Medicare Medical Policy

Leadless Cardiac Pacemakers

MEDICARE MEDICAL POLICY NUMBER: 425

Effective Date: 3/1/2025

Last Review Date: 12/2024

Next Annual Review: 12/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Leadless Pacemakers (Single-Chamber and Dual-Chamber)	National Coverage Determination (NCD): Leadless Pacemakers (20.8.4) **NOTES:** 1. According to the NCD, "Effective for dates of service on or after January 18, 2017, contractors shall cover leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies." 2. To confirm a study is Medicare-approved, the NCT number must be provided to the Plan by the provider, and it can be cross-referenced with the CMS CED website for leadless pacemakers. 3. Formal review is required for initial insertion, replacement, and removal ***with*** replacement (CPTs 33274, 0795T-0797T, 0801T-0803T, 0823T, 0825T, and HCPCS C1605. 4. CPT codes representing programming/device evaluation (CPT 0804T, 0826T) may be considered **medically necessary** when the implantation of the pacemaker system meets medical necessity criteria.[1]
Removal of Leadless Pacemakers	CPT codes representing removal only (***without*** replacement) (CPTs 33275, 0798T-0800T, and 0824T) may be considered **medically necessary**, without formal review. Medicare considers the removal of implanted devices due to complications, as well as other reasons such as non-functioning device, to be a separate and distinct medically reasonable and necessary clinical situation from the initial placement, and would be considered medically necessary, even if the coverage criteria for the placement were not met.[1]

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is

uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

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

POLICY GUIDELINES

BACKGROUND[2]

While there has been significant technological advancement in traditional pacemaker technology over the years, traditional pacemaker devices continue to require the creation of a surgical pocket for the device to be implanted, and the use of leads to reach the pacing site. The implantation procedure for traditional pacemakers is usually performed under local anesthesia and typically requires a brief hospitalization. The leads are threaded through a catheter that is inserted in the chest to the appropriate chamber(s) of the heart. While this procedure is well validated, despite the several million pacemakers that have been implanted worldwide, serious adverse events remain a concern.

Leadless pacemakers have the potential to significantly reduce serious adverse events related to pacemaker implantation by eliminating transvenous leads and the need for a surgical pocket. These devices are self-contained enclosed capsules that include the pacemaker electronics and battery, and currently range from around 26 mm to 42 mm in length, with a maximum diameter between 6 mm and 7 mm. Leadless pacemakers are currently delivered via catheter to the right ventricle of the heart, and function similarly to other transvenous single-chamber ventricular pacemakers. However, these devices have not been tested in broader, long term studies that include real world practice settings and are currently being followed in FDA-required post market studies.

Therefore, CMS may allow coverage of leadless pacemakers when procedures are performed in Food and Drug Administration (FDA) approved studies. CMS may also consider coverage leadless pacemakers that are used in accordance with the FDA approved label for devices that have either of the following when provided in the context of prospective longitudinal studies:

- an associated ongoing FDA approved post-approval study; or
- completed an FDA post-approval study.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the

availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Table 1: FDA-Approved Leadless Cardiac Pacemakers

Note: The list of devices below may not be all-inclusive. Approved indications and contraindications may change over time, so for the most current information of approved devices and supplemental approval order statements, it is recommended to refer to the FDAs Premarket Approval (PMA) website.

Device/ Manufacturer	Contraindications
Aveir™ DR Dual-Chamber Pacemaker (Abbott)	• 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. • 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. • Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates. • 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. • 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. • For the MRI contraindications for patients implanted with Aveir™ Leadless Pacemaker, refer to the MRI Procedure Manual. • There are no contraindications for use of the Aveir™ Link Module.
Micra™ Model MC1VR01 pacemaker	Patients who have the following types of devices: • An implanted device that would interfere with the implant of the Micra™ device in the judgment of the implanting physician • An implanted inferior vena cava filter • A mechanical tricuspid valve • An implanted cardiac device providing active cardiac therapy which may interfere with the sensing performance of the Micra™ device Patients who have the following conditions: • 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)

	• Morbid obesity that prevents the implanted device to obtain telemetry communication within. • 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.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- LCA: Billing and Coding: Leadless Pacemakers (A59828)

CODES*		
Single-Chamber Leadless Pacemakers		
CPT	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
	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
	0826T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, leadless pacemaker system in single-cardiac chamber
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 code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf. Accessed 11/21/2024.
2. CMS. Decision Memo for Leadless Pacemakers (CAG-00448N). Dated 1/18/2017. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=285. Accesssed 11/21/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2025	New Medicare Advantage medical policy
3/2025	Interim update; no change to criteria, add additional CPT codes