Medtronic

Engineering the extraordinary

Reimbursement guide

Micra™ leadless pacemakers

Hospital & physician coding, coverage, and payment

May 2023

Hospital & physician reimbursement guide

For Micra™ leadless pacemakers

This guide has been developed to help you understand Medicare coverage, coding, and payment for Micra leadless pacemakers.

Please contact Reimbursement Customer Support for further information:

Website: http://www.medtronic.com/crhfreimbursement

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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.

Overview of Micra™ leadless pacemakers

Micra leadless pacemakers are miniaturized and delivered percutaneously via a minimally invasive approach without the use of leads.

Micra VR leadless pacemakers are FDA-approved for patients who have experienced one or more of the following conditions:

- 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 leadless pacemakers are FDA-approved for patients who are indicated for VDD pacing. See product labelling[3] for indication details.

Coverage for leadless pacemakers

Medicare covers leadless pacemakers under an NCD specifying coverage with evidence development (CED)[4]

- This NCD can be found in Section 20.8.4 of the Medicare NCD Manual.[4]
- This NCD applies to all leadless pacemaker systems and both traditional Medicare and Medicare Advantage beneficiaries
- CED requirements are met when procedures are performed as part of an ongoing, CMS-approved study and used according to the FDA-labeled indications.

Micra CED studies meet Medicare coverage requirements

Medicare approved coverage for beneficiaries enrolled in the Micra CED Study (for patients with Micra VR devices) and the Micra AV CED Study (for patients with Micra AV devices).[6] The clinicaltrials.gov registration provides study descriptions for the Micra CED studies.[7,8]

When a Micra™ procedure claim is submitted to Medicare, the patient is automatically enrolled in a CED study

Click here for more about CED Billing Instructions

Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare but may require prior authorization[11]

We recommend you contact your patient's Medicare Advantage plan for information on requirements that may be applicable.

Click here for more about Medicare Advantage Coverage

Coverage with non-Medicare payers

Non-Medicare payers typically determine coverage for procedures based on coverage policies and prior authorization. We recommend you review the specific payer coverage policies applicable to your patient to verify all the criteria for coverage are met. Not all published policies apply to all patients covered by a particular payer. We recommend that you check for any applicable coverage policy and contact the payer to obtain a prior authorization or prior approval. Asking about coverage after an implant procedure may result in unpaid claims, leaving both the hospital and the physician without compensation.

For additional information regarding the prior authorization process, please refer to our Coverage and Prior Authorization Information document here.

Medicare coverage detail

When a Micra™ procedure claim is submitted to Medicare,

the patient is automatically enrolled in a CED study

Micra claims for traditional Medicare and Medicare Advantage must include the appropriate National Clinical Trials (NCT) to meet the Medicare coverage criteria for the Leadless Pacemaker NCD.[23]

No additional work is required for CED study participation*

Device	Model #	NCT #	CED Study name
Micra VR pacemaker	MC1VR01	03039712	Micra CED study
Micra VR2 pacemaker	MC2VR01		
Micra AV pacemaker	MC1AVR1	04235491	Micra AV CED study
Micra AV2 pacemaker	MC2AVR1		

Click here for more about CED Billing Instructions

*The CED studies have received central IRB approval, so IRB approval at individual hospitals is not necessary.[22, 24] The central IRB also provided a waiver of consent, which means providers are not required to consent patients to the CED studies.[25] For further detail, see guidance issued from the Office of Human Research Protections.[23]

Coding for Micra™ Leadless Pacemakers

The coding information below is for information only and does not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. All diagnosis and procedure codes must be supported by clear documentation within the medical record.[12]

CPT® codes

The following CPT®[13] codes describe procedures associated with Micra™ leadless pacemakers. Documentation will dictate the appropriate coding. These codes may be used by physicians in any setting and may be used by facilities when services are rendered in the outpatient hospital or ambulatory surgery center setting. Leadless pacemaker procedures are not reimbursed in the ASC setting by Medicare.[9]

It is the physician's discretion as to what codes to report based on what procedures were performed and documented.

CPT® code[13]	CPT® code description[13]
Insertion or removal of Micra™ leadless pacemaker	
33274 ⓘ	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed
In-person monitoring	
93279	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead pacemaker system or leadless pacemaker system in one cardiac chamber
93286	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
93288	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead pacemaker system, or leadless pacemaker system
Remote monitoring	
93294	Interrogation device evaluation, remote, up to 90 days, single, dual, or multiple lead pacemaker system, or leadless pacemaker system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
93296	Interrogation device evaluation, remote, up to 90 days, single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

ⓘ Medicare policy requires specific additional information on claims. See billing instructions section here.

HCPCS codes (C-codes) & ICD-10-PCS procedure codes

Medicare provides device C-codes for hospital use in billing Medicare for medical devices in the outpatient setting.[14] The following HCPCS codes relate to the implantation of leadless pacemaker services.

One or more of the following codes may be appropriate depending on the components used in the associated procedure:

HCPCS code	HCPCS code description
C1786	Pacemaker, single chamber, rate-responsive (implantable)
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser

ICD-10-PCS procedure codes

Hospitals assign ICD-10-PCS codes for procedures performed during an inpatient admission. The following ICD-10-PCS codes describe commonly performed leadless pacemaker procedures.

ICD-10-PCS code[15]	ICD-10-PCS code description
Insertion of Micra™ leadless pacemaker	
02HK3NZ (!)	Insertion of intracardiac pacemaker into right ventricle, percutaneous approach
Revision of leadless pacemaker	
02WA3NZ	Revision of intracardiac pacemaker in heart, percutaneous approach
Removal of leadless pacemaker	
02PA3NZ	Removal of intracardiac pacemaker from heart, percutaneous approach
Removal and replacement of leadless pacemaker	
02PA3NZ and 02HK3NZ	Removal of intracardiac pacemaker from heart, percutaneous approach; and insertion of intracardiac pacemaker into right ventricle, percutaneous approach

(!) Medicare policy requires specific additional information on claims. See billing instructions section here.

ICD-10-CM diagnosis codes

Hospitals and other providers assign ICD-10-CM codes to indicate a patient's diagnosis or clinical status. The following is a list of examples of possible ICD-10-CM diagnosis codes that may relate to indications associated with leadless pacemaker procedures. This is not an all-inclusive list and the diagnosis codes reported should be based on documentation appropriate to individual patient presentation.

ICD-10-CM diagnosis code[16]	ICD-10-CM diagnosis code description
Primary (Principal) diagnosis	
I44.1	Atrioventricular block, second degree
I44.2	Atrioventricular block, complete
I49.5	Sick sinus syndrome (Tachy-brady syndrome)
Q24.6	Congenital heart block
Secondary diagnosis	
Z00.6 ⓘ	Encounter for examination for normal comparison and control in clinical research program
Tertiary diagnosis (Used only if applicable)	
I48.0	Paroxysmal atrial fibrillation
I48.1	Persistent atrial fibrillation
I48.2	Chronic atrial fibrillation

ⓘ Medicare policy requires specific additional information on claims. See billing instructions section here.

Payment for Micra™ Leadless Pacemakers

The following information reflects the Medicare national allowable amount published by CMS and does not include Medicare payment reductions resulting from sequestration adjustments to the amount payable to the provider, as mandated by the Budget Control Act of 2011.

The Medtronic Customer Economics and Reimbursement teams can provide site-specific information upon request.

Physician payment

Effective January 1, 2023–December 31, 2023[17]

Physicians use CPT® codes to represent procedures and services performed in all places of service. Under Medicare's methodology for physician payment, each CPT® code is assigned a value, known as relative value units (RVUs). RVUs are part of how Medicare determines a payment amount. RVUs are then converted to a flat payment amount.

CPT® code[13]	Modifier	CPT® description[13]	2023 Medicare national non-facility		2023 Medicare national facility	
			Total RVUs[17]	Payment rate[17]	Total RVUs[17]	Payment rate[17]
Leadless permanent pacemaker procedures						
33274 ⓘ		Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed	N/A	N/A	14.18	$481
33275		Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed	N/A	N/A	14.79	$501
Pacemaker device programming – in person						
93279		Programming device evaluation; single lead or leadless pacemaker system	2.03	$69	N/A	N/A
93279	26		0.92	$31	0.92	$31
93279	TC		1.11	$38	N/A	N/A

ⓘ Medicare policy requires specific additional information on claims. See billing instructions section (pages 19-23) here.

CPT® code[13]	Modifier	CPT® description[13]	2023 Medicare national non-facility		2023 Medicare national facility	
			Total RVUs[17]	Payment rate[17]	Total RVUs[17]	Payment rate[17]
Pacemaker device interrogation – in person						
93288		Interrogation device evaluation; single, dual, or multiple lead or leadless pacemaker system	1.69	$57	N/A	N/A
93288	26		0.60	$20	0.60	$20
93288	TC		1.09	$37	N/A	N/A
Pacemaker device evaluation – remote						
93294	26	Interrogation device evaluation(s); dual, multiple lead or leadless pacemaker system	0.88	$30	0.88	$30
93296	TC	Interrogation device evaluation(s); single, dual, multiple lead or leadless pacemaker system	0.67	$23	N/A	N/A
Peri-procedural device programming						
93286		Peri-procedural device evaluation (in person) and programming device system parameters before or after a surgery, procedure, or test; pacemaker system	1.38	$47	N/A	N/A
93286	26		0.43	$15	0.43	$15
93286	TC		0.95	$32	N/A	N/A

Hospital outpatient payment

Effective January 1, 2023–December 31, 2023[18]

The following CPT®[13] codes describe procedures associated with Micra™ leadless pacemakers. Documentation will dictate the appropriate coding. These codes may be used by physicians in any setting and may be used by facilities when services are rendered in the outpatient hospital or ambulatory surgery center setting. Leadless pacemaker procedures are not reimbursed in the ASC setting by Medicare.[9]

It is the physician's discretion as to what codes to report based on what procedures were performed and documented.

CPT® code[13]	CPT® description	2023 APC[18]	APC title[18]	Status indicator[18]	2023 Medicare national unadjusted rate[18]
Leadless permanent pacemaker procedures					
33274 ⓘ	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed	5194	Level 4 endovascular procedures	J1	$17,178
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed	5183	Level 3 vascular procedures	J1	$2,979

ⓘ Medicare policy requires specific additional information on claims. See billing instructions section (pages 19-23) here.

CPT® code[13]	CPT® description	2023 APC[18]	APC title[18]	Status indicator[18]	2023 Medicare national unadjusted rate[18]
Pacemaker device programming – in person					
93279	Programming device evaluation; single lead or leadless pacemaker system	5741	Level 1 electronic analysis of devices	Q1	$35
Pacemaker device interrogation – in person					
93288	Interrogation device evaluation; single, dual, or multiple lead or leadless pacemaker system	5741	Level 1 electronic analysis of devices	Q1	$35
Pacemaker device evaluation – remote					
93294	Interrogation device evaluation(s); single, dual, multiple lead or leadless pacemaker system	N/A	N/A	M	-
93296	Interrogation device evaluation(s); single, dual, multiple lead or leadless pacemaker system	5741	Level 1 electronic analysis of devices	Q1	$35
Peri-procedure device programming; pacemaker					
93286	Peri-procedural device evaluation (in person) and programming device system parameters before or after a surgery, procedure, or test; pacemaker system	N/A	N/A	N	-

Hospital inpatient payment

Effective October 1, 2022–September 30, 2023[19]

For Medicare, inpatient hospital reimbursement is facilitated through Medicare Severity Diagnosis Related Groups (MS-DRGs).

For each admission, the ICD-10 diagnosis and procedure codes are grouped into one of over 750 MS-DRGs. Regardless of the number of codes, only one MS-DRG is assigned to the inpatient hospital admission.

If medical necessity criteria are met to support an inpatient admission for the leadless pacemaker procedure the MS-DRG[20] assignment may be:

ICD-10-PCS procedure code	MS-DRG description	FY2023 MS-DRG Medicare national unadjusted payment rate[19]
02HK3NZ or 02PA3NZ or 02WA3NZ ⓘ	228: other cardiothoracic procedures with MCC 229: other cardiothoracic procedures without MCC	$33,806 $22,643

ⓘ Medicare policy requires specific additional information on claims. See billing instructions section (pages 19-23) here.

Billing instructions

Click here for visual Medicare claim requirement examples

Medicare has published specific claims submission instructions for leadless pacemakers for traditional Medicare and Medicare Advantage claims

- Medicare Claims Processing Manual 100-04, Transmittal 3815 instructs how to properly submit claims under national coverage determination (NCD) 20.8.4. for leadless pacemakers.[9]
- Instructions apply to Medicare Advantage and traditional Medicare claims.[4, 11] For non-Medicare payers, coverage and specific billing instructions may vary. We recommend contacting each individual plan for information.
- The tables below summarizes the CED billing instructions found in the Medicare Claims Processing Manual 100-04, Transmittal 3815.[21]

Claim Requirement	Identifying information required by leadless pacemaker NCD
National Clinical Trial (NCT) number	Micra VR devices: 03039712 Micra AV devices: 04235491
Modifier to CPT® implant code	-Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Secondary diagnosis code	Z00.6 Encounter for examination for normal comparison and control in clinical research program
Condition code (facility claims only)	30[21] qualifying clinical trial
Value codes (facility claims only)	D4 (“code”) and NCT number (“Amount”)

Billing instructions

Physician claim

CMS 1500 form locator (or electronic equivalent)	Identifying information required by leadless pacemaker NCD
Item 23	Micra VR devices: 03039712 Micra AV devices: 04235491
Item 24D	-Q0 modifier is required on CPT 33274
Item 21	Diagnosis code Z00.6 is required as a secondary diagnosis

Billing instructions

Outpatient hospital claim

UB-04 form locator (or electronic equivalent)	Identifying information required by leadless pacemaker NCD
Form Locator 39	D4 is reported in the Code field. The NCT number is reported in the Amount field. Micra VR devices: 03039712 Micra AV devices: 04235491 Do not include “NCT” prefix.
Form Locator 44	-Q0 modifier is required on CPT 33274
Form Locator 67	Diagnosis code Z00.6 is required as a secondary diagnosis
Form Locator 18	Condition code 30[21] is required

Billing instructions

Inpatient hospital claim

UB-04 form locator	Identifying information required by leadless pacemaker NCD
Form Locator 39	D4 is reported in the Code field. The NCT number is reported in the Amount field. Micra VR devices: 03039712 Micra AV devices: 04235491 Do not include “NCT” prefix.
Form Locator 67	Diagnosis code Z00.6 is required as a secondary diagnosis
Form Locator 18	Condition code 30^{21} is required

Billing instructions

Medicare Advantage payers

Medicare NCDs apply to both traditional Medicare and Medicare Advantage plans.

The Medicare Managed Care Manual establishes that Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare for NCDs requiring CED.[11]

Scan for more information from CMS on Medicare Advantage

(navigate to sections 10.7.1 and 10.7.3)

Medicare Advantage plans

may have specific instructions requiring the specification of the NCT for proper billing. In addition, prior authorization for Micra™ pacemaker insertion procedures may be required from Medicare Advantage plans to determine the applicability of covered benefits for a specific patient case. We recommend you contact your patient's Medicare Advantage plan for information on any claims processing requirements that may be applicable to your Medicare Advantage patients.

Billing instructions

Non-Medicare payers

Important

Providers should confirm coverage with the payer prior to implanting Micra™ Leadless Pacemakers in a patient with commercial insurance. Consult the specific payer coverage policy to determine requirements for coverage and any specific billing instructions, if applicable.

For additional information on private payer coverage, review our FAQ for Micra Leadless Pacemakers U.S. private payer authorization.

Click here to learn more

Frequently asked questions

01

Are leadless pacemaker included in the Medicare single and dual pacemaker NCD?

No, leadless pacemakers have a unique NCD and criteria. See Coverage section of this document for details

02

Are Medicare Advantage (MA) plans required to provide coverage for Micra™ pacemakers?

Yes. Medicare Advantage plans are required by Medicare to process CED claims for their patients. These plans may require additional steps such as prior authorization so check with the specific insurance for any additional requirements. See Billing Instructions section of this document for more details.

03

Is my hospital considered to be engaged in research because of the Micra CED Study protocols?

No. These studies are data collection through billing claims. Hospitals do not need to enroll as a study participant or obtain IRB approval. See Medicare Detailed Coverage section of this document for details.

Frequently asked questions

04

Why do I need to enter the NCT number on leadless pacemaker claims for traditional Medicare and Medicare Advantage?

The NCT number for the CED is required by Medicare and Medicare Advantage to identify that this claim meets the coverage criteria in the Leadless Pacemaker NCD.[4]

05

How do I know which Micra™ CED Study a specific Medicare patient is participating in?

There are separate CED studies for Micra AV and Micra VR devices. The patient's procedure report should have information on which device a patient received.[4] Click here to find the specific NCT numbers for each study.

06

Do CED billing instructions apply for commercial payers or Medicaid?

No, these billing instructions are only required by Medicare and Medicare Advantage. Providers should consult specific payer coverage policy to determine coverage. For additional information, see our Micra Coverage and Prior Authorization resource.

07

Are CMS NCDs binding on all MACs? What about all Medicare Advantage plans?

Yes. CMS NCD decisions are binding on all Medicare contractors, and local Medicare policies cannot be more restrictive than the NCD. Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare but may require prior authorization[11]

Frequently asked questions

08

Are Micra™ procedures reimbursed in the Ambulatory Surgical Center (ASC) for Medicare beneficiaries?

Leadless pacemaker procedures are not reimbursed in the ASC setting by Medicare.[9] While leadless pacemaker procedures are included on the ASC approved procedure list, CMS specifies in Transmittal 3815, Change Request 10117, these procedures can only be performed in certain locations and ASCs are not included in these locations.

09

Why is Micra™ AV reported with the same procedure code as Micra VR? Isn't Micra AV a dual pacing device?

While the Micra AV functions has some functionality like a dual chamber pacemaker, it is physically located in one chamber of the heart so it is reported as a single.

10

Do Micra pacemakers claims need the KX modifier like transvenous pacemaker claims?

No, the KX modifier is not required on leadless pacemaker claims since they are not included in the pacemaker policy that requires it.

References

[1] Williams E, Whiting J. Micra Transcatheter Pacing System Size Comparison. November 2014. Medtronic data on file.

[2] Medtronic Micra™ AV MC1AVR1 Reference Manual. February 2020.

[3] http://manuals.medtronic.com/manuals/main/en_US/home/index.

[4] Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Leadless PACEMAKERS (20.8.4). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=370 Accessed on December 21, 2022.

[5] Centers for Medicare and Medicaid Services. Decision Memo for Leadless Pacemakers (CAG-00448N) Available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=285 Accessed on December 21, 2022.

[6] Centers for Medicare and Medicaid Services. Coverage with Evidence Development: Leadless Pacemakers. Accessed via https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Leadless- Pacemakers Accessed on December 21, 2022.

[7] NIH US National Library of Medicine. Longitudinal Coverage With Evidence Development Study on Micra Leadless Pacemakers (Micra CED). https://clinicaltrials.gov/ct2/show/NCT03039712, Accessed on December 21, 2022.

[8] NIH US National Library of Medicine. Longitudinal Coverage With Evidence Development Study on Micra AV Leadless Pacemakers (Micra AV CED) https://clinicaltrials.gov/ct2/show/NCT04235491 Accessed on December 21, 2022.

[9] Centers for Medicare and Medicaid Services. Medicare Claims Processing Manual 100-04, Transmittal 3815. National Coverage Determination (NCD20.8.4): Leadless Pacemakers. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf Accessed on December 21, 2022

[10] Centers for Medicare and Medicaid Services. Claims Processing Manual Available at. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf. Accessed on December 21, 2022

[11] Centers for Medicare and Medicaid Services. Medicare Managed Care Manual – Chapter 4 section 10.7.1 and 10.7.3 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf Accessed on December 21, 2022

[12] CMS has posted a "Clinical Concepts in Cardiology" tip sheet on their website identifying several clinical documentation tips for Cardiology services and ICD-10-CM diagnosis codes. Codes may have been revised or updated since its publication. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/ICD10ClinicalConceptsCardiology1.pdf Accessed on December 21, 2022

[13] CPT codes and descriptions only are copyright ©2022 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained or not contained herein.

[14] HCPCS 2023 Level II Professional Edition. American Medical Association; 2022.

[15] 2023 ICD-10-PCS. cms.gov. Updated May 26, 2022. Accessed November 21, 2022.

[16] Centers for Disease Control and Prevention, National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). https://www.cdc.gov/nchs/icd/icd10cm.htm. Accessed January 14, 2022.

[17] The Medicare Physician Fee Schedule (MPFS) 2023 National payment rates based on information published in the MPFS final rule CMS-1770-F and updates from the legislation signed on December 29, 2022. PFS Federal Regulation Notices. cms.gov https://www.cms.gov/medicaremedicare-fee-service-paymentphysicianfeeschedpfs-federal-regulation-notices/cms-1770-f Accessed January 10, 2023. PFS Relative Value Files. cms.gov https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files . Local physician rates will vary based on location specific factors not reflected in this document. CMS may make adjustments to any or all ofthe data inputs from time to time.

[18] The OPPS 2023 National payment rates based on information published in the OPPS/ASC final rule CMS-1772-FC and corresponding Addendum B table which was released on November 1, 2022.Hospital Outpatient Regulations and Notices. cms.gov. https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc Accessed November 21, 2022. Hospital specific rates will vary based on various hospital-specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

[19] The IPPS FY 2023 National payment rates based on information published in the IPPS final rule CMS-1771-F and correcting amendment CMS-1771-F2 and corresponding tables and data files which was published on August 10, 2022. IPPS Final Rule Home Page. cms.gov https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page Updated November 17, 2022. Accessed November 21, 2022. Hospital specific rates will vary based on various hospital-specific factors not reflected in this document and CMS may make adjustments to any or all of the data inputs from time to time.

[20] MS-DRG v40.0 Definitions Manual. Cms.gov. https://www.cms.gov/icd10m/version40-fullcode-cms/fullcode_cms/P0001.html Accessed November 21, 2022.

[21] Centers 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 December 21, 2022.

[22] Western IRB. REGULATORY OPINION LETTER – INSTITUTION NOT ENGAGED IN RESEARCH. Letter from WIRB to

Medtronic. April 13, 2017. Available upon request.

[23] U.S. Department of Health & Human Services Office of Human Research Protections. Engagement of Institutions in Human Subjects Research (2008). https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on- engagement-of-institutions/index.html Accessed December 21, 2022.

[24] Western IRB. WIRB Certificate of Approval. STUDY NUM: 117223, WIRB PRO NUM: 20170198. Letter from WIRB to Medtronic. February 6, 2017. Available upon request.

[25] Waiver of consent information. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45- cfr-46/. Accessed December 21, 2022.

Brief Statement

Combined Micra™ VR2 and Micra™ AV2 Indications (or Intended Use)

Micra VR2 Model MC2VR01 is indicated for use in patients who have experienced one or more of the following conditions:

- 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

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 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.
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 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 synchrony.

Potential Adverse Events or Potential Complications

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