MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Maze Procedures for Atrial Fibrillation and Flutter**
Policy Number	**7.01.27**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 10/20/05, 07/20/06, 05/17/07, 05/14/08, 05/28/09, 04/22/10, 06/16/11, 05/24/12, 06/20/13, 05/22/14, 04/16/15, 03/17/16, 03/16/17, 01/18/18, 04/18/19, 04/16/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, Maze procedures performed on a non-beating heart during cardiopulmonary bypass have been medically proven to be effective and, therefore, are considered **medically appropriat**e for the treatment of medically refractory, chronic, symptomatic atrial fibrillation or flutter, with or without concurrent cardiac surgery.

II. Based upon our criteria and assessment of the peer-reviewed literature, minimally invasive, off-pump Maze procedures (e.g., mini thoracotomy), including Hybrid or convergent ablation procedures (defined as a combined percutaneous catheter and thoracoscopic surgical ablation approach), are considered **investigational** as a treatment of atrial fibrillation or flutter.

This policy does not address percutaneous transcatheter ablation procedures for the treatment of cardiac arrhythmias.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a prevalence estimated at 0.4% of the population, increasing with age. AF is a supraventricular tachyarrhythmia, characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves an interplay between electrical triggering events 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. Atrial flutter is considered a variant of AF. Due to the necessity of long-term drug therapy and its associated potential toxicity in patients with AF, surgical techniques have been developed as part of the armamentarium of alternative non-pharmacological treatments. Literature describes patients with drug-resistant AF and flutter as having experienced their arrhythmias for an average of seven years or more and having unsuccessful results with an average of five or more antiarrhythmic medications.

The classic Cox Maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt potential re-entrant circuits, which interrupts the aberrant atrial conduction pathways in the heart in cases of AF. 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 conditions of the heart, such as valve repair or replacement. The procedure has become the gold standard technique for the surgical treatment of drug-resistant AF. This procedure is performed on a non-beating heart during cardiopulmonary bypass.

The Maze procedure entails making incisions in the heart that:

I. guide an impulse from the sinoatrial (SA) node to the atrioventricular (AV) node;
II. preserve activation of the entire atrium; and
III. block re-entrant impulses that are responsible for AF or atrial flutter (AFl).

Despite its high success rate, the traditional "cut and sew" Maze procedure has not been widely utilized other than for those patients who also require concomitant cardiac surgery necessitating the need for cardiopulmonary bypass. Therefore, simplification of the Maze procedure, sometimes referred to as the Cox-Maze IV procedure, has evolved with the use of different ablation tools, such as microwave, cryothermy, ultrasonography and radiofrequency energy sources to create atrial ablative lesions instead of employing the incisional technique used in the traditional Maze procedure.

Due to the complexity and technical difficulty, associated with the Cox-Maze procedure, less invasive, trans-thoracic, endoscopic, off-pump procedures to treat refractory AF are also being developed and evaluated. Examples of these minimally invasive, off-pump surgical techniques include the thoracoscopic Wolf Mini-Maze and the Ex-Maze which use a paracardioscopic approach.

Studies are also starting to emerge investigating a hybrid approach that combines off- pump surgical and endocardial percutaneous catheter ablation. Hybrid ablation or convergent procedure refers to a procedure that uses 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, 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. This convergent ablation procedure has been proposed for highly symptomatic patients with persistent AF and long-standing persistent AF for whom stand-alone surgical or endocardial ablation procedures have provided unsatisfactory outcomes.

RATIONALE

In January 2002, the FDA approved the Medtronic Cardioblate System, which uses radiofrequency energy to ablate cardiac tissues. The Cardima SAS (surgical ablation system) used during a mini-thoracotomy procedure received 510(K) approval by the FDA in 2003 as substantially equivalent to the Medtronic device, amongst others for performing ablation of cardiac tissue during heart surgery via the use of RF energy. Another bipolar RF device used to perform ablations is manufactured by Aticure, Inc. The device has FDA approval for ablation and coagulation of soft tissue during General, ENT, Thoracic, Gynecology & Urology surgical procedures.

Evidence from a number of prospective and retrospective studies conclude that the Maze procedure is effective in restoring sinus rhythm in up to 90% of patients with medically refractory, chronic, symptomatic AF. In addition, there is evidence that, when performed in conjunction with valve repair or replacement, the Maze procedure may reduce the risk of stroke, compared with valve replacement alone (e.g., Reston et al., 2005, Lim et al., 2010, Budera et al., 2012, and Ad et al., 2013).

There are numerous modifications on the original maze procedure, with variations in the surgical approach, the lesion set used, and the methods for creating lesions (e.g., cut and sew, RFA, etc.). While the evidence on comparative effectiveness of the different approaches is not of high quality, there is evidence from matched case series that indicate that there are not large differences in efficacy among the different approaches (e.g., Khargi et al., 2005 and Stulak et al., 2007).

Some case series investigating minimally invasive, off-pump procedures include only patients who have failed previous catheter ablation. These studies report high success rates following thoracoscopic ablation, suggesting that patients who fail catheter ablation may still benefit from thoracoscopic ablation. However, these series are small and do not provide complete information on comparative efficacy or adverse events (e.g., Okada et al., 2013).

The Heart Rhythm Society (HRS) (2017) has stated that a hybrid approach could hold significant promise for those patients with persistent lone or long-standing persistent, drug-resistant AF, offering improved results over minimal-access surgical ablation or catheter ablation alone. It might be reasonable to apply the indications for stand-alone surgical ablation described above to patients being considered for hybrid surgical ablation (Class IIb, LOE C).

The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos MC, et al.) state the gold standard of surgical ablation has remained the Cox maze procedure and its iteration, based on the original work of Dr. Cox. Given stronger longitudinal evidence of efficacy and longitudinal freedom from atrial fibrillation, antiarrhythmic drugs, as well as oral anticoagulation following a full biatrial Cox Maze, the field awaits more Journal Pre-proof homogeneous or randomized evidence on hybrid or epicardial ablation procedures that adhere to the concept of the Cox Maze lesion set. Epicardial ablation with atypical lesions remains exploratory until more robust evidence becomes available.

There is limited literature related to the use of the hybrid approach in the treatment of AF. While short-term outcomes appear promising, further studies are necessary to determine whether the hybrid approach is effective, especially in patients with persistent lone or long-standing persistent, drug-resistant AF (LaMeir et al., 2012, Pison et al., 2012, Bisleri et al., 2013, Gehi et al., 2013). Recent studies and reviews focusing on the convergent ablation procedure include Delurgio et al., 2020; Larson et al., 2020 and Makati et al., 2020. Large population studies are needed as well as comparative studies to include direct comparisons of the hybrid ablation procedures with alternative treatment options.

In 2023, updated American College of Cardiology (ACC) /American Heart Association (AHA) /American College of Clinical Pharmacy (ACCP)/ Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation were released (Joglar J, et al.). These updated guidelines state a hybrid procedure might be reasonable to reduce the risk of recurrent atrial arrhythmia citing a weak level of evidence 2B recommendation.

The CONVERGE trial (Delurgio et al. 2020) was a prospective, multi-center, randomized controlled clinical trial, longitudinal study performed from December 2013 to August 2018 to compare the effectiveness of Hybrid Convergent procedure to endocardial catheter ablation (CA) and to demonstrate its safety for treatment of symptomatic persistent and long-standing persistent AF. The trial enrolled 153 patients at 27 locations (25 in the USA and two in the UK). Patients were randomized at a rate of 2:1 and received either the hybrid Convergent procedure or an endocardial catheter ablation alone. Of 149 evaluated patients at 12 months post-procedure, primary effectiveness was achieved in 67.7 percent (67/99) patients with Hybrid Convergent and 50.0 percent (25/50) with CA (p=0.036) on/off previously failed AADs and in 53.5 percent (53/99) versus 32.0 percent (16/50) (p=0.0128) respectively off AADs. At 18-months using a 7-day Holter monitor, 74.0 percent (53/72) Hybrid Convergent and 55 percent (23/42) CA patients experienced >90 percent AF burden reduction. There were no deaths, cardiac perforations or atrio-esophageal fistulas reported in the trial. The major adverse events (MAEs) rate through 30-days post intervention (primarily reported as inflammatory pericardial effusions) was 7.8 percent in the treatment arm, which was lower than the protocol pre-specified performance goal of 12 percent. There were also no long-lasting safety events observed in the trial. The clinical trial data showed a greater than 23 percent advantage for the Convergent arm over the control arm.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure)
33255 **(E/I)**	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass
33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified maze procedure) (List separately in addition to code for primary procedure)
33258 **(E/I)**	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure) without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure) with cardiopulmonary bypass (List separately in addition to code for primary procedure)
33265 **(E/I)**	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass
33266 **(E/I)**	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass

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HCPCS Codes

Code	Description
No Codes	

ICD10 Codes

Code	Description
I48.0-I48.92	Atrial fibrillation and flutter (code range)

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KEY WORDS

Atrial fibrillation (AF), Atrial Flutter, MAZE, Convergent procedure, COX-III, Epicardial Maze, Ex-Maze, Hybrid, MiniMaze, Thoracoscopic off-pump surgical ablation (TOPS).

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, the Maze procedure as treatment for atrial fibrillation is not addressed in National or Regional Medicare coverage determinations or policies.