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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Pacemakers

- Single Chamber
- Dual Chamber
- Leadless Pacemakers
- Cardiac Resynchronization Therapy (CRT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Hospital Outpatient Regulations and Notices Medicare Claims Processing Manual, Change Request - Transmittal 187: The National Coverage Determination (NCD) for Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (NCD 20.8.3)
National Coverage Determinations (NCD)	Leadless Pacemakers (20.8.4) **Leadless pacemakers are non-covered when furnished outside of a CMS approved CED study.* Singe & Dual Chamber Cardiac Pacemakers require Level of Care review **AND** Medical necessity review using Cardiac Pacemakers: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers (20.8.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Singe & Dual Chamber Cardiac Pacemakers require Level of Care review **AND** Medical necessity review using Billing and Coding: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers Coding and Billing (A54931)
Kaiser Permanente Medical Policy	Requires Level of Care review **AND** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cardiac Resynchronization Therapy (CRT)"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Leadless Pacemakers	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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Cardiac Resynchronization Therapy (CRT)	Requires Level of Care review **AND** medical necessity review below: CRT will be considered medically necessary when the following criteria for a given beneficiary are met: • LVEF ≤ 35%, with ischemic or non-ischemic cardiomyopathy, on maximally tolerated guideline-directed medical therapy (GDMT) for at least 3 months and with no reversible causes; *and* a. QRS ≥ 150 ms; and b. Any type bundle branch block with evidence of dyssynchrony; and c. NYHA class III or ambulatory IV HF • LVEF ≤ 35%, on maximally tolerated GDMT for at least 3 months and with no reversible causes; *and* a. QRS ≥ 150 ms; and b. LBBB; and c. NYHA classes II, III or ambulatory IV HF • LVEF ≤ 35%, on maximally tolerated GDMT for at least 3 months and with no reversible causes; *and* a. QRS 130-149 ms; and b. LBBB; and c. NYHA class II, III or ambulatory IV HF • In patients with atrial fibrillation (AF) or in sinus rhythm who have an indication for pacemaker implant for second or third degree atrioventricular (AV) block (including those who have or will have AV nodal ablation), or very prolonged first degree block with PR > 300 ms, *and*: a. with an EF < 50%; and b. with NYHA I, II or III class; and c. anticipated frequent ventricular pacing • Patients who are being paced from the RV frequently (generally considered at least > 40% of the time) and who develop worsening HF symptoms (NYHA class II-IV) with a decline in LVEF to a value < 40% may be considered for upgrade to CRT.* *For an upgrade from standard pacing to CRT, Kaiser Permanente would expect documentation narrative regarding the risk-benefit balance for that individual patient and his/her degree of HF, QRS duration/morphology, etc. A “stand-alone” upgrade in patients with an existing pacemaker or implanted cardiac defibrillator should be considered carefully and based on the individual patient’s unique circumstances. Upgrades to CRT from conventional RV pacing at the time of a needed generator change will be covered per the usual criteria as noted in all preceding coverage bullets. In patients with AF and HF for whom CRT is planned, narrative in the medical record is expected regarding plans for AF control so that CRT may be most effective. It is understood that the future for such patients cannot be predicted and thus future therapy cannot be defined precisely; however, a reference to the need for focus on AF control is desirable. HF patients with concomitant moderate-severe chronic obstructive pulmonary disease (COPD) should have documentation related to a reasonable hope for CRT response with a clinically guided rationale that the dyspnea is at least in part significantly related to HF. Patients with end stage or advanced renal disease may benefit less from CRT. Documentation regarding the risk-benefit balance in these patients would also be expected. Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in the NCD for Implantable Automatic Defibrillators (20.4), may receive the combined devices in 1 procedure, at the time the biventricular pacemaker is clinically indicated.

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	Patients with an existing CRT device may receive a generator replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction. **Limitations:** Noncovered Services: ((CRT is unlikely to offer benefit and is probably associated with harm) 1. Patients with a QRS < 130 ms (Exception to this non-coverage criterion would be in the case of patients undergoing AV nodal ablation or in need of RV pacing (due to second- or third-degree block or very long first degree block) that is expected to occur a majority of the time.) 2. Patients with an EF ≥ 50% 3. CRT in patients with non-ambulatory NYHA IV HF symptoms or on chronic inotropic HF therapy or with LV assist devices in place
Single & Dual Chamber Cardiac Pacemakers	Requires Level of Care review ***AND*** medical necessity review. Kaiser Permanente has elected to use coverage guidance from Medicare's National Coverage Determination (NCD) 20.8.3 Cardiac Pacemakers: Single and Dual Chamber Permanent Cardiac Pacemakers

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Cardiac arrhythmias occur when there is interruption of the normal sinus rhythm. Symptoms include palpitations, dizziness, lightheadedness, syncope, dyspnea, anxiety, weakness, and chest discomfort. One therapeutic option is the implantation of pacemaker which provides electrical impulses to the heart. Conventional pacemakers consist of a pulse generator, which provides electrical impulses, and leads delivering electrical impulses from the generator to the heart. The pulse generator is the battery and is placed in the anterior part of the chest (pre-pectoral) while the leads are placed transvenously.

However, there are several complications associated with traditional pacemakers. Complications due to the pulse generator include hematoma, skin breakdown, and pocket infection (Udo et al., 2012). Complications due to the leads include venous obstruction, lead dislodgement, lead malfunction, lead fractures, and infection (Cheng, Wang, Curtis, & Varosy, 2010; Kirkfeldt et al., 2011; Udo et al., 2012).

Leadless pacemakers have been the center of attention due to its ability to address the limitations of traditional transvenous pacemakers. Two leadless pacemakers have been assessed for single-chamber right ventricular pacing. These include Nanostim LP (Abbott, formerly St. Jude, Lake Bluff, IL) and Micra Transcatheter Pacing System (Medtronic, Minneapolis, MN). Nevertheless, Nanostim is out of the market due to premature battery depletion (Yarlagadda et al., 2018). Leadless pacemakers are composed of a pulse generator, battery, and electrode in the same device (Reddy et al., 2015). It is placed through a catheter and is directly implanted into the right ventricle (Yarlagadda et al., 2018).

The leadless pacemaker's (Nanostim) length is 42 mm and a maximum diameter of 5.99 mm with a battery life ranging from 8.4 to of 12.4 years (Reddy et al., 2015). A sheath is placed in the femoral vein, and with a sleeve-based catheter, the device is delivered to the right ventricle. The sleeve is then withdrawn, and the pacemaker is implanted into the endocardium while the device remains docked. The device is then undocked from the catheter but is still connected to the catheter through tether connections. This allows for device measurements and

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evaluation of stability without the catheter. Repositioning can be performed if the device is not well positioned. Once positioning is assured and the pacemaker parameters are optimal [(R wave amplitude ≥5.0 mV) and pacing threshold (≤2.0 V at 0.4 ms)] (Yarlagadda et al., 2018), the device is untethered from the catheter resulting in the final implant position (Reddy et al., 2015). The procedure is performed under fluoroscopy. After the procedure, patients are observed over a period of 24 hours and discharged (CADTH 2015). An external programmer is used to program Micra transcatheter pacing system.
Some differences are worth noted. The Nanostim pacemaker is smaller than the traditional pacemaker (<10%), with a battery life ranging between 8.4 years and 12.4 years. The Micra Transcatheter Pacing System pacemaker is 30% smaller than the Nanostim and its estimated battery life ranges from 10 to 15 years. Micra transcatheter pacing is 93% smaller than conventional pacemakers, about the size of a large vitamin capsule (https://www.medtronic.com/us-en/patients/treatments-therapies/pacemakers/our/micra.html). The insertion of these devices takes 20 to 45 minutes compared to 60 minutes for the conventional pacemaker (CADTH 2015).

Medical Technology Assessment Committee (MTAC)

Leadless Pacemakers for the treatment of cardiac arrhythmias

Date: 04/21/2019

Evidence Conclusion:

- In patients with cardiac arrhythmias who require single-chamber ventricular pacing, there is insufficient evidence to compare leadless pacemakers with conventional pacemakers. However, serious complications are non-negligible.
- Randomized controlled trials with longer-term follow-up and direct comparisons are warranted.

Articles: PubMed was searched through March 8, 2019 with the search terms ((Nanostim Leadless Pacemaker OR Micra Transcatheter Pacing System OR leadless pacemaker)) AND (traditional pacemakers OR conventional pacemakers). Other search terms included (Nanostim Leadless Pacemaker OR Micra Transcatheter Pacing System OR leadless pacemaker) filters: observational study. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Randomized controlled trials, and observational studies were included in the search. Clinicaltrials.gov was also searched. Three studies were retained and reviewed. See Evidence Table**.**

The use of Leadless Pacemakers for the treatment of cardiac arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

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

Date: July 3, 2022

The Micra TPS is a single-chamber right ventricular pacing device. The device senses electrical activity of the heart via electrodes within the device's titanium capsule. Heart rhythm is monitored for bradycardia. Rate-adaptive pacing therapy is provided based on programmed pacing parameters. The Micra TPS is self-contained and does not require a surgical incision in the chest or intravascular leads. It is inserted via a 23-French catheter placed in the femoral vein and held in place within the right ventricle of the heart via nitinol tines that attach to the myocardium.

Conclusion

A 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. Major complications are comparable with and perhaps lower for Micra TPS versus TVPM, and revision and retrieval rates are lower for Micra TPS than TVPM. 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.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Micra Transcatheter Pacing System(Medtronic Inc.) for Single-Chamber Pacemaker Indications. Dallas, TX: Hayes; July 3, 2022. Retrieved May 15, 2023, from https:// https://evidence.hayesinc.com/report/htb.micrapacing4178

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Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. National Coverage Determinations (NCDs). Updated January 3, 2008. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed November 07, 2023.

Applicable Codes

Leadless Pacemaker

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
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

Single & Dual Chamber Cardiac Pacemaker placement
Medicare- Considered medically necessary when criteria in the applicable policy statements listed above are met
Non-Medicare- Considered medically necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
C1779	Lead, pacemaker, transvenous VDD single pass
C1785	Pacemaker, dual chamber, rate-responsive (implantable)
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1898	Lead, pacemaker, other than transvenous VDD single pass
C2619	Pacemaker, dual chamber, nonrate-responsive (implantable)
C2620	Pacemaker, single chamber, nonrate-responsive (implantable)
C2621	Pacemaker, other than single or dual chamber (implantable)
C7537	Insertion of new or replacement of permanent pacemaker with atrial transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7538	Insertion of new or replacement of permanent pacemaker with ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7539	Insertion of new or replacement of permanent pacemaker with atrial and ventricular transvenous electrode(s), with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time

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	of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)
C7540	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator, dual lead system, with insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (e.g., for upgrade to dual chamber system)

Cardiac Resynchronization Therapy (CRT)
Medicare- Considered medically necessary when criteria in the applicable policy statements listed above are met
Non-Medicare- Considered medically necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
C2621	Pacemaker, other than single or dual chamber (implantable)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/07/2019	05/07/2019[MPC], 05/05/2020[MPC] , 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	11/07/2023

[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt a non-coverage policy for leadless pacemakers
05/05/2020	Added applicable CPT codes 33274 and 33275 to policy
05/15/2023	Updated References to include Hayes Technology assessment
11/07/2023	MPC approved adopting Medicare coverage criteria of Defibrillator and Pacemaker placement for Medicare and non-Medicare. 60-day notice required, effective date April 1, 2024.

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