Medtronic

Reimbursement Guide

Micra™ Transcatheter pacing system

Hospital & physician coding, coverage, and payment

April 2022

Hospital & physician reimbursement guide

For the Micra™ Transcatheter pacing system

This guide has been developed to help you understand Medicare coverage, coding, and payment for transcatheter pacemaker procedures.

Please contact Reimbursement Customer Support for further information:

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

Phone: 866-877-4102 (M–F, 8:00 a.m. to 5:00 p.m. CT)

Email: rs.healthcareeconomics@medtronic.com

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Overview of the Micra™

Transcatheter pacing systems

Brief background

The Micra™ Transcatheter Pacing System (TPS) is the world's smallest pacemaker, 93% smaller than traditional pacemakers.[1] It is delivered percutaneously via a minimally invasive approach, directly into the right ventricle without the use of leads.

Leadless pacemakers, also known as intracardiac or transcatheter pacemakers, are pacemakers in which the lead(s) and generator are combined into a single device implanted directly within the heart, without any subcutaneous pocket or tunneling.

This contrasts with traditional transvenous pacemakers that require implant of a subcutaneous generator plus transvenous/epicardial lead(s).

Leadless pacemaker device descriptions

The original Micra pacing system, referred to in this document as the Micra™ VR device,* is a single-chamber pacemaker pacing the ventricle.

The Micra™ AV device extends leadless pacing to AV Block-only patients, including a portion of patients who may have traditionally received a dual-chamber transvenous pacing system.

This technology has the unique ability to sense mechanical atrial activity, allowing the device to provide AV synchronous ventricular pacing to indicated patients.[2] The Micra AV device is the same size and maintains the same streamlined implant procedure as the Micra VR device.

*The single chamber Micra™ Transcatheter Pacing System is being described herein as Micra™ VR in order to distinguish it from the Micra™ AV product. When information in this document relates to both Micra AV and VR, "Micra™ Transcatheter Pacing Systems" is used to represent the portfolio of devices.

FDA–approved indications

The Micra TPS

is FDA-approved for patients who have experienced one or more of the following conditions.

Not every Micra TPS model is approved for all indications; please see the product labeling[3] for indication details:

- 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

The Micra AV device 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 individual patients and may not be predictable prior to implant.

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.

Coverage for leadless pacemaker therapy

Medicare national coverage determination criteria for leadless pacemakers[4]

Medicare has a national coverage determination (NCD) designating coverage for leadless pacemakers. This NCD applies to all leadless pacemaker systems, including both Micra™ AV and Micra™ VR devices and can be found in Section 20.8.4 of the Medicare NCD Manual.[4]

Under the NCD, Medicare covers leadless pacemakers through coverage with evidence development (CED), which means CMS will provide coverage for leadless pacemakers when procedures are performed as part of an ongoing, CMS-approved study and used according to the FDA-labeled indications for the device. CMS does not cover leadless pacemakers outside of CMS-approved studies.[5,6]

A current copy of the CMS NCD as well as any related policy articles can be found on the CMS NCD website.[5]

Micra CED studies approved by CMS for coverage

CED studies for both the Micra AV and the Micra VR devices are approved by CMS for purposes of coverage under the NCD, and are posted on the CMS CED website.[7,8] These claims-based studies, in which Medicare beneficiaries receiving leadless pacemakers with Micra devices are automatically enrolled through standard billing practices, satisfy the basis for coverage and enable Medicare reimbursement.

Device	Model #	Study name	NCT #
Micra VR system	MC1VR01	Micra CED study	03039712
Micra AV system	MC1AVR1	Micra AV CED study	04235491

All Medicare patients who undergo a Micra™ implantation procedure in the U.S. will be automatically included in the CED Study specific to the Micra System implanted as described in the table on the previous page.

These studies use retrospective Medicare claims analyses to study patient outcomes, so there is no active data collection from individual hospitals.

Claims for the analysis are identified by CPT® codes and ICD-10 diagnosis and procedure codes and must adhere to the billing requirements from Medicare to meet the coverage criteria.[9,10]

Details can be found in the Billing Instructions section of this document.

In addition, the Micra™ VR and Micra™ AV CED studies have received central IRB approval, so IRB approval at individual hospitals is not necessary.

The clinicaltrials.gov registration provides study descriptions for the Micra AV and Micra VR CED studies.[7,8]

Medicare Advantage coverage

Medicare NCDs apply to both traditional Medicare and Medicare Advantage plans, whether administered directly by CMS or by commercial Medicare Advantage plans. The Medicare Managed Care Manual establishes that Medicare Advantage plans are subject to the same coverage requirements as traditional Medicare for NCD requiring CED, such as the Micra CED studies as described above.[11] Prior authorization for Micra TPS insertion procedures may be required from some commercial insurers to determine the applicability of covered benefits for a specific patient case. We recommend that you contact your patient's Medicare Advantage plan for information on any additional claims processing requirements that may be applicable to your Medicare Advantage patients.

Coverage with non-Medicare payers

Non-Medicare payers typically determine coverage for procedures based on coverage policies and prior authorization. Medtronic recommends that 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.

Coding for leadless pacemaker therapy

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 leadless pacemaker therapy. 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.

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 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 (pages 19-23) here.

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HCPCS codes (C-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, nonlaser

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 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 (pages 19-23) 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

Payment for leadless pacemaker therapy

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, 2022–December 31, 2022[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.

				Medicare Total RVUs		Medicare national Unadjusted rate[17]	
				For physician services provided in:			
Procedure	CPT® code[13]	Mod	CPT® description	Physician office	Facility	Physician office	Facility
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	14.26	N/A	$493
	33275		Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral ventriculography), when performed	N/A	14.85	N/A	$514
Pacemaker device programming-in person	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	2.05	N/A	$71	N/A
	93279	TC		1.13	N/A	$39	N/A
	93279	26		0.92	0.92	$32	$32
Device interrogation-in person	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	1.73	N/A	$60	N/A
	93288	TC		1.12	N/A	$39	N/A
	93288	26		0.61	0.61	$21	$21

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

				Medicare Total RVUs		Medicare national Unadjusted rate[17]	
				For physician services provided in:			
Procedure	CPT® code[13]	Mod	CPT® description	Physician office	Facility	Physician office	Facility
Peri-procedural device programming; pacemaker	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	1.42	N/A	$49	N/A
	93286	TC		0.98	N/A	$34	N/A
	93286	26		0.44	0.44	$15	$15
Device evaluations-remote	93294		Interrogation device evaluation(s) (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	0.88	0.88	$30	$30
	93296		Interrogation device evaluation(s) (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	0.69	N/A	$24	N/A

Hospital outpatient payment

Effective January 1, 2022–December 31, 2022[18]

The following CPT®[13] codes describe procedures associated with Leadless Pacemaker Therapy. These codes may be reported by facilities when services are rendered in the outpatient hospital or ambulatory surgery center setting, when supported by documented medical necessity.

Under Medicare's Ambulatory Payment Classification (APC) methodology for hospital outpatient payment, each CPT® code is assigned to an ambulatory payment class. Each APC has a relative weight that is then converted to a flat payment amount.

CPT® code[13]	CPT® description	2022 APC[18]	APC title[18]	Status indicator[18]	Relative weight[18]	2022 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	194.86	$16,402
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	34.73	$2,924

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

CPT® code[13]	CPT® description	2022 APC[18]	APC title[18]	Status indicator[18]	Relative weight[18]	2022 Medicare national unadjusted rate[18]
Pacemaker device programming-in person						
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	5741	Level 1 electronic analysis of devices	Q1	0.45	$38
Pacemaker device interrogation-in person						
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	5741	Level 1 electronic analysis of devices	Q1	0.45	$38

CPT® code[13]	CPT® description	2022 APC[18]	APC title[18]	Status indicator[18]	Relative weight[18]	2022 Medicare national unadjusted rate[18]
Peri-procedure device programming; pacemaker						
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	N/A	N/A	N	-	-
Pacemaker device evaluation - remote						
93294	Interrogation device evaluation(s) (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	N/A	N/A	M	-	-
93296	Interrogation device evaluation(s) (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	5741	Level 1 electronic analysis of devices	Q1	0.45	$38

Hospital inpatient payment

Effective October 1, 2021–September 30, 2022[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 (Medicare Severity Diagnosis Related Group)[20] assignment may be:

ICD-10-PCS procedure code	MS-DRG description	FY2022 MS-DRG Medicare national unadjusted payment rate[19]
02HK3NZ (!) or 02PA3NZ or 02WA3NZ	228: other cardiothoracic procedures with MCC or 229: other cardiothoracic procedures without MCC	$35,150 $22,692

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

MCC = Major Complication or Comorbidity

Billing instructions

Medicare

Click here for Medicare claim requirement examples

The NCD for Leadless Pacemakers (20.8.4) applies to both traditional Medicare and Medicare Advantage (MA) Plans.4,11 Medicare has published CED claims instructions via Medicare Claims Processing Manual 100-04, Transmittal 3815, which instructs billing staff on how to properly submit claims under NCD 20.8.4.[21]

To facilitate the Medicare claims process, include all the information from the table below, which summarizes the CED billing instructions found in the Medicare Claims Processing Manual 100-04, Transmittal 3815.[21]

Please review the Claims Processing instructions and CMS Claims Processing Manual 100-04 chapter 32 section 69.6 — Requirements for Billing Routine Costs of Clinical Trials, and section 380 — Leadless Pacemakers, for the most up-to-date instructions from CMS for billing for routine services for clinical trials, and for leadless pacemaker services prior to Medicare claims submission.[21,2]

Claims identifying information to signify patient is participating in a study	CED study	
National Clinical Trial (NCT) number	Micra™ VR CED study NCT03039712	Micra™ AV CED study NCT04235491
Modifier to category I 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[23] qualifying clinical trial	

Billing instructions

Hospital claim

Claims identifying information to signify patient is participating in a study	UB-04 form locator hospital claim
National Clinical Trial (NCT) number	NCT03039712 or NCT04235491 FL 39 Value Codes Code: D4 — Amount: ####### D4 is reported in the Code field. The NCT number, without the "NCT" prefix is reported in the Amount field. This will be either "03039712" for patients with a Micra™ VR device or "04235491" for patients with a Micra™ AV device
Modifier to category I CPT® implant code	Modifier to CPT code on hospital outpatient claim -Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study
Secondary diagnosis code	Secondary diagnosis code area of UB-04 Z00.6 Encounter for examination for normal comparison and control in clinical research program
Condition code (facility claims only)	30[23] qualifying clinical trial FL18

Billing instructions

Physician claim

Claims identifying information to signify patient is participating in a study	CMS 1500 form locator physician claim; paper	CMS 1500 form locator physician claim; electronic
National Clinical Trial (NCT) number	NCT03039712 for Micra™ VR device NCT04235491 for Micra™ AV device The NCT number is reported in item 23	NCT03039712 for Micra™ VR device NCT04235491 for Micra™ AV device The NCT number is reported in the electronic equivalent of item 23
Modifier to category I CPT® implant code	-Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study	-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	Z00.6 Encounter for examination for normal comparison and control in clinical research program

Billing instructions

Medicare Advantage payers

As noted earlier,

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

Medicare Advantage plans

may have specific instructions requiring the specification of the NCT for proper billing. In addition, prior authorization for Micra™ TPS 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™ TPS 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 TPS U.S. private payer authorization.

Click here to learn more

Frequently asked questions

01

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

The study is based on which device the patient receives. Leadless pacemaker procedures performed according to FDA indications are eligible for Medicare coverage and reimbursement.

Device	Model number	NCT number
Micra™ VR	MC1VR01	03039712
Micra™ AV	MC1AVR1	04235491

Frequently asked questions

02

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

No. The study involves data collection through CMS standard billing processes for CED studies. Hospitals are not considered a party to the research and are not required to obtain individual IRB approval. Medtronic and CMS are parties to the research and have received IRB approval from Western IRB. Western IRB has also provided a waiver of consent, which means physicians and hospitals are not required to consent patients prior to enrolling them into this study. [24]

WIRB cannot provide a formal regulatory opinion regarding individual institutions without the institution's agreement to rely on WIRB. Many institutions have internal policies for making these decisions, and WIRB cannot provide an opinion for an institution that does not choose to use WIRB as an IRB.

Further detail on this may be accessed from guidance issued from the Office of Human Research Protections (OHRP) "Guidance on Engagement of institutions in Human Subjects Research," (2008).[25]

Click here to learn more

Hospitals do not need to take any action in order to enroll in or approve the Micra™ VR CED Study or Micra™ AV CED Study. As claim-based studies, enrollment will occur through regular claims submission. Similar to other clinical studies, hospitals and physicians need to follow specific claims submission instructions to identify study participation in order to ensure proper claims adjudication and payment.

03

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

The hospital does not have a direct role in this research, and the entities that do have a role in the research (CMS and Medtronic) have obtained IRB approval through WIRB. The Micra VR CED received WIRB approval in 2017 and the Micra AV CED Study was approved by WIRB on January 17, 2020.[26] Any hospital considering a local IRB approval should carefully review its own policies an procedures in addition to this document to determine whether it is necessary to do so.

Frequently asked questions

04

If my hospital is not engaged in research, why do I have to enter the National Clinical Trials (NCT) clinical trial number ofthe billing forms? Which NCT number should I enter?

The NCT number is required for billing to indicate that the procedure is furnished within a CMS-approved CED Study, and therefore meets the Medicare coverage criteria for the Leadless Pacemaker NCD.[23]

- Chapter 32 Section 69.5 from the Medicare Claims Processing Manual instructs[22]: "…it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED."

The inclusion of the NCT number for CED studies does not indicate that a hospital is "engaged in research," but rather specifies that the CED conditions for Medicare coverage have been satisfied.

The NCT number is study-specific as defined in the table below.

Device	Model number	Study name	NCT number
Micra™ VR system	MC1VR01	Micra CED study	03039712
Micra™ AV system	MC1AVR1	Micra AV CED study	04235491

05

When were the Micra CED studies approved and when was coverage effective?

Effective March 9, 2017, Medicare approved coverage for beneficiaries enrolled in the Micra CED Study. This study applies to patients with Micra VR devices.

Medicare approved the Micra AV CED Study as meeting the eligibility requirements for the leadless pacemaker NCD, effective on February 6, 2020.[6] This study applies to patients with Micra AV devices.

Click here to learn more

Frequently asked questions

06

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

Yes. Medicare coverage for leadless pacemaker procedures performed as part of the Micra CED applies to all Medicare plans, whether administered directly by CMS or by commercial MA plans. The Medicare Managed Care Manual establishes that MA plans are subject to the same coverage requirements as traditional Medicare for NCD requiring CED, such as the Micra CED as described above. Prior authorization for Micra TPS insertion procedures may be required from some commercial insurers to determine the applicability of covered benefits for a specific patient case.

07

Are CMS NCDs binding on all MACs?

Yes. CMS NCD decisions are binding on all Medicare contractors, and local Medicare policies cannot be more restrictive than the NCD.

08

Why were the Micra CED studies designed as claims analyses?

The Micra™ VR and Micra™ AV CED studies were designed as prospective longitudinal studies using only the data that CMS requires as part of their standard billing process and requires no special data collection responsibility for the provider that is for research purposes. The use of administrative claims data for research is meant to impose the least amount of administrative burden on the provider.[5]

Frequently asked questions

09

My hospital already has physicians who have been trained on Micra™ via the Medtronic Micra Academy Training program. How does my site enroll in the Micra CED Study or Micra AV CED Study to be reimbursed for procedures?

Hospitals do not need to enroll in the Micra™ VR or Micra™ AV CED studies. As a claims-based studies, enrollment will occur through regular claims submission. Similar to other clinical studies, hospitals and physicians need to follow specific claims submission instructions to identify study participation, however in the case of CED studies, this information further demonstrates that the conditions of coverage under the CMS NCD are met.

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Do I need to notify patients that they are going to be included in the Micra CED studies?

No, it is not required for any hospital to provide notification or informed consent to any Medicare patient treated with a Micra TPS device. This is primarily because the hospital is not considered to be engaged in research.

The entities that are engaged in research are CMS and Medtronic. These entities are required to abide by the HIPAA (Health Insurance Portability and Accountability Act) regulations. For access by these entities to the data for research, the central IRB (WIRB) has found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(d).[27]

11

In what settings can a leadless pacemaker be inserted?

Leadless pacemaker insertions with Micra systems are covered and paid by Medicare in hospital inpatient and hospital outpatient settings. Leadless pacemaker procedures are not payable in the ASC setting.[21]

Frequently asked questions

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Does the CMS Medicare NCD apply to state Medicaid patients?

No. We suggest that a patient's physician contact Medicaid to request pre-authorization for specific patients, providing supporting documentation as to why a Micra TPS is the optimal option for each patient.

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Are there separate remote monitoring codes for leadless pacemakers?

No. The same remote monitoring codes that are used for transvenous pacemaker are applicable to leadless pacemaker monitoring services. Please refer to CPT manual for appropriate CPT® codes.

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Who should I contact for more information about coding, coverage and/or reimbursement pertaining to the Micra™ leadless pacemaker system?

If you have additional questions on leadless pacemaker reimbursement, please visit our website at: medtronic.com/micrareimbursement, call us at 1-866-877-4102, Monday–Friday from 8 a.m. to 5 p.m. CST, or email us at: rs.healthcareeconomics@medtronic.com, or contact your local Medtronic Regional Economic Manager (REM).

If you need to learn who is the REM for your institution, please contact your Medtronic sales representative, or send an email to: rs.healthcareeconomics@medtronic.com.

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[13] CPT codes and descriptions only are copyright ©2021 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.

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Indications (or intended use)

Micra™ devices, Micra Model MC1VR01 and Micra™ AV Model MC1AVR1, are 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

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 individual patients and may not be predictable prior to implant.

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.

Contraindications

Micra Model MC1VR01 and Micra AV Model MC1AVR1 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.

Warning 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. For Micra Model MC1VR01, asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome. 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, 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, acceleration of tachycardia, necrosis, myocardial infarction 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 1-800-328-2518 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.

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

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