



Cohere Medicare Advantage Policy – Leadless Cardiac Pacemakers

Clinical Policy for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease

Policy Name: Cohere Medicare Advantage Policy – Leadless Cardiac Pacemakers

Type: ☒ Adult (18+ years of age) | ☒ Pediatric (0-17 years of age)

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Medical Necessity Criteria

Service: Leadless Cardiac Pacemakers

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\). Leadless pacemakers \(20.8.4\)](#)
 - [Billing and Coding: Leadless Pacemakers \(A59819\)](#)
 - [Billing and Coding: Leadless Pacemakers \(A59828\)](#)
- [National Coverage Analysis \(NCA\). Decision memo: Leadless pacemakers \(CAG-00448N\)](#)
- [Coverage with Evidence Development \(CED\). Leadless pacemakers](#)

Description

A leadless pacemaker is delivered percutaneously via a catheter through the femoral vein to the heart; the device(s) is/are implanted directly in the right atrium and/or ventricle walls. Leadless cardiac pacemakers eliminate the need for a device pocket and insertion of a pacing lead, which is integral to traditional pacing systems. The elimination of these elements minimizes complications while providing similar benefits. Leadless pacemakers function similarly to other transvenous pacemakers.^{1,5-6}

Medical Necessity Criteria

Indications

Leadless cardiac pacemakers are appropriate if **ALL** of the following are **TRUE**¹:

- The patient is enrolled in a Centers for Medicare and Medicaid Services (CMS)-approved Coverage with Evidence Development (CED) study; **AND**
- The device is used in accordance with the US Food and Drug Administration (FDA)-approved label for the device.⁷⁻¹⁰

Non-Indications

Leadless cardiac pacemakers are not considered appropriate when **ANY** of the following is **TRUE**¹⁵:

- Leadless cardiac pacemakers are non-covered when furnished outside of a CMS-approved CED study.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

HCPCS/CPT Code	Code Description
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; complete system (i.e., right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including

	imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system(i.e., right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0801T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; dual-chamber system (i.e., right

	atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual chamber leadless pacemaker, including imaging guidance (e.g., fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when

	performed
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Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Benefits and Potential Harms

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical coverage criteria for leadless cardiac pacemakers were fully defined and established by NCDs and/or LCDs. Cohere Health did not supplement this policy with any additional criteria or interpretations.

Medical Evidence

Ngo et al. (2021) performed a systematic review and meta-analysis on the safety and efficacy of leadless pacemakers placed in the right ventricle. Thirty-six observational studies were reviewed that included Nanostim (30%) and Micra (70%) leadless pacemakers. Fewer complications were found with Micra; at one-year follow-up, complications were 51% less when compared with transvenous pacemakers. At one-year follow-up, capture thresholds with Micra pacemakers were reported among 98.96% of patients. Among patients with a Nanostim pacemaker, complications were reported in 6.06% to 23.54% at 90-day follow-up and 5.33% to 6.67% at one-year follow-up. Good pacing capture was reported in 90% to 100% of patients at one-year follow-up.¹¹

Reynolds et al. (2016) report on the Micra Transcatheter Pacing Study. A multicenter study without controls included 719 patients who had a successful procedure. At the six-month follow-up, performance goals were met. The pacing capture threshold was adequate in 98.3% of patients, higher than the performance goal of 80%. Complications were reported in 4% including invasive revision, termination of therapy, hospitalization or extension of hospitalization, and death.¹²

Glikson et al. (2021) discuss the *Cardiac Pacing and Cardiac Resynchronization Therapy* guideline published by the European Society of Cardiology (ESC). In this guideline, two recommendations are included. First, leadless pacemakers should be considered an alternative to transvenous pacemakers when no upper extremity venous access exists, or when the risk of device pocket infection is particularly high, such as previous infection and patients on hemodialysis. Lastly, leadless pacemakers may also be considered as an alternative to standard single lead ventricular pacing, taking into consideration life expectancy and using shared decision-making.⁶

References

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3. Centers for Medicare and Medicaid Services (CMS). Billing and Coding: Leadless Pacemakers (A59828). Revision Effective Date October 08, 2024. Accessed April 21, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59828>
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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	06/11/2024	422.101 Disclaimer added
Version 3	05/22/2025	Annual Review Coverage with Evidence language from CMS clarified and simplified from previous version with direction to CMS NCD 20.8.4 for Leadless Pacemakers