



## Coding and payment overview

### CardioInsight™ noninvasive 3D mapping system

#### Brief background

The CardioInsight™ Mapping Vest is a single-use, disposable multi-electrode vest that gathers cardiac electrophysiological data from the body surface. The CardioInsight™ Noninvasive 3D Mapping System combines these signals with CT scan data to produce and display simultaneous, bi-atrial and biventricular, 3-D cardiac maps.

The CardioInsight Mapping Vest and the CardioInsight Workstation function together as the CardioInsight Noninvasive 3D Mapping System.

#### Commonly billed codes and associated Medicare rates

There are currently no specific codes or separate payment for the CardioInsight 3D mapping system. This document reflects the commonly billed codes and the associated 2023 Medicare National reimbursement rates for the CT scans that are performed in conjunction with the CardioInsight system. This is not an all-inclusive list.

#### 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.

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## Hospital outpatient

### Procedure codes and 2023 Medicare national payment information

Hospital outpatient reimbursement is subject to various packaging rules, including Comprehensive APCs (C-APCs). Under C-APCs, only one payment is made for all procedures and supplies provided during the outpatient episode of care.

CPT® Code <sup>1</sup>	Description	C-APC	2023 Medicare national unadjusted APC* hospital outpatient payment <sup>2</sup>	Status indicator <sup>3,4</sup>
75571	Computed tomography, heart, <b>without contrast material</b> , with quantitative evaluation of coronary calcium	5521	\$87	Q1 <sup>a</sup> - bundles into any other procedure performed
75572	Computed tomography, heart, with contrast material, <b>for evaluation of cardiac structure and morphology</b> (including 3-D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)	5571	\$180	S <sup>b</sup> - significant procedure not subject to multiple procedure discounting.
75573	Computed tomography, heart, with contrast material, <b>for evaluation of cardiac structure and morphology in the setting of congenital heart disease</b> (including 3-D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)			NOTE: Ablation procedures are assigned a status code J1: all covered Part B services on the claim are packaged with the primary service for the claim
75574	Computed tomographic angiography, <b>heart, coronary arteries and bypass grafts</b> (when present), with contrast material, including 3-D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)			

\*APC: Ambulatory Payment Classification

<sup>a</sup>: If this procedure is performed during the same (or concurrent) episode of care as a procedure assigned status indicator "S," "T," or "V," this procedure will be packaged into the APC payment and not paid separately.

<sup>b</sup>: If the heart CT is performed during the same (or concurrent) episode of care as an ablation, the heart CT will bundle into the Comprehensive-Ambulatory Payment Classification (C-APC) for ablation procedure and will not be paid separately (status indicator J1.) If the heart CT is performed outside the surgical episode, the service is separately reimbursable.

## Physician

### Procedure codes and 2023 Medicare national payment information

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 Healthcare Economics and Reimbursement team can provide site-specific information reflective of sequestration upon request.

CPT® Code <sup>1</sup>	Description	2023 Medicare national unadjusted physician payment <sup>5</sup>	2023 physician work RVU <sup>6</sup>	2023 total RVU <sup>6</sup>
75571-26	Computed tomography, heart, <b>without contrast material</b> , with quantitative evaluation of coronary calcium, would be used for the study without contrast (3-D imaging is considered bundled into this service and is not separately reimbursed.)	\$28	0.58	0.83
75572-26	Computed tomography, heart, with contrast material, <b>for evaluation of cardiac structure and morphology</b> (including 3-D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)	\$83	1.75	2.45
75573-26	Computed tomography, heart, with contrast material, <b>for evaluation of cardiac structure and morphology in the setting of congenital heart disease</b> (including 3-D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)	\$121	2.55	3.57
75574-26	Computed tomographic angiography, <b>heart, coronary arteries and bypass grafts</b> (when present), with contrast material, including 3-D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)	\$114	2.40	3.36

- -26 Professional Component
- Physician interpretation and report is separately reimbursable when medical necessity is met

## Medical necessity

Medical necessity may be established through documentation of:

- Any prior incidents, signs, or symptoms, that might suggest a history of possible arrhythmia
- Any significant risk factors or comorbidities that may affect clinical management

## Documentation

Physician documentation must include description of images, the use of an independent workstation for 3-D image postprocessing, and findings. An “independent workstation” is a separate computer or workstation used for the purpose of 3-D reconstruction. Documentation should also include why the service is medically necessary including signs, symptoms, and diagnosis that required the mapping.

## Payment scenarios

Hospital payment in the outpatient setting is differentiated by whether the heart CT procedure is performed in the same episode of care as other procedures, such as an ablation. Hospital outpatient procedures are generally considered the same episode of care when they have the same date of service but could include an overnight stay. If the heart CT is performed during the same (or concurrent) episode of care as an ablation, payment for the heart CT, will be bundled into the Comprehensive-Ambulatory Payment Classification (C-APC) for the ablation procedure. If the heart CT is performed outside the surgical episode, the service may be separately reimbursable. Physician interpretation and report may be separately reimbursed under either scenario.

## Billing scenarios

1. Patient has known focal VT in the left ventricular outflow tract, a heart CT with the CardiInsight system is used for mapping only a day prior to ablation.

Provider	Reimbursed?
Hospital	<b>Yes</b> , CT may be separately reimbursed
Physician	<b>Yes</b> , CT may be separately reimbursed

2. Patient has known persistent AF, but the precise location for treatment is unknown. A CT with the CardiInsight system is used to aid the physician in analyzing the location for treatment on the same date as the ablation.

Provider	Reimbursed?
Hospital	<b>No</b> , bundled into ablation; CT receives no separate additional reimbursement
Physician	<b>Yes</b> , CT may be separately reimbursed

### Billing scenarios (cont'd.)

3. Patient has paroxysmal AF and has previously been ablated. Symptoms remain and a CT with the CardioInsight system is being used by the physician to determine where to ablate in a redo procedure.

Provider	Reimbursed?
Hospital	<p><b>Yes</b>, may be separately reimbursed if done prior to the day of the ablation</p> <p><b>No</b>, if done on the same date or encounter as the ablation, reimbursement is bundled into the ablation procedure; CT receives no separate, additional reimbursement</p>
Physician	<b>Yes</b> , CT may be separately reimbursed

4. Patient has premature ventricular contraction (PVC) that have previously been unable to map with intracardiac mapping systems. CIT system is used by the physician to determine the treatment strategy with the analysis of the PVC location.

Provider	Reimbursed?
Hospital	<p><b>Yes</b>, may be separately reimbursed if done prior to the day of the ablation</p> <p><b>No</b>, if done on the same date or encounter as the ablation, reimbursement is bundled into the ablation procedure; CT receives no separate, additional reimbursement</p>
Physician	<b>Yes</b> , CT may be separately reimbursed

5. A CT with the CardioInsight system is used intra-procedurally to re-map after ablation therapy is delivered, to see how the heart's activity has changed and whether any further ablation lesions may be needed.

Provider	Reimbursed?
Hospital	<b>No</b> , if done on the same date or encounter as the ablation, reimbursement is bundled into the ablation procedure; CT receives no separate, additional reimbursement
Physician	<b>Yes</b> , CT may be separately reimbursed

## Contact

Cardiac Rhythm and Heart Failure, Cardiac Catheter Ablation, and Cardiac Diagnostic coding, coverage, and reimbursement information is available at [medtronic.com/CRHFreimbursement](https://www.medtronic.com/CRHFreimbursement).

For questions or more information, please contact Reimbursement Customer Support at 1-866-877-4102 (M-F, 8:00 a.m. to 5:00 p.m. CT) or [rs.healthcareconomics@medtronic.com](mailto:rs.healthcareconomics@medtronic.com).

### References

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<sup>2</sup> 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/medicare/medicare-fee-service-payment/hospitaloutpatientppshospital-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.

<sup>3</sup> Some services may be bundled into base imaging procedure or index procedure. Reference NCCI for coding guidance for specific coding combinations.

<sup>4</sup> Status S: Significant procedure not subject to multiple procedure discounting.

Status Q1: Q1, for STVX-packaged. The STVX-packaged codes (status indicator Q1) are packaged when billed on the same date of service with any other code with a status indicator of S, T, V, or X. If not, they are separately payable under a separate APC. Status J1: All covered Part B services on the claim are packaged with the primary service for the claim, except services with OPPS SI = F, G, H, L, and U; ambulance services.

<sup>5</sup> PFS Federal Regulation Notices. cms.gov <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeeschedpfs-federal-regulation-notices/cms-1770-f> Accessed January 10, 2022. 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 of the data inputs from time to time.

<sup>6</sup> PFS 2023 Final Rule CMS-1770-F released November 2, 2022 and updates from the legislation signed on December 29, 2022. <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeeschedpfs-federal-regulation-notices/cms-1770-f>

## CardioInsight Cardiac Mapping System Brief Statement

### Indications

The CardioInsight Cardiac Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.

### Contraindications

There are no known contraindications.

### Warnings and Precautions

#### Cardiac Mapping System

Warnings:

- Do not modify the attachment plug or use a power adapter. This could cause an electrical hazard. If you require a different electrical socket plug, contact your local Medtronic Representative. CardioInsight™ must always be connected to the power source properly.
- Ensure that all power sources are appropriately rated and are properly grounded or earthed. If the CardioInsight™ system is not properly grounded or earthed, it becomes a possible electric shock hazard. Protection against electrical shock has been provided through an isolation transformer and chassis grounding via a plug to an appropriate power source.

- Electroanatomical mapping with Cardiolnsight™ should ONLY be performed after the risks of the entire procedure, including radiation exposure and time required for signal collection, have been adequately considered for each patient.

Precautions:

- The installation and setup of Cardiolnsight™ and its software should ONLY be performed by trained Medtronic personnel.
- Portable or mobile RF communications equipment may affect Cardiolnsight™.
- Extension cords and electrical power bars should NEVER be used with Cardiolnsight™.
- Cardiolnsight™ should not be connected to any equipment that is not supported by or part of the system.
- The isolation transformer should NEVER be placed on the floor for use.
- Do not stack other equipment on the mapping amplifier or the system cart.
- Do not use the cart for any other purpose than storing and using Cardiolnsight™.
- The workstation that is supplied as part of Cardiolnsight™ is not intended for use without the isolation transformer.
- Devices that connect to Cardiolnsight™ via Universal Serial Bus (USB) such as an external hard drive should be used ONLY after approval by Medtronic as they may introduce computer viruses.
- Installation of software not authorized by Medtronic on the Cardiolnsight™ workstation can cause the system to display inaccurate results or otherwise malfunction, and will void the terms of the product warranty.
- Do not replace the amplifier fuses while the system is in use or connected to the patient.
- Assembly, repair, and modifications of the system over its service life will be evaluated based on the requirements of IEC 60601-1 prior to implementation.
- Cardiolnsight™ should ONLY be used by trained personnel or under the guidance of trained Medtronic personnel.
- Cardiolnsight™ should ONLY be used in an institution's environment.
- Do not use Cardiolnsight™ in the presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide.
- The Cardiolnsight™ acquisition should be performed on the same day as the completion of the CT scan.
- The system cables, including the Sensor Array signal cables and patient ground reference cable are provided non-sterile. DO NOT sterilize the cables.

Sensor Array:

Warnings:

- DO NOT use the Sensor Array if the patient has sensitivity, open sores, or a severe skin condition or disease of the thorax area.
- DO NOT perform magnetic resonance (MR) imaging with the Sensor Array on the patient. The Sensor Array may cause harm to the patient if used in MR imaging. Remove Sensor Array prior to performing MR imaging studies.
- Remove or peel back front Sensor Array panels prior to using an external defibrillator on the patient.

Precautions:

- The Sensor Array should only be connected to the Cardiolnsight™ Cardiac Mapping System.
- The Sensor Array is meant to be used only during computed tomography (CT) imaging procedures that use legally marketed CT scanners.
- The Cardiolnsight™ acquisition should be performed on the same day as the completion of the CT scan. The Sensor Array should not be removed or repositioned between the CT scan and the acquisition.
- The Sensor Array is not sterile and cannot be sterilized. Care should be taken to keep the Sensor Array outside of any sterile field.
- DO NOT expose the Sensor Array to organic solvents such as alcohol. If an organic solvent is used on patient, allow to dry for at least one minute prior to applying Sensor Array.

- DO NOT expose the Sensor Array and electrical connectors to fluids or solvents, except when following the cleaning instructions in the Operator's Manual.
- Store Sensor Array flat (parallel to the floor) with the correct side facing up, as labeled, according to the environmental storage conditions.
- Store Sensor Array panels in their sealed protective pouches until use.
- The Sensor Array is intended for single use ONLY. Reusing the Sensor Array may result in poor system performance or transmission of infection.
- Panels from different Sensor Array sizes should NEVER be mixed and matched for use.
- DO NOT cut or fold the circuitry on the Sensor Array.

### Potential Adverse Events

None known

*Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at [www.medtronic.com](http://www.medtronic.com).*

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

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