Leadless Cardiac Pacemakers

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiology
Guideline Name: Leadless Cardiac Pacemakers (Single Service)

Literature review current through: 9/20/2023
Document last updated: 9/20/2023
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Service: Leadless Cardiac Pacemakers

General Guidelines

- **Units, Frequency, & Duration:** Single procedures performed as needed for defined criteria.
- **Criteria for Subsequent Requests:** Device dislodgement may require redo and/or re-implantation and when initial implant reaches end-of-life/battery depletion
- **Recommended Clinical Approach:** Leadless 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. 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. Dual-chamber devices are now available. Leadless pacemakers function similarly to other transvenous pacemakers.[1-2]
- **Exclusions:** When furnished outside of CMS-approved Coverage with Evidence Development (CED) study or when the patient has a contraindication for a leadless pacemaker.

Medical Necessity Criteria

Indications

➔ **Leadless Cardiac Pacemakers** are appropriate if **ANY** of the following is **TRUE:**

- ◆ **Single-Chamber Ventricular Leadless Pacemakers** are considered appropriate if **ALL** of the following is **TRUE**:[3-6]
  - Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity; **AND**
  - The patient meets **ANY** of the following criteria:
    - Paroxysmal or permanent high-grade AV block in the presence of AF; **OR**

        - Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high-risk, or not deemed necessary for effective therapy; **OR**
        - Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high-risk, or not deemed necessary for effective therapy; **AND**
    - **ANY** of the following is **TRUE**:
        - Transvenous pacemakers are not suitable due to no upper extremity venous access exists[2]; **OR**
        - High risk of device pocket infection (e.g., previous infection, on hemodyalysis)[2]; **AND**
    - Device is provided through Coverage with Evidence Development (CED) (effective January 18, 2017)[1]; **AND**
    - Procedure to be performed in a Food and Drug Administration (FDA) approved study[1] (current list available here[8]).
- ◆ **Dual-Chamber Ventricular Leadless Pacemakers** are considered appropriate if **ALL** of the following is TRUE:[3-6]
    - Rate-modulated pacing is indicated for patients with chronotropic incompetence and for those who would benefit from increased stimulation rates concurrent with physical activity; **AND**
    - Patient meets the criteria due to **ANY** of the following causes of symptomatic, irreversible bradycardia:
        - VDD pacing is indicated in patients with adequate sinus rates who may benefit from maintenance of AV synchrony; **OR**
        - Sick sinus syndrome; **OR**
        - Chronic, symptomatic second- and third-degree AV block; **OR**
        - Recurrent Adams-Stokes syndrome; **OR**
        - Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out; **AND**
    - **ANY** of the following is **TRUE**:

    - Transvenous pacemakers are not suitable due to no upper extremity venous access exists[2]; **OR**
    - High risk of device pocket infection (e.g., previous infection, on hemodyalysis)[2]; **AND**
- Device is provided through Coverage with Evidence Development (CED) (effective January 18, 2017)[1]; **AND**
- Procedure to be performed in a Food and Drug Administration (FDA) approved study[1] (current list available here[8]).

Non-Indications

➔ **Single- and Dual-Chamber Leadless Pacemakers** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ When furnished outside of CMS approved Coverage with Evidence Development (CED) study[1]; **OR**
- ◆ An implanted inferior vena cava filter is present; **OR**
- ◆ A mechanical tricuspid valve is present; **OR**
- ◆ Another implanted cardiac device providing active cardiac therapy may interfere with the sensing performance of the device; **OR**
- ◆ Another implanted device would interfere with the implant of the device in the judgment of the implanting physician; **OR**
- ◆ Femoral venous anatomy is unable to accommodate a 7.8 mm (23 Fr) introducer sheath or implant on the right side of the heart (e.g., due to obstructions, severe tortuosity); **OR**
- ◆ Morbid obesity prevents the implanted device from obtaining adequate telemetry communication within 12.5 cm (4.9 in); **OR**
- ◆ Known intolerance to heparin or the tissue contacting materials in the device; **OR**
- ◆ Sensitivity to contrast media cannot be adequately pre-medicated; **OR**
- ◆ Steroid dose from this device cannot be tolerated; **OR**
- ◆ Patient meets ANY of the following contraindications for a leadless pacemaker:[7]
    - 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; **OR**

- 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; **OR**
- Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates; **OR**
- 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.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (HCPCS/CPT)

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

Medical Evidence

Ngo et al. (2021) performed a systematic review and meta-analysis on the safety and efficacy of leadless pacemakers that are 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.[9]

Reynolds et al. (2016) report on the Micra Transcatheter Pacing Study (ClinicalTrials.gov ID NCT02004873). 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.[10]

National and Professional Organizations

The **European Society of Cardiology (ESC)** published the *2021 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy.* Two recommendations are included for leadless pacemakers:[7]

- Leadless pacemakers should be considered as 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 Haemodialysis; and
- Leadless pacemakers may be considered as an alternative to standard single lead ventricular pacing, taking into consideration life expectancy and using shared decision-making.

References

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3. Centers for Medicare and Medicaid Services (CMS). National coverage analysis (NCA) - decision memo: Leadless pacemakers (CAG-00448N). Published January 18, 2017. Accessed September 6, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
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Clinical Guideline Revision History/Information

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