



**ABLATION SYSTEMS FOR ATRIAL FIBRILLATION  
(CARDIOBLATE®)  
HS-181**



*Harmony Behavioral Health, Inc.*

*Harmony Behavioral Health of Florida, Inc.*

*Harmony Health Plan of Illinois, Inc.*

*HealthEase of Florida, Inc.*

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WellCare Health Insurance of Arizona, Inc.*

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**Ablation Systems for Atrial  
Fibrillation (Cardioblate®)**

**Policy Number: HS-181**

**Original Effective Date: 7/20/2010**

**Revised Date(s): 8/2/2011**

**DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## **BACKGROUND**

Atrial fibrillation (AF) is the most commonly diagnosed cardiac rhythm disturbance and it is characterized by rapid, uncoordinated contractions of the upper chambers of the heart. Although AF occurs in a high percentage of patients who have mitral valve disease, it can also occur in individuals who have no associated cardiac abnormalities. During AF, atrial blood flow can become relatively stagnant, allowing clots to form that can cause strokes. In addition, the atrial arrhythmia can spread to the lower chambers of the heart, causing dangerous ventricular arrhythmias that may result in loss of blood pressure, fainting, heart attack, or death. AF is usually classified as paroxysmal, chronic, permanent, or persistent. Paroxysmal AF occurs intermittently and varies in frequency and duration from a few seconds to several hours or even days. In contrast, chronic AF is persistent and usually fails to respond to drug therapy or other nonpharmacologic treatments.

Many different types of surgical procedures have been developed that attempt to disrupt the abnormal conduction pathways that cause AF. One variant relies on use of one or more Cardioblate radiofrequency ablation devices to create lesions on and around specific sites such as the right atrium and pulmonary veins. To perform this procedure, the heart can be accessed via a traditional open approach or via a minimally invasive thoracoscopic approach. Like laparoscopic surgery, thoracoscopic surgery involves manipulating the surgical instruments through small incisions. For treatment of AF, a unipolar and/or bipolar device is used. The unipolar device has an electrode at its tip, whereas the bipolar device has two electrodes with a lever that pulls the sides of the electrodes together to clamp onto the targeted tissue. An electrical current is then applied, generating heat and partially destroying the tissue at the tip of the unipolar device or between the electrodes of the bipolar device. Treatment of AF with a Cardioblate device is typically performed by a cardiovascular surgeon on an inpatient basis with the patient under general anesthesia.

Results of the available studies do not provide sufficient evidence to determine whether treatment of AF with Cardioblate devices is as safe and effective as standard surgical procedures for AF treatment. The available studies found that 40% to 75% of patients were in normal sinus rhythm up to 20 months after treatment, which corresponded to 59% to 86% freedom from atrial fibrillation. Although these results are positive, some patients experienced severe complications or death after treatment and none of the available studies compared Cardioblate procedures with standard Cox Maze surgery for AF. Additional controlled studies are needed to evaluate the safety and efficacy of radiofrequency ablation with Cardioblate devices versus standard surgical methods for AF treatment (Hayes, 2010).

## **POSITION STATEMENT**

The Cardioblate® (Medtronic Inc.) irrigated surgical ablation system for the treatment of atrial fibrillation is **considered experimental and investigational and its use is NOT a covered benefit.**

## **CODING**

### **Non-Covered CPT®\* Codes**

- 33254** Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)
- 33257+** Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)
- 33265** Endoscopy, surgical; operative tissue ablation & reconstruction of atria, limited, without cardiopulmonary Bypass (eg, modified maze procedure)

**Non-Covered ICD-9-CM Procedure Codes**

**37.33** Excision / Destruction by radiofrequency of other lesion or tissue of heart; Open approach; Modified Maze  
**37.34** Excision / Destruction by radiofrequency ablation of other lesion or tissue of heart; Endovascular; Modified Maze

**HCPCS Codes** - No applicable codes

**Non-Covered ICD-9-CM Diagnosis Codes**

**427.31** Atrial fibrillation

\*Current Procedural Terminology CPT® ©2010 American Medical Association: Chicago, IL.

**REFERENCES**

**Peer Reviewed**

1. Hayes Technology Brief. Cardioblate® Ablation Systems (Medtronic Inc.) for Atrial Fibrillation. July 9, 2010.
2. Mesana TG, Kulik A, Ruel M, et al. Combined atrial fibrillation ablation with mitral valve surgery. *J Heart Valve Dis.* 2006;15(4):515-520.
3. von Oppell UO, Masani N, O’Callaghan P, Wheeler R, Dimitrakakis G, Schiffelers S. Mitral valve surgery plus concomitant atrial fibrillation ablation is superior to mitral valve surgery alone with an intensive rhythm control strategy. *Eur J Cardiothorac Surg.* 2009;35(4):641-650.
4. Wisser W, Seebacher G, Fleck T, et al. Permanent chronic atrial fibrillation: is pulmonary vein isolation alone enough? *Ann Thorac Surg.* 2007;84(4):1151-1157.
5. Wisser W, Khazen C, Deviatko E, et al. Microwave and radiofrequency ablation yield similar success rates for treatment of chronic atrial fibrillation. *Eur J Cardiothorac Surg.* 2004;25(6):1011-1017.

**Government Agencies, Professional and Medical Organizations**

N/A

**HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.