

OHCA Guideline

Medical Procedure Class:	Micra Transcatheter Pacing System (TPS) – Leadless Cardiac Pacemaker
Initial Implementation Date:	7/1/2022
Last Review Date:	N/A
Effective Date:	7/1/2022
Next Review/Revision Date:	June 2025
* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.	
<input checked="" type="checkbox"/> New Criteria <input type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p>Arrhythmia – 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.</p> <p>Atrial Fibrillation (AF) – a condition in which the atrium (the heart’s two upper chambers) produce uncoordinated electrical signals.</p> <p>Bradycardia – a condition where an individual has a slow heart rate, typically under 60 beats per minute in adults.</p> <p>Bradycardia-Tachycardia Syndrome – a condition where the heart rate alternates between unusually slow and fast rhythms, often with a long pause between heartbeats.</p> <p>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.</p> <p>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.</p> <p>Leadless Cardiac Pacemaker System – a small, battery-operated electrical device which is placed in the right ventricle of the heart to aid in maintaining a regular heart rhythm; the device is delivered directly to the ventricle through a catheter inserted into the femoral vein and attaches to the cardiac tissue with fixation tines or coils.</p>	

Sinus Node Dysfunction (aka sick sinus syndrome or sinoatrial disease) – a group of abnormal heart rhythms (arrhythmias) 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 of the heart. Leadless pacemakers function similarly to traditional single-chamber ventricular 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.

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

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.

INDICATIONS

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.

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.

Additional Information

Currently, the only FDA approved leadless cardiac pacemaker is the Micra transcatheter pacing system (Micra TPS).

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

References

- 1. Oklahoma Health Care Authority; Policies and Rules, OAC 317:30-3-1(f)(2).
- 2. CMS National Coverage Determination (NCD), Leadless Pacemakers 20.8.4.
- 3. CMS Decision Memo for Leadless Pacemakers (CAG-00448N), effective date 1/28/2017.
- 4. Blue Cross Blue Shield of OK Leadless Cardiac Pacemaker Medical Coverage Policy #SUR707.030, effective date 7/15/2021.

5. Health Blue LA Leadless Pacemaker Medical Policy #SURG.00150, effective date 4/13/2022.
6. Cigna Cardiac Resynchronization therapy (CRT) and Advanced Cardiac Pacing Technologies Medical Coverage Policy #0174, effective date 12/15/2021.
7. Humana Leadless Cardiac Pacemakers Policy #HCS-0553-008, effective date 4/22/2022.
8. 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.
9. Glikson, Michael, et al. ESC Scientific Document Group, "2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA)." *European Heart Journal*, Volume 42, Issue 35, 14 September 2021, Pages 3427–3520, <https://doi.org/10.1093/eurheartj/ehab364>. Retrieved on 6/16/2022.
10. United Healthcare Medicare Advantage Cardiac Procedures: Pacemakers, Defibrillators and Pulmonary Artery Pressure Measurements Policy #MCS012.02, effective date 5/18/2021.