atrial fibrillation or flutter.

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

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.

### Policy Guideline

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

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

---

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.**

### References

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

1. 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.
2. Khargi K, Hutten BA, Lemke B et al. Surgical treatment of atrial fibrillation; a systematic review. Eur J Cardiothorac Surg 2005; 27(2):258-65.
3. 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):E614-7.
4. 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 2007; 133(2):389-96.
5. 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 2007; 133(4):1022-7.

6. Reston JT, Shuhaiber JH. Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation. *Eur J Cardiothorac Surg* 2005; 28(5):724-30.
7. 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* 2012; 33(21):2644-52.
8. Chevalier P, Leizorovicz A, Maureira P et al. Left atrial radiofrequency ablation during mitral valve surgery: a prospective randomized multicentre study (SAFIR). *Arch Cardiovasc Dis* 2009; 102(11):769-75.
9. von Oppell UO, Masani N, O'Callaghan P et al. Mitral valve surgery plus concomitant atrial fibrillation ablation is superior to mitral valve surgery alone with an intensive rhythm control strategy. *Eur J Cardiothorac Surg* 2009; 35(4):641-50.
10. Liu X, Tan HW, Wang XH et al. Efficacy of catheter ablation and surgical CryoMaze procedure in patients with long-lasting persistent atrial fibrillation and rheumatic heart disease: a randomized trial. *Eur Heart J* 2010; 31(21):2633-41.
11. 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* 2010; 21(5):511-20.
12. 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* 2007; 31(2):261-6.
13. 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* 2012; 125(1):23-30.
14. 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* 2011; 91(6):1882-8; discussion 88-9.
15. Wang J, Li Y, Shi J et al. Minimally invasive surgical versus catheter ablation for the long-lasting persistent atrial fibrillation. *PloS One* 2011; 6(7):e22122.
16. 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* 2010; 139(2):326-32.
17. 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* 2010; 140(4):823-8.
18. 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* 2009; 2(4):370-7.
19. Pruitt JC, Lazzara RR, Ebra G. Minimally invasive surgical ablation of atrial fibrillation: the thoracoscopic box lesion approach. *J Interv Card Electrophysiol* 2007; 20(3):83-7.
20. Sirak J, Jones D, Sun B et al. Toward a definitive, totally thoracoscopic procedure for atrial fibrillation. *Ann Thorac Surg* 2008; 86(6):1960-4.
21. 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* 2010; 90(1):161-7.

22. Wudel JH, Chaudhuri P, Hiller JJ. Video-assisted epicardial ablation and left atrial appendage exclusion for atrial fibrillation: extended follow-up. *Ann Thorac Surg* 2008; 85(1):34-8.
23. 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* 2010; 38(3):356-60.
24. 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* 2008; 136(2):521-2.
25. La Meir M, Gelsomino S, Luca F et al. Minimal invasive surgery for atrial fibrillation: an updated review. *Europace* 2013; 15(2):170-82.
26. Krul SP, Driessen AH, Zwinderman AH et al. Navigating the mini-maze: Systematic review of the first results and progress of minimally-invasive surgery in the treatment of atrial fibrillation. *Int J Cardiol* 2011 [Epub ahead of print].
27. 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* 2011; 91(5):1371-7; discussion 77.
28. 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* 2010; 140(3):633-8.
29. 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* 2012 [Epub ahead of print].
30. 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* 2013 [Epub ahead of print].
31. Gehi AK, Mounsey JP, Pursell I et al. Hybrid epicardial-endocardial ablation using a pericardioscopic technique for the treatment of atrial fibrillation. *Heart Rhythm* 2013; 10(1):22-8.
32. 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* 2012; 23(10):1059-66.
33. 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* 2012; 7:71.
34. Muneretto C, Bisleri G, Bontempi L et al. Successful treatment of lone persistent atrial fibrillation by means of a hybrid thoracoscopic-transcatheter approach. *Innovations* 2012; 7(4):254-8.
35. 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* 2012; 144(6):1460-5; discussion 65.
36. Pison L, La Meir M, van Opstal J et al. Hybrid thoracoscopic surgical and transvenous catheter ablation of atrial fibrillation. *J Am Coll Cardiol* 2012; 60(1):54-61.
37. 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* 2012; 70(8):819-28.
38. 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* 2012; 14(4):528-606.

39. Page P, Committee CCSAFG. Canadian Cardiovascular Society atrial fibrillation guidelines 2010: surgical therapy. *Can J Cardiol* 2011; 27(1):67-73.
40. Calkins H, Brugada J, Packer DL et al. HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for personnel, policy, procedures and follow-up. A report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation developed in partnership with the European Heart Rhythm Association (EHRA) and the European Cardiac Arrhythmia Society (ECAS); in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), and the Society of Thoracic Surgeons (STS). Endorsed and approved by the governing bodies of the American College of Cardiology, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, and the Heart Rhythm Society. *Europace* 2007; 9(6):335-79.