Cohere Medical Policy - Leadless Cardiac Pacemakers

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: December 12, 2024

Important Notices

Notices & Disclaimers:

GUIDELINES 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 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.

Other Notices:

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.

Guideline Information:

Specialty Area: Cardiology
Guideline Name: Cohere Medical Policy - Leadless Cardiac Pacemakers

Date of last literature review: 10/31/2024
Document last updated: 12/12/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Leadless Cardiac Pacemakers

Recommended Clinical Approach

Leadless cardiac pacemakers are self-contained pacemakers small enough to be implanted directly into the ventricle, in contrast to conventional pacemakers, which require the surgical creation of a "device pocket" and insertion of transvenous pacing leads. The elimination of these elements minimizes complications, such as the risk of pneumothorax, while providing the same clinical function with added benefits, including an improved cosmetic appearance, avoidance of hematoma, and eliminated risk of lead dislodgement or lead fracture.[1] A leadless pacemaker is implanted percutaneously via a femoral catheter, which delivers the device directly into the right atrial or ventricular wall. Dual-chamber leadless pacing systems are leveraged to modulate the contraction of both the right atrium and ventricle. Device dislodgement, though rare, may require re-implantation replacement, as would battery depletion, which is thought to occur after approximately one decade of use. Should retrieval and replacement not be feasible, leadless pacemakers can be safely abandoned and left in place. Leadless pacemakers are of special utility among patients who are at high risk of infection or upper extremity venous occlusion, as leadless devices are associated with reduced rates of these complications.[2]

Medical Necessity Criteria

Indications

- ➔ A **leadless cardiac pacemaker** is appropriate if **ALL** of the following is **TRUE:**
  - ◆ **ANY** of the following is **TRUE**:
    - No upper extremity venous access exists[2]; **OR**
    - High risk of device pocket infection (e.g., active or previous systemic/device infection, on hemodialysis, etc.)[2]; **OR**
    - When a conventional transvenous pacing system is otherwise considered difficult, high-risk, or not sufficient for effective therapy; **AND**
  - ◆ **ANY** of the following is true:

- 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 as evidenced by **ANY** of the following:
    - 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; **OR**
- Symptomatic, irreversible bradycardia caused by **ANY** of the following:
    - VDD pacing is indicated in patients with adequate sinus rates who may benefit from maintenance of AV synchrony; **OR**
    - Sick sinus syndrome (sinus node dysfunction); **OR**
    - Chronic second- or third-degree AV block; **OR**
    - Recurrent Adams-Stokes syndrome; **OR**
    - Bilateral bundle-branch block not caused by tachyarrhythmia.

Non-Indications

➔ A **leadless cardiac pacemaker** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Another implant (device or otherwise) would interfere with the implantation or performance of the leadless pacemaker, in the judgment of the implanting physician; **OR**
- ◆ Known intolerance to the tissue-contacting materials in the device (e.g. - titanium, nickel, Nitinol titanium-nickel alloy, epoxy resin); **OR**
- ◆ Implanted vena cava filter; **OR**
- ◆ Mechanical tricuspid valve.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS 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

In May 2023, the New England Journal of Medicine published an extensive study of the Aveir dual-chamber leadless pacemaker. This prospective, multicenter study (ClinicalTrials.gov ID NCT05252702) evaluated the safety and efficacy of the new-to-market dual-chamber leadless pacemaker when compared to the traditional transvenous model. Among 300 patients, 90.2% were free from complications at 90 days - surpassing the performance goal of 82.5%. The second performance endpoint (achievement of at least 70% AV synchrony) was accomplished in 97.3% of patients, again exceeding the performance goal of 83%. A similar study of dual-chamber leadless pacemakers found that reliable performance of the device continued through the six-month period.[7]

In April of 2024, El-Chami et al. completed a 5-year follow-up study of the Micra leadless pacemaker. A total of 1809 patients were included, with a median duration of 51.1 months. No Micra devices were removed due to infection, reinforcing the idea that leadless pacemakers are associated with less infection risk. The complication risk at 3 years, at 4.1%, was less than half the rate associated with traditional transvenous systems (8.5%). The authors endorsed the continued safety and quality of the Micra system, particularly as compared to the standard transvenous pacemaker.[10]

Ngo et al. (2021) performed an earlier systematic review and meta-analysis on the safety and efficacy of the Micra and the Nanostim (now discontinued) leadless pacemakers. Thirty-six observational studies were reviewed that included Nanostim (30%) and Micra (70%) leadless pacemakers. Micra was well-tolerated, with just 1.77% of patients experiencing complications at one-year follow-up. As compared to conventional transvenous pacemakers, the odds of complications with Micra were 51% less. At one-year follow-up, capture thresholds with Micra pacemakers were reported among 98.96% of patients. With this review, the authors concluded leadless pacemakers were associated with “markedly” fewer complications when compared with the standard transvenous system while maintaining clinical efficacy.[8]

Reynolds et al. (2016) reported on the Micra Transcatheter Pacing Study (ClinicalTrials.gov ID NCT02004873). This 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.[9]

The European Society of Cardiology (ESC) published the *2021 ESC Guidelines on Cardiac Pacing and Cardiac Resynchronization Therapy*. Two recommendations were included, endorsing the use of leadless pacemakers among patients for whom no upper extremity venous access exists or for those patients with a particularly high risk of device pocket infection - including patients with prior or active systemic infection and patients on hemodialysis. The ESC also endorsed the broader sentiment that leadless pacemakers could be "considered as an alternative" to standard pacing when also weighing life expectancy and utilizing the principles of shared decision-making.[2]

References

1. Gangannapalle M, Monday O, Rawat A, et al. Comparison of safety of leadless pacemakers and transvenous pacemakers: A meta-analysis. *Cureus*. 2023 Sep;15(9).
2. 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.
3. Middour TG, Chen JH, El-Chami MF. Leadless pacemakers: A review of current data and future directions. *Prog Cardiovasc Dis*. 2021 May 1;66:61-9. doi: 10.1016/j.pcad.2021.06.00.
4. United States Food and Drug Administration (FDA). Premarket approval: Aveir™ VR and DR leadless pacemakers (PMA no. P150035). Decision August 24, 2023. Accessed December 11, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
5. 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. Accessed December 11, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
6. United States Food and Drug Administration (FDA). Premarket approval: Aveir VR leadless pacemaker (PMA no. P150035). Decision Date May 31, 2022. Accessed December 11, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
7. Knops RE, Reddy VY, Ip JE, et al. A dual-chamber leadless pacemaker. *N Engl J Med*. 2023 Jun 22;388(25):2360-70. doi: 10.1056/NEJMoa2300080.
8. 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.
9. Reynolds D, Duray GZ, Micra Transcatheter Pacing Study Group, et al. A leadless intracardiac transcatheter pacing system. *N Engl J Med*. 2016 Feb 11;374(6):533-41. doi: 10.1056/NEJMoa1511643. PMID: 26551877.
10. El-Chami MF, Garweg C, Clementy N, et al. Leadless pacemakers at 5-year follow-up: the Micra transcatheter pacing system post-approval registry. *European Heart Journal*. 2024 Apr 7;45(14):1241-51. https://doi.org/10.1093/eurheartj/ehae101

Clinical Guideline Revision History/Information

Original Date: September 20, 2023		
Review History		
Version 2	12/12/2024	• Annual policy review and restructure. • Updated recommended clinical approach • Combined indications to allow provider discretion for the selection of device. • Updated Medical Evidence section. • Updated references.