Medtronic

Medicare Billing Instructions

for Micra™ leadless pacemakers



- Medicare has published coverage with evidence development (CED) claims instructions via Medicare Claims Processing Manual 100-04, Transmittal 3815, which instructs billing staff on how to properly submit claims under national coverage determination (NCD) 20.8.4. for leadless pacemakers.1
- These instructions apply for both traditional Medicare and Medicare Advantage claims.
- For non-Medicare payers, coverage and specific billing instructions may vary. We recommend contacting each individual plan for information.
- Additional coverage, coding, and payment information, along with frequently asked questions, is available in the Micra reimbursement guide found here.
- Example claims that follow contain appropriate additional billing information required by Medicare and are provided for your information only.

Coding for Micra TM implants

Place of service	CPT® ² code and description
Professional and outpatient	33274 Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular,
hospital	including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral
	venography) and device evaluation (e.g., interrogation or programming), when performed
Inpatient hospital	02HK3NZ Insertion of intracardiac pacemaker into right ventricle, percutaneous approach

Medicare leadless pacemaker billing requirements

(all elements are required for claims submission)

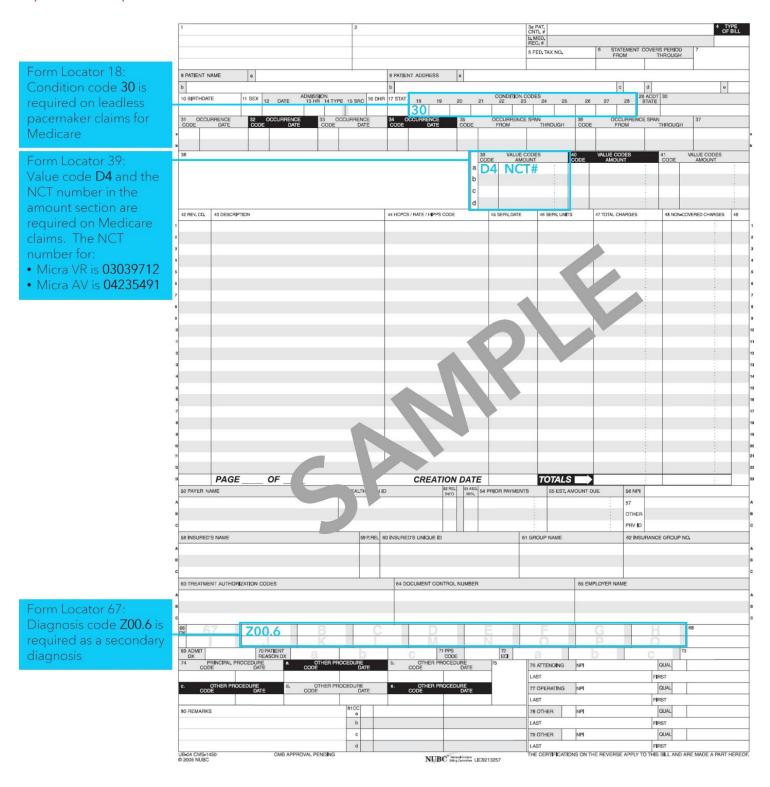
Claim requirement	Identifying information required by leadless pacemaker NCD				
Professional <u>and</u> facility claim requirements					
National clinical trial (NCT) number	Micra VR devices: 03039712 Micra AV devices: 04235491				
Modifier to CPT® implant code (professional and outpatient facility claims only)	Q0 (zero) Investigational clinical service provided in a clinical research study that is in approved clinical research study				
Secondary diagnosis code	Z00.6 Encounter for examination for normal comparison and control in clinical research program				
Additional facility claim requirements					
Condition code	30 ³ Qualifying clinical trial				
Value code	D4 ("Code") and NCT number ("Amount")				

Disclaimer:

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage and payment policies. This document provides assistance for FDA approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA cleared or approved labeling (e.g., instructions for use, operator's manual or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

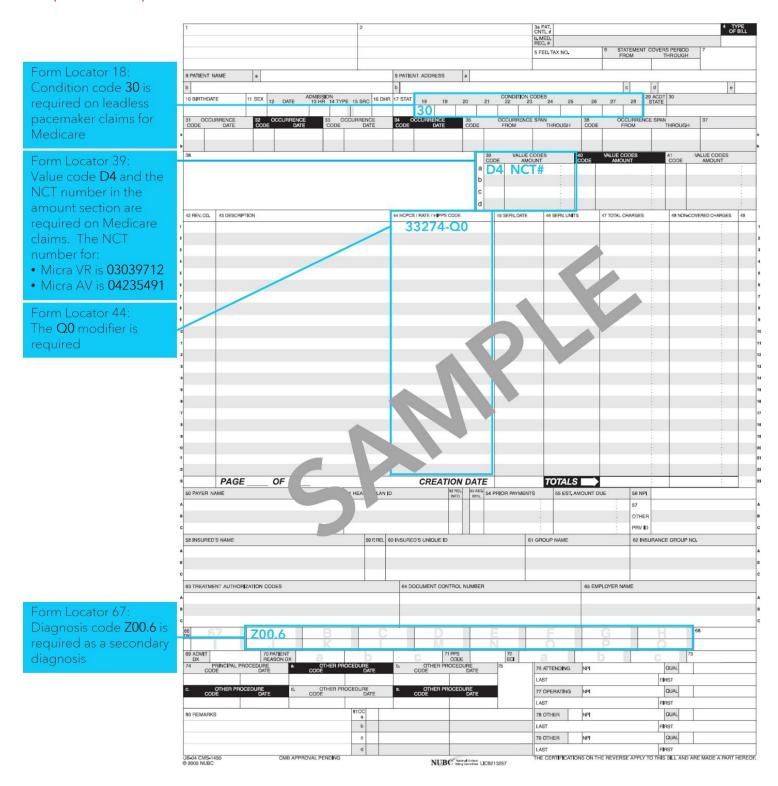
Medicare leadless pacemaker required fields

Inpatient hospital claim form



Medicare leadless pacemaker required fields

Outpatient hospital claim form



Medicare leadless pacemaker required fields

Professional claim form

	APPROVED BY NATIONAL UNIFORM CLAIM COMMITTE	E (NUCC) 02/12			
	PICA				PICA
	MEDICARE MEDICAID TRICARE (Medicare#) (Medicaid#) (ID#/DoD#)	CHAMPVA (Member ID)	- HEALTH PLAN - BLK LUNG	OTHER 1a. INSURED'S I.D. NO	JMBER (For Program in Item 1)
	2. PATIENT'S NAME (Last Name, First Name, Middle Initia				Last Name, First Name, Middle Initial)
	5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSUI	RED 7. INSURED'S ADDRE	SS (No., Street)
	CITY	STATE	8. RESERVED FOR NUCC USE	Other	STATE
	ZIP CODE TELEPHONE (Include	Area Code)		ZIP CODE	TELEPHONE (Include Area Code)
	9. OTHER INSURED'S NAME (Last Name, First Name, M	adata taisinti	10, IS PATIENT'S CONDITION RELATE	ED TO. 14 INCHESTVE BOLLO	Y GROUP OR FECA NUMBER
					and the control of th
	a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previou	a. INSURED: TE C	F BIRTH SEX
	b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? PL	ACE (State) b. OTHE	Designated by NUCC)
	c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT?	c. INSURANCE N	E OR PROGRAM NAME
	d. INSURANCE PLAN NAME OR PROGRAM NAME		YES NO	JCC) THE NOTHE	R HEALTH BENEFIT PLAN?
m 23:	READ BACK OF FORM BEFO	RE COMPLETING	& SIGNING THIS FO	13. INSURED'S OR AU	NO // yes, complete items 9, 9a, and 9d. THORIZED PERSON'S SIGNATURE I authorize
NCT number in the bunt section are	 PATIENT'S OR AUTHORIZED PERSON'S SIGNATUR to process this claim. I also request payment of government. 	tE I authorize the re ent benefits either to	elease of any medical of command of myself or to the party	payment of medical services described	benefits to the undersigned physician or supplier to below.
uired on Medicare	SIGNED			SIGNED	
ns. The NCT nber for:	14. DATE OF CURRENT ILLNESS, INJURY, or PREGNA	NCY (LMP) 45, 0	OTHER DA	YY 16, DATES PATIENT U	NABLE TO WORK IN CURRENT OCCUPATION TO DD YY
icra VR is 03039712	17. NAME OF REFERRING PROVIDER OR OTHER SOU	RCE a.		18. HOSPITALIZATION MM DE	DATES RELATED TO CURRENT SERVICES
icra AV is 04235491	19. ADDITIONAL CLAIM INFORMATION (Designa by I	NUCC)		20. OUTSIDE LAB?	\$ CHARGES
121:	21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY	Helate A- service	Se line below (24E) ICD Ind.	22. RESUBMISSION CODE	NO ORIGINAL REF, NO.
iagnosis code Z00.6 is quired as a secondary	B. 200.6	C. L	D	23. PRIOR AUTHORIZ	
nosis	E F	. G. ∟ . K. ∟	H. L	NCT#	
24D :	From To PLACE OF	C. D. PROCED (Explain MG CPT/HCPC	DURES, SERVICES, OR SUPPLIES in Unusual Circumstances) CS MODIFIER	E. F. DIAGNOSIS POINTER \$ CHARGES	G. H. I. J. J. PSDT ID. RENDERING Plan QUAL. PROVIDER ID. #
Q0 modifier is	1	33274	4 Q0	A,B	NPI
ired	2	1		1	
	3				NPI
					NPI
	4				NPI
	5				NPI
	6				NPI
	25. FEDERAL TAX I.D. NUMBER SSN EIN	26. PATIENT'S AC	(For govt, claims,	GNMENT? 28. TOTAL CHARGE NO \$	29. AMOUNT PAID 30. Rsvd for NUCC
	31. SIGNATURE OF PHYSICIAN OR SUPPLIER	32. SERVICE FAC	CILITY LOCATION INFORMATION	33. BILLING PROVIDE	R INFO & PH # (

Coding, coverage, and reimbursement information is available at: medtronic.com/crhfreimbursement. For questions or for more information, please contact Medtronic Reimbursement Customer Support at 1-866-877-4102 (8:00 a.m. to 5:00 p.m. CT, Monday-Friday) o<u>r rs.healthcareeconomics@medtronic.com</u>.

References

¹Center for Medicare and Medicaid Services. Medicare Claims Processing Manual 100-04, Transmittal 3815. National Coverage Determination (NCD 20.8.4): Leadless Pacemakers. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf. Accessed April 6, 2022.

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³Centers for Medicare and Medicaid Services. Change Request #MM8401 Revised. Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2955CP.pdf. Accessed April 6, 2022.

Brief Statement Micra™ VR2 and Micra™ AV2 Indications

Micra Model MC1VR01, Micra VR2 Model MC2VR01, and Micra AV Model MC1AVR1, are indicated for use in patients who have experienced one or more of

- Paroxysmal or permanent high-grade AV block in the presence of AF
- 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
- 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

Micra AV Model MC1AVR1 is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

The device is designed to be used only in the right ventricle.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity.

Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned

The device is designed to be used only in the right ventricle.

Contraindications

Micra Model MC1VR01, Micra AV Model MC1AVR1, Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 are contraindicated for patients who have the following types of medical devices implanted: 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, or an implanted cardiac device providing active cardiac therapy that may interfere with the $\,$ sensing performance of the Micra device.

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The device is contraindicated for 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 from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

Warnings and Precautions

End of Service (EOS) - When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use - Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the . device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual. Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents. The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explanation of the Micra device, which should be turned off. For Micra AV Model MC1AVR1 and Micra AV2 Model MC2AVR1, patient activities

and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV

Potential Adverse Events or Potential Complications

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 800-328-2518 and/or consult Medtronic's website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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