MEDICAL POLICY

Excellus

SUBJECT: MAZE PROCEDURES FOR ATRIAL FIBRILLATION AND FLUTTER	EFFECTIVE DATE: 09/16/99 REVISED DATE: 03/21/01, 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
POLICY NUMBER: 7.01.27 CATEGORY: Technology Assessment	(ARCHIVED 02/21/02 – 10/20/05) PAGE: 1 OF: 9

- ***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 product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare 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.***

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 **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, 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 and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a prevalence estimated at 0.4% of the population, increasing with age. Atrial fibrillation 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 atrial fibrillation. 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 nonbeating 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 atrial fibrillation (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 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 MiniMaze and the Ex-Maze which uses a paracardioscopy approach.

Studies are also starting to emerge investigating a hybrid approach that combines off- pump surgical and endocardic 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 atrial fibrillation and long-standing persistent atrial fibrillation for whom stand-alone surgical or endocardial ablation procedures have provided unsatisfactory outcomes.

RATIONALE:

In Jan 2002, the FDA approved the Medtronic Cardioblate System, which uses radiofrequency energy to ablate cardiac tissues. The Cardima SAS (surgical ablation system) used during mini-thoracotomy 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, 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, Stulak, et al. 2007).

While studies have evaluated the minimally invasive, off-pump, epicardial maze procedures, the data are insufficient to reach conclusions about the relative effectiveness of these procedures compared to the classic Maze procedure for the treatment of atrial fibrillation (e.g., Wang, et al. 2011, La Meir, et al. 2013). Some case-series investigating 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).

There is limited literature related to the use of the hybrid approach in the treatment of atrial fibrillation. While short-term outcomes appear promising, further studies are necessary to determine whether the hybrid approach is effective, especially in patients with long-standing persistent and persistent lone atrial fibrillation (LaMeir, et al. 2012, Pison, et al. 2012, Bisleri, et al. 2013, Gehi, et al. 2013).

CODES: Number Description

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:	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
	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

HCPCS: No codes

ICD10: I48.0-I48.92 Atrial fibrillation and flutter (code range)

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* key article

KEY WORDS:

AF, Atrial fibrillation, 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 on our review, the Maze procedure as treatment for atrial fibrillation is not addressed in National or Regional Medicare coverage determinations or policies. "Though no formal coverage determination exists, Medicare may provide coverage without a formal coverage determination."