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

(70114)

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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

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 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 classic Cox maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt potential re-entrant circuits that interrupt the aberrant atrial conduction pathways in the heart for patients with atrial fibrillation. The procedure is also intended to preserve atrial function (pumping). 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.

In addition, less invasive, transthoracic, endoscopic, off-pump procedures to treat drug-resistant AF are being developed and evaluated. The evolution of these procedures involves both different surgical approaches and different lesion sets. Alternative surgical approaches include mini-thoracotomy, and total thorascopy 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 policy statement, the variations on surgical procedures for AF will be combined under the heading of ‘modified Maze’ procedures.

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 Protocol:
Catheter Ablation of the Pulmonary Veins as Treatment of Atrial Fibrillation

Corporate Medical Guideline
The 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, including those done via mini-thoracotomy, are considered investigational for treatment of drug-resistant 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.


