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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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

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.

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.

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.

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

Description: (cont.)

Minimally Invasive (Thoracoscopic) Techniques or Modified Maze:
Less invasive, trans-thoracic, 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.

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

Criteria:

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

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

Resources:

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

Resources: (cont.)

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

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