



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/14/13
LAST REVIEW DATE: 06/19/18
LAST CRITERIA REVISION DATE: 06/20/17
ARCHIVE DATE:

OPEN AND THORACOSCOPIC APPROACHES TO TREAT ATRIAL FIBRILLATION AND ATRIAL FLUTTER (MAZE AND RELATED PROCEDURES)

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Maze Procedure:

The classic Cox maze III procedure is a surgical treatment for atrial fibrillation or flutter that has not responded to medical antiarrhythmic therapies. Small sequential atrial incisions are made, causing scar tissue to form and interrupt the aberrant atrial conduction pathways. The incisions are strategically placed to form a specific channel in an attempt to direct the electrical signals through a controlled path, or maze, to the ventricles. The maze procedure may be performed in conjunction with other cardiac surgery, such as valve repair or replacement. The classic Cox maze III procedure is performed on a non-beating heart during cardiopulmonary bypass. Simplification of the maze procedure (modified maze) has evolved using different ablation tools such as microwave, cryotherapy, ultrasound and radiofrequency (RF) energy sources to create the atrial lesions instead of the traditional incisional technique.

Minimally Invasive (Thoracoscopic) Techniques or Modified Maze:

Less invasive, transthoracic, endoscopic and off-pump procedures to treat drug-resistant atrial fibrillation have been investigated. 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 do not enter the heart and use epicardial ablation lesion sets performed on a beating heart. RF energy is most commonly applied. Other types of energy sources such as cryoablation and high-intensity ultrasound have also been used. Minimally invasive procedures may be referred to as modified maze.

Hybrid Techniques:

Hybrid ablation utilizes both thoracoscopic and percutaneous approaches in the same individual. 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.

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.



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Criteria:

- Maze or modified maze procedure for treatment of symptomatic atrial fibrillation or flutter performed on a non-beating heart during cardiopulmonary bypass with concomitant cardiac surgery is considered **medically necessary**.
- Maze or modified maze procedure for treatment of atrial fibrillation or flutter performed on a non-beating heart during cardiopulmonary bypass without concomitant cardiac surgery is considered **not medically necessary**.
- Minimally invasive, off-pump maze procedures (i.e., modified maze procedures), including those done via mini-thoracotomy, for treatment of atrial fibrillation or flutter are considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.
- Hybrid ablation for the treatment of atrial fibrillation or flutter is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.



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Resources:

Literature reviewed 06/19/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 7.01.14 BCBS Association Medical Policy Reference Manual. Open and Thoracoscopic Approaches to Treat Atrial Fibrillation (Maze and Related Procedures). Re-issue date 05/04/2018, issue date 12/01/1995.
2. Ad N. The multi-purse string maze procedure: a new surgical technique to perform the full maze procedure without atriotomies. *J Thorac Cardiovasc Surg.* 2007 Sep 2007;134(3):717-722.
3. American College of Cardiology, Oral, H. Catheter Ablation vs Surgical Cox Maze: Myths and Realities. Accessed 05/11/2009.
4. Boschert, S. Minimally Invasive Ablation Helps Some Afib: Paroxysmal atrial fibrillation is aided by isolation of pulmonary veins with bipolar radiofrequency. *Thoracic Surgery news.* 11-12/2006 2006.
5. Edgerton JR. Stand Alone Surgical Ablation Minimally Invasive Pulmonary Vein Isolation and Partial Autonomic Denervation for Surgical Treatment of Atrial Fibrillation.
6. Edgerton JR. Total thoracoscopic ablation of atrial fibrillation using the Dallas Lesion Set Partial Autonomic Denervation and Left Atrial Appendectomy. *Operative Techniques in Thoracic and Cardiovascular Surgery.* 2009 Sept 2009.
7. 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 Oct 2010;140(4):823-828.
8. Edgerton JR, Edgerton ZJ, Weaver T, et al. Minimally invasive pulmonary vein isolation and partial autonomic denervation for surgical treatment of atrial fibrillation. *Ann Thorac Surg.* 2008 Jul 2008;86(1):35-38; discussion 39.
9. Edgerton JR, McClelland JH, Duke D, et al. Minimally invasive surgical ablation of atrial fibrillation: six-month results. *J Thorac Cardiovasc Surg.* 2009 Jul 2009;138(1):109-113; discussion 114.

OPEN AND THORACOSCOPIC APPROACHES TO TREAT ATRIAL FIBRILLATION AND ATRIAL FLUTTER (MAZE AND RELATED PROCEDURES) (cont.)

Resources: (cont.)

10. External Consultant Review. Cardiovascular Disease/Clinical Cardiac Electrophysiology. 07/21/2009.
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12. 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 Aug 2009;2(4):370-377.
13. Heart Rhythm Society. HRS EHRA ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation Recommendations for Personnel Policy Procedures and Follow Up. June 2007.
14. Hemmer W, Bohm JO. [New developments for surgical ablation of atrial fibrillation]. *Herzschrittmacherther Elektrophysiol.* 2007 Jun 2007;18(2):92-100.
15. International Society of Minimally Invasive Cardiothoracic Surgery ISMICS, Ad N, Cheng DCH. Surgical Ablation for Atrial Fibrillation in Cardiac Surgery A Consensus Statement of the International Society of Minimally Invasive Cardiothoracic Surgery ISMICS 2009. *Innovations.* 2010 2010.
16. Kiser AC, Wimmer-Greinecker G, Chitwood WR. Totally extracardiac Maze procedure performed on the beating heart. *Ann Thorac Surg.* 2007 Nov 2007;84(5):1783-1785.
17. Kiser AC, Wimmer-Greinecker G, Kapelak B, et al. Achieving metrics during beating-heart ex-maze procedures improves outcomes. *Heart Surg Forum.* 2008 2008;11(4):E237-242.
18. Lee AM, Clark K, Bailey MS, Aziz A, Schuessler RB, Damiano RJ. A Minimally Invasive Cox-Maze Procedure: Operative Technique and Results. *Innovations (Phila).* 2010 Jul 1 2010;5(4):281-286.



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Resources: (cont.)

19. Longoria J, Wolff LJ, Kim BH, Stark S. Totally Thoracoscopic Bipolar Radiofrequency Ablation for the Treatment of Atrial Fibrillation. *45th Annual Meeting Society of Thoracic Surgeons*. 01/26/2009.
20. McClelland JH, Duke D, Reddy R. Preliminary results of a limited thoracotomy: new approach to treat atrial fibrillation. *J Cardiovasc Electrophysiol*. 2007 Dec 2007;18(12):1289-1295.
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22. Sirak J, Jones D, Sun B, Sai-Sudhakar C, Crestanello J, Firstenberg M. Toward a definitive, totally thoracoscopic procedure for atrial fibrillation. *Ann Thorac Surg*. 2008 Dec 2008;86(6):1960-1964.
23. 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 Jul 2010;90(1):161-167.
24. 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 Jan 2008;85(1):34-38.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į' hodilnih 877-475-4799.

Chinese: 如果您, 或是您正在協助的對象, 有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題, 您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員, 請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

