Cohere Medicare Advantage Policy - Leadless Cardiac Pacemakers

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: June 11, 2024

Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy - Leadless Cardiac Pacemakers

Date of last literature review: 6/11/2024
Document last updated: 6/11/2024
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Leadless Cardiac Pacemakers

Benefit Category
Inpatient Hospital Services
Physicians' Services
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1]

Recommended Clinical Approach
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. 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]

Evaluation of Clinical Benefits and Potential Harms
Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of leadless cardiac pacemakers. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, adverse reactions, and infection.

The potential clinical harms of using these criteria may include:

- Adverse effects from delayed or denied treatment: Delays or denials in implanting leadless cardiac pacemakers can lead to increased symptoms and complications, especially in patients with severe arrhythmias. The 2021 ESC Guidelines emphasize the importance of timely and appropriate use of cardiac devices to manage arrhythmias effectively.[2]

- Risks with inappropriate surgical procedures: This includes infection, bleeding, injury to cardiac structures, anesthetic risk, and the need for repeat or additional procedures due to complications. According to the FDA's summary of safety and effectiveness data, careful selection of candidates for leadless pacemakers is crucial to minimize these risks.[7]
- Increased healthcare costs and complications: This includes inappropriate use of emergency services and additional treatments. The CMS coverage with evidence development initiative for leadless pacemakers highlights the importance of evidence-based criteria to minimize complications and optimize patient outcomes.[8]

The clinical benefits of using these criteria include:

- Improved patient outcomes: Ensuring timely and appropriate access to leadless cardiac pacemakers for the patients selected for best outcomes. The goal is to provide accurate diagnostics and effective treatment planning, reducing the risk of complications and improving overall patient health. Proper use of leadless pacemakers is crucial for reducing the risk of adverse events in patients with certain arrhythmias.[9]
- Enhanced diagnostic accuracy: This is crucial for complex arrhythmias such as atrial fibrillation and bradyarrhythmias. Accurate diagnostics and treatment planning help to prevent complications and improve patient outcomes. The guidelines by Glikson et al. highlight the benefits of leadless pacemakers for managing arrhythmias.[2]
- Reduction in complications and adverse effects: Proper use of leadless cardiac pacemaker criteria helps to avoid unnecessary interventions and their associated risks, thus safeguarding patient health. Reynolds et al. reported on the safety and efficacy of leadless pacemakers, emphasizing their role in improving patient outcomes with fewer complications.[10]
- Enhanced overall patient satisfaction: Ensuring that leadless cardiac pacemakers are used appropriately leads to better patient outcomes and higher satisfaction rates due to effective treatment and reduced complications. Ngo et al. highlighted the benefits of leadless pacemakers in a systematic review and meta-analysis, supporting their use in improving patient satisfaction and outcomes.[9]

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Leadless cardiac pacemakers** are appropriate if **ALL** of the following are **TRUE**[1]:
  - ◆ Is covered through Coverage with Evidence Development (CED); **AND**
  - ◆ **ANY** of the following:
    - The study is FDA-approved; **OR**
    - The study is used in accordance with the FDA-approved label for a device that has **ANY** of the following:
      - An associated ongoing FDA-approved post-approval study; **OR**
      - Completed an FDA post-approval study; **AND**
  - ◆ The study is CMS-approved and as a fully-described, written part of its protocol, addresses **ALL** of the following:
    - Peri-procedural and post-procedural complications of leadless pacemakers; **AND**
    - Long-term outcomes of leadless pacemakers; **AND**
    - Effects of patient characteristics (e.g., age, gender, comorbidities) on the use and health effects of leadless pacemakers.

Non-Indications

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

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

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 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]

Glikson et al. (2021) discuss guidelines published by the European Society of Cardiology (ESC) titled *Cardiac Pacing and Cardiac Resynchronization Therapy.* 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. 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.[2]

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Clinical Guideline Revision History/Information

Original Date: May 24, 2024		
Review History		
Version 2	6/11/2024	422.101 Disclaimer added