# Leadless Cardiac Pacemakers

**MEDICAL POLICY NUMBER:** 424

**Effective Date:** 5/6/2025

**Last Review Date:** 5/2025

**Next Annual Review:** 12/2025



**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**SCOPE:** Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

## *PLAN PRODUCT AND BENEFIT APPLICATION*

☒ **Commercial (self-funded groups only)** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

*Oregon*: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

## COVERAGE CRITERIA

**This policy and the criteria therein only apply to self-funded employer groups. For all other commercial groups, please refer to the Carelon Cardiovascular Guidelines.**

I. A single chamber leadless pacemaker (right ventricular) is considered medically necessary when all of the following criteria are met (A.-C.):

   A. The device is approved by the U.S. Food and Drug Administration; **and**
   B. The individual has an indication for a pacemaker; **and**
   C. A leaded transvenous pacemaker cannot be placed because of any of the following (1.-3.):
      1. Venous access issues; **or**
      2. History of or high risk for cardiac implanted electronic device (CIED) infection; **or**
      3. Prosthetic tricuspid valve.

II. Single chamber leadless pacemaker (right ventricular) device replacement may be considered **medically necessary** when any of the following are met (A.-C.):

   A. Device interrogation indicates that the device is nearing end of life (elective replacement indicator); **or**
   B. Device is not functioning correctly or cannot be reprogrammed to provide optimal pacemaker support; **or**
   C. Device needs to be explanted due to infection.

III. Leadless pacemakers, initial placement or device replacement, are considered **not medically necessary** when criterion I. or II. above is not met, including but not limited to the following:

A. Single chamber leadless pacemaker (right atrial)
B. Dual chamber leadless pacemaker.

Link to Evidence Summary

## POLICY CROSS REFERENCES

- Cardiac Disease Risk Screening, MP148
- External Ambulatory Electrocardiography, MP188
- Implantable Loop Recorder, MP76
- Implantable Pulmonary Artery Pressure Monitoring, MP416
- Left Atrial Appendage Devices, MP66
- Transcatheter Aortic Valve Replacement (TAVR), MP77

**The full Company portfolio of current Medical Policies is available online and can be accessed here.**

## POLICY GUIDELINES

**DOCUMENTATION REQUIREMENTS**

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
  - History and Physical/Chart Notes
  - Documentation of symptoms, associated diagnoses and treatments
  - Name of FDA-approved leadless device
  - Documentation that supports contraindication of placement of conventional single-chamber ventricular pacemaker leads

**BACKGROUND**

**Leadless Cardiac Pacemakers**

Unlike traditional pacemakers, leadless pacemakers are self-contained devices implanted directly into the heart without leads, which are wires that traditionally connect the pacemaker to the heart muscle. This leadless design reduces the risk of lead-related complications, such as infections or lead displacement. The most common type of leadless pacemaker is the single-chamber pacemaker, which is implanted into the right ventricle and is used to treat patients with bradycardia, a condition characterized by an abnormally slow heart rate. Single-chamber pacemakers regulate the heart rate by sending electrical impulses directly to the right ventricle.

Dual-chamber leadless pacemakers aim to provide pacing support to both the right atrium and the right ventricle. Dual-chamber systems purport to ensure that the atria and ventricles work in synchrony, improving the efficiency of the heart's pumping action.

## *REGULATORY STATUS*

### U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

### FDA-Approved Leadless Cardiac Pacemakers

**Note:** The list of devices below may not be conclusive. Additionally, approved indications and contraindications may change before the policy is annually reviewed. For the most current information of approved devices and supplemental approval order statements, please refer to the U.S. Food and Drug Administration's Premarket Approval (PMA) website (product code: PNJ).

| Device | Contraindications |
|---|---|
| **Micra™ Model MC1VR01 pacemaker[1]** | Patients who have the following types of devices:<br>• An implanted device that would interfere with the implant of the Micra™ device in the judgment of the implanting physician<br>• An implanted inferior vena cava filter<br>• A mechanical tricuspid valve<br>• An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra™ device<br><br>Patients who have the following conditions:<br>• Femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity)<br>• Morbid obesity that prevents the implanted device to obtain telemetry communication within.<br>• Known intolerance to titanium, titanium nitride, parylene C, primer for parylene C, polyether ether ketone, siloxane, nitinol, platinum, iridium, liquid silicone rubber, silicone medical adhesive, and heparin or sensitivity to contrast medical which cannot be adequately premedicated. |
| **Aveir™ DR Leadless System[2]** | • Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks damage the pacemaker, and the pacemaker could reduce shock effectiveness.<br>• Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde |

| | |
|---|---|
| | VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.<br>• Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates.<br>• Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.<br>• Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in IFU Product Materials) contained in the device and a thorough history of allergies must be discussed.<br>• For the MRI contraindications for patients implanted with Aveir™ Leadless Pacemaker, refer to the MRI Procedure Manual.<br>• There are no contraindications for use of the Aveir™ Link Module. |

## *CLINICAL EVIDENCE AND LITERATURE REVIEW*

**EVIDENCE REVIEW**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of leadless cardiac pacemakers. Below is a summary of the available evidence identified through November 2024.

**Systematic Reviews**

*Aveir DR Dual-Chamber Leadless Pacemaker (Abbott Vascular)*

- In 2024, ECRI conducted an evidence review of the Aveir DR dual-chamber leadless pacemaker for treating cardiac arrythmias.[3] In total, one study was included for review, a multicenter, prospective cohort study (Knops et al. 2023, n = 300) that evaluated Aveir DR in patients with cardiac arrythmias (sinus-node dysfunction, atrioventricular block) and reported procedure success, procedure- and device-related adverse events, and atrioventricular synchrony at 3 months. The study reported that the dual-chamber leadless pacemaker system met the primary safety end point and provided atrial pacing and reliable atrioventricular synchrony for 3 months after implantation. Limitations in the study included the lack of a control group, lack of blinding, and lack of long-term follow-up. ECRI concluded that "very-low-quality evidence" suggests that use of Aveir DR is safe and may be an effective pacemaker; however, the study's follow-up is too short and included no comparison group. The findings were judged to be at high risk of bias and needed validation with additional trials.

*Micra Transcatheter Pacing System (Medtronic Inc.) for Single-Chamber Pacemaker Indications*

- In 2024, Hayes published an evidence review assessing the safety and efficacy of the Micra Transcatheter Pacing System (Medtronic Inc.) for single-chamber pacemaker indications.[4] The

literature search identified 8 clinical studies in 12 publications that evaluated the efficacy and safety of the Micra TPS in adults with an indication for single-chamber pacing. Two studies were prospective cohort studies with historical controls, 1 was a retrospective comparative database review of United States Medicare claims data, 2 were retrospective comparative cohort studies, and 3 were prospective comparative cohort studies. Sample sizes ranged from 180 to 6219 total patients, and follow-up times ranged from 30 days to 3 years. Authors wrote that substantial uncertainty surrounds the Micra TPS for the treatment of adults with an indication for single-chamber PM. Eligible studies generally showed a high rate of procedural success and demonstrated that pacing capture thresholds remained low and stable after implantation for up to 36 months. Patient-centered outcomes were limited: 1 study reported that quality of life (QOL) was statistically significantly higher for patients treated with the Micra TPS than TVPM at 6 months post implantation; other patient-centered outcomes, such as activities of daily living or alleviation of symptoms, were not reported. Authors assigned a "C" rating (potential but unproven benefit), concluding that low-quality body of evidence suggests that Micra TPS is associated with a high rate of procedural success and that pacing capture thresholds remained low and stable after implantation for up to 36 months. However, the clinical significance of any benefits introduced by use of the Micra TPS is uncertain due to the small body of evidence directly evaluating patient-centered outcomes.

- In 2022, ECRI published an evidence review assessing the safety and efficacy of the Micra VR and AV Transcatheter Pacing Systems (Medtronic plc.) for cardiac pacing.[5] Authors wote that evidence from a systematic review and seven additional nonrandomized controlled studies shows that Micra TPSs work as well as TVPs and are associated with a roughly 50% lower overall complication rate after two years. Cardiac perforation, a rare but serious pacemaker placement complication, can also occur with Micra devices; however, how the risk compares between Micra and TVP recipients is unclear. Authors concluded that evidence was "somewhat favorable" with available studies providing consistent evidence of sufficient quality to support conclusions. Large sample sizes, multicenter sampling, matched historical controls from large multicenter studies, and data synthesis with meta-analysis mitigate the risk of bias in reviewed studies. However, longer follow-up is needed to evaluate device longevity and long-term clinical outcomes. Additional studies are needed to assess Micra TPS longevity and compare long-term outcomes (i.e., 5 to 10 years) in Micra and TVP recipients. Studies comparing Micra and Aveir TPSs would also be useful.

**CLINICAL PRACTICE GUIDELINES**

*American College of Cardiology Foundation, American Heart Association, and Heart Rhythm Society*

In 2023, the Heart Rhythm Society (HRS), along with the International Society for Cardiovascular Infectious Diseases (ISCVID) and several other Asian, European and Latin American societies, endorsed the European Heart Rhythm Association (EHRA), published international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections.[6] The consensus states that these devices may be considered among patients with a single-chamber ventricular pacing indication with high risk of infection. Authors also wrote that leadless pacemakers could be preferred in patients at high risk of infection requiring VVI pacing and could be implanted sooner to serve as a bridge to permanent CIED placement without the need for a long wait time between CIED extraction and

reimplantation, especially in patients who otherwise might require temporary pacing and a long hospitalization before reimplantation.

*National Institute for Health and Care Excellence*

In 2018, the NICE published guidelines addressing leadless cardiac pacemaker implantation for bradyarrhythmia.[7] Authors wrote that "evidence on the safety of leadless cardiac pacemaker implantation for bradyarrhythmia shows that there are serious but well-recognized complications."

**EVIDENCE SUMMARY**

Low-quality but consistent evidence supports the use of leadless cardiac pacemakers in treating cardiac arrhythmias. Evidence conducted to date highlight the devices' procedural success and reliable atrioventricular synchrony, as well as stable pacing capture thresholds up to 36 months. Clinical practice guidelines endorse leadless pacemakers, particularly for patients at high infection risk and affirms their safety for bradyarrhythmia treatment. Despite limited evidence and unknown long-term effectiveness and safety, the short-term benefits of this pacing system could outweigh the risks, especially given its life-saving potential for patients who are ineligible for conventional pacing systems. Therefore, this pacemaker system may be considered medically necessary. There is insufficient evidence to demonstrate that dual chamber leadless pacing systems can improve health outcomes for patients. Currently, no dual chamber leadless pacemaker devices have received FDA approval.

## *HEALTH EQUITY CONSIDERATIONS*

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

## *BILLING GUIDELINES AND CODING*

| CODES* | | |
|---|---|---|
| **Single-Chamber Leadless Pacemakers (Ventricular)** | | |
| **CPT** | 33274 | Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., 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 |
| **Single-Chamber Leadless Pacemakers (Atrial)** | | |
| | 0823T | Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed |
| | 0824T | Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed |
| | 0825T | Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed |
| **Dual-Chamber Leadless Pacemakers** | | |
| | 0795T | Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components) |
| | 0796T | Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, 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 (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, 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 (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components) |

| | | |
|---|---|---|
| | 0799T | Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, 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 (eg, 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 (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components) |
| | 0802T | Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component |
| | 0803T | Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, 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 |
| **HCPCS** | C1605 | Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation |

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## *REFERENCES*

1. U.S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data (SSED): Micra Transcatheter Pacing System (PMS P150033). https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150033B.pdf. Published 2016. Accessed 11/19/2024.
2. U.S. Food and Drug Administration (FDA). Aveir™ DR Leadless System Summary of Safety and Effectiveness Data (SSED). https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150035S003B.pdf. Published 2023. Accessed 11/19/2024.
3. ECRI. Aveir DR Dual-Chamber Leadless Pacemaker (Abbott Vascular) for Treating Cardiac Arrythmias. https://www.ecri.org/components/ProductBriefs/Pages/213404.aspx. Published 2024. Accessed 11/19/2024.
4. Hayes Inc. Micra Transcatheter Pacing System (Medtronic Inc.) for Single-Chamber Pacemaker Indications. https://evidence.hayesinc.com/report/htb.micrapacing4178. Published 2024. Accessed 11/19/2024.
5. ECRI. Micra VR and AV Transcatheter Pacing Systems (Medtronic plc.) for Cardiac Pacing. https://www.ecri.org/components/ProductBriefs/Pages/24372.aspx. Published 2022. Accessed 11/19/2024.
6. Baddour LM, Esquer Garrigos Z, Rizwan Sohail M, et al. Update on cardiovascular implantable electronic device infections and their prevention, diagnosis, and management: a scientific statement from the American Heart Association. *Circulation.* 2024;149(2):e201-e216
7. National Institute for Health and Care Excellence. Leadless cardiac pacemaker implantation for bradyarrhythmias. https://www.nice.org.uk/guidance/ipg626. Published 2018. Accessed 11/19/2024.

## *POLICY REVISION HISTORY*

| DATE | REVISION SUMMARY |
|---|---|
| 3/2025 | New policy. |
| 5/2025 | Note added to criteria. |