OHCA Guideline

Medical Procedure Class:	**Leadless Cardiac Pacemaker Systems**
Initial Implementation Date:	7/1/2022
Last Review Date:	March 2026
Effective Date:	4/1/2026
Next Review/Revision Date:	April 2029
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☐ New Criteria	■ Revision of Existing Criteria

Summary

Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.

Definitions

Arrythmia – problems that affect the electrical system of the heart muscle, producing abnormal heart rhythms; may be classified as either atrial or ventricular, depending on which part of the heart they originate from.

Atrial Fibrillation (AF) – a condition in which the atrium (the heart's two upper chambers) produce uncoordinated electrical signals.

Bradycardia – a condition where an individual has a slow heart rate, typically under 60 beats per minute in adults.

Bradycardia-Tachycardia Syndrome – a condition where the heart rate alternates between unusually slow and fast rhythms, often with a long pause between heartbeats.

Electrocardiogram (ECG or EKG) – a recording of the electrical activity of the heart achieved by placing electrodes on the skin of the chest and connecting them in a specific order to a machine that measures electrical activity all over the heart.

Heart Block – a disease or inherited condition that causes a fault within the heart's natural pacemaker due to obstruction (or "block") in the electrical conduction system of the heart. Blockages are classified based on where the blockage occurs – the SA node (Sinoatrial block), AV node (AV block or AVB) and at or below the bundle of His (Intra-Hisian or Infra-Hisian block). In severe cases where the heart's ability to control and trigger heartbeats may be completely ineffective or unreliable, heart block can usually be treated by inserting an artificial pacemaker that provides correct electrical impulses to trigger heart beats, compensating for the natural pacemaker's unreliability.

Leadless Cardiac Pacemaker System: a small, battery-operated electrical device which is placed in the right ventricle or right atrium of the heart to aid in maintaining a regular heart rhythm; the device is delivered directly to the ventricle or atrium through a catheter inserted into the femoral vein and attaches to the cardiac tissue with fixation tines, coils, or a screw-in helix design.

Sinus Node Dysfunction (aka sick sinus syndrome or sinoatrial disease) – a group of abnormal heart rhythms (arrythmias) presumably caused by a malfunction of the sinus node, the heart's primary pacemaker.

Tachycardia – a sinus rhythm (emanating from the SA node) with an elevated rate of impulses, defined as a rate greater than 100 beats per minute in an average adult.

Description

Pacemakers are intended to be used as a substitute for the heart's intrinsic pacing system to correct cardiac rhythm disorders. By providing an appropriate heart rate and heart rate response, cardiac pacemakers can reestablish effective circulation and more normal hemodynamics that are compromised by a slow heart rate. Current leadless pacemaker devices are self-contained enclosed capsules that include the pacemaker electronics and battery and are delivered via catheter to the right ventricle or right atrium of the heart. Leadless pacemakers function similarly to traditional single-chamber ventricular or atrial pacemakers without requiring transvenous leads or the need for a surgical pocket.

CPT Codes Covered Requiring Prior Authorization (PA)

33274 - Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (interrogation or programming) when performed.

33275 - Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (fluoroscopy, venous ultrasound, ventriculography, femoral venography) when performed.

0823T - Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed.

Approval Criteria

I. GENERAL

A. Documentation submitted to request services must demonstrate through adequate objective medical records, evidence sufficient to justify the clients need for the service in accordance with OAC 317:30-3-1(f)(2).

B. The diagnosis of bradycardia as the cause of symptoms is a combination of clinical presentation and monitoring by ECG to establish a connection between the bradycardia and the reported symptoms; other diagnostic tests may include blood tests, tilt table test to assess syncope and heart imaging tests. Longer-term monitoring such as Holter monitors, event recorders or implantable loop recorders may be used as well.

II. INDICATIONS for Micra TPS 33274:

A. Placement:

1. The Micra TPS may be considered medically necessary in patients when **BOTH** conditions below are met:
   a. The patient has symptomatic paroxysmal or permanent high-grade arteriovenous block or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses); **AND**
   b. The patient has a significant contraindication precluding placement of **conventional** single-chamber ventricular pacemaker leads such as **any** of the following:

i. History of an endovascular or cardiovascular implantable electronic device (CIED) infection or who are at high risk for infection; **OR**
ii. Limited access for transvenous pacing due to venous anomaly, occlusion of axillary veins or planned use of such veins for a semi-permanent catheter or current or planned use of an AV fistula for hemodialysis; **OR**
iii. Presence of a bioprosthetic tricuspid valve.

B. Removal:
1. Indications for removal of Micra TPS include:
a. Elevations in pacing threshold; **OR**
b. Reductions in sensing amplitude; **OR**
c. Development of right ventricle pacing-mediated cardiomyopathy; **OR**
d. Infection; **OR**
e. End of battery life.

Note: The clinician has the option of permanently programming the device to OFF and leaving it in the heart. Removal of the Micra device may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician with expertise in the removal of implanted leads.

III. INDICATIONS for Aveir AR LP 0823T:

A. Placement:
1. The Abbott Aveir AR LP may be considered medically necessary in patients when the following conditions are met:
a. Meets the following indication for leadless right atrial pacemaker:
i. Sinus node dysfunction with normal AV and intraventricular conduction systems; **AND**
b. The following contraindications for leadless pacemaker are **NOT** present:
i. An implanted inferior vena cava filter
ii. A mechanical tricuspid valve.

B. Removal:
1. Indications for removal of Aveir AR include:
a. Infection; **OR**
b. Dislodgement or embolization; **OR**
c. Malfunction or failure; **OR**
d. Cardiac complications:
i. cardiac perforation
ii. pericardial effusion;
iii. pericarditis requiring intervention; **OR**
e. End of battery life.

Note: The Aveir AR is designed to be retrievable, where the implanted device can be removed and replaced at end of service or as clinical circumstances dictate, without leaving hardware behind.

Contraindications

The Micra leadless pacemaker is contraindicated for individuals who already have the following types of devices implanted:

- An implanted device that would interfere with the implant of the Micra device in the judgement of the provider; **OR**
- An implanted inferior vena cava (IVC) filter; **OR**
- A mechanical tricuspid valve; **OR**

- An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra device.

In addition, the device is contraindicated for persons with **ANY** of the following conditions:

- Femoral venous anatomy unable to accommodate a 23 French introducer sheath or implant on the right side of the heart (e.g. due to obstruction or severe tortuosity); **OR**
- Morbid obesity that prevents the implanted device from obtaining telemetry communication within <12.5 cm; **OR**
- Intolerance to materials in the device or to heparin, or sensitivity to contrast media who cannot be adequately premedicated.

Note: The Micra TPS is not for use in individuals who cannot tolerate a single dose of 1 mg dexamethasone acetate.

The Aveir AR leadless pacemaker is contraindicated for individuals who already have the following types of devices implanted:

- An implanted inferior vena cava filter
- A mechanical tricuspid valve.

Additional Information

Battery longevity for the Micra TPS is estimated at 7 to 12 years, depending on the programmed parameters.

Battery longevity for the Aveir AR is estimated at 7 to 10 years, depending on pacing mode and settings.

References

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3. CMS Decision Memo for Leadless Pacemakers (CAG-00448N), effective date 1/28/2017.
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5. Reddy, Vivek, et al. "Retrieval of the Leadless Cardiac Pacemaker." *Circulation: Arrhythmia and Electrophysiology*, Volume 9, Issue 12, December 2016. *Circ Arrhythm Electrophysiol*, https://doi.org/10.1161/CIRCEP.116.004626. Retrieved on 6/20/2022.
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