



# **Cohere Medicare Advantage Policy – Leadless Cardiac Pacemakers**

*Clinical Policy for Medical Necessity Review*

**Version:** 3  
**Revision Date:** May 22, 2025

# Important Notices

## Notices & Disclaimers:

**GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.**

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice. This policy may be superseded by existing and applicable Centers for Medicare & Medicaid Services (CMS) statutes.

© 2025 Cohere Health, Inc. All Rights Reserved.

---

## Other Notices:

HCPCS® and CPT® copyright 2025 American Medical Association. All rights reserved.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

HCPCS and CPT are registered trademarks of the American Medical Association.

---

## 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)

## **Table of Contents**

<b>Important Notices</b>	<b>2</b>
<b>Medical Necessity Criteria</b>	<b>4</b>
<b>Service: Leadless Cardiac Pacemakers</b>	<b>4</b>
Related CMS Documents	4
Description	4
Medical Necessity Criteria	4
Indications	4
Non-Indications	5
Level of Care Criteria	5
Procedure Codes (CPT/HCPCS)	5
Evaluation of Clinical Benefits and Potential Harms	8
<b>Medical Evidence</b>	<b>10</b>
<b>References</b>	<b>11</b>
<b>Clinical Guideline Revision History/Information</b>	<b>13</b>

# 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.<sup>1-5</sup>

- [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.<sup>1,5-6</sup>

### **Medical Necessity Criteria**

#### **Indications**

**Leadless cardiac pacemakers** are appropriate if **ALL** of the following are **TRUE**<sup>1</sup>:

- 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.<sup>7-10</sup>

## Non-Indications

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

- 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
--	-----------

**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 422.137 guidance outlining CMS' 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.<sup>11</sup>

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.<sup>12</sup>

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.<sup>6</sup>

## References

1. Centers for Medicare and Medicaid Services (CMS). National coverage determination: Leadless pacemakers (20.8.4). Effective Date January 18, 2017. Accessed April 8, 2025. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=370>
2. Centers for Medicare and Medicaid Services (CMS). Billing and Coding: Leadless Pacemakers (A59819). Revision Effective Date October 08, 2024. Accessed April 21, 2025. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59819>
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>
4. Centers for Medicare and Medicaid Services (CMS). National coverage analysis (NCA) -decision memo: Leadless pacemakers (CAG-00448N). Published January 18, 2017. Accessed April 8, 2025. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=285>
5. Centers for Medicare and Medicaid Services (CMS). Coverage with evidence development – leadless pacemakers. Updated June 30, 2022. Accessed April 8, 2025. <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcid=38>
6. Glikson M, Nielsen JC, ESC Scientific Document Group, et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. *Eur Heart J*. 2021 Sep 14;42(35):3427–3520. doi: 10.1093/eurheartj/ehab364. PMID: 34455430
7. United States Food and Drug Administration (FDA). Premarket approval: Aveir™ VR and DR Leadless Pacemakers (PMA no. P150035). Decision

August 24, 2023. Accessed September 6, 2023.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>

8. United States Food and Drug Administration (FDA). Premarket approval: Aveir™ VR Leadless System: Aveir™ Leadless Pacemaker (Right Ventricular), Aveir™ Delivery System Catheter, Aveir™ Link M (PMA no. P150035). Decision Date May 4, 2022.  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
9. United States Food and Drug Administration (FDA). Premarket approval: Aveir VR Leadless Pacemaker (PMA no. P150035). Decision Date May 31, 2022.  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
10. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Aveir VR Leadless System (PMA P150035). Notice of Approval March 31, 2022.  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/P150035B.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150035B.pdf)
11. Ngo L, Nour D, Denman RA, et al. Safety and efficacy of leadless pacemakers: A systematic review and meta-analysis. *J Am Heart Assoc.* 2021 Jul 6;10(13):e019212. doi: 10.1161/JAHA.120.019212. PMID: 34169736; PMCID: PMC8403316
12. Reynolds D, Duray GZ, et al. A leadless intracardiac transcatheter pacing system. *N Engl J Med.* 2016 Feb 11;374(6):533–41. doi: 10.1056/NEJMod1511643. PMID: 26551877

# 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