



2022 ABBOTT REIMBURSEMENT GUIDE AND FAQ

CardioMEMS™ HF System

Effective February 18, 2022

The CardioMEMS™ HF System Reimbursement Guide and FAQ is intended to provide educational material tied to the reimbursement of the CardioMEMS HF System when used consistently with product labeling. This guide includes information regarding coverage, coding and payment, as well as general information regarding appealing denied claims and providing supporting documentation.

In addition to this guide, Abbott offers a reimbursement hotline that provides live coding and billing information from dedicated reimbursement specialists. Hotline support is available from 8a.m. to 5 p.m. Central Time, Monday through Friday, at 1-855-569-6430 or email PTAHotline@abbott.com.

This guide and all supporting documents are available for download at www.cardiovascular.abbott/reimbursement.

This guide and all hotline reimbursement assistance is provided subject to the disclaimers set forth herein.

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HEALTH ECONOMICS & REIMBURSEMENT

CODING FOR THE CARDIOMEMS™ HF SYSTEM

For in depth coding guidance and reimbursement rates, please refer to Abbott’s 2022 Coding Guide for the CardioMEMS™ HF System.

OUTPATIENT¹ and PHYSICIAN² CODING

HCPCS CODE	DESCRIPTION	OUTPATIENT APC	PHYSICIAN WORK RVU
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography	5200	6.00
C2624	Implantable wireless pulmonary pressure sensor with delivery catheter, including all system components	Packaged	N/A
REMOTE MONITORING			
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	N/A	0.70
G2066	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	5741	N/A

INPATIENT CODING³

ICD-10-PCS CODE	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT
IMPLANT		
02HQ30Z	Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach	264
02HR30Z	Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach	

COVERAGE FOR THE CARDIOMEMS HF SYSTEM

Coverage refers to the criteria and policies under which a payer determines what services and procedures it will reimburse. Coverage is usually described in medical policies and is payer specific.

MEDICARE COVERAGE

Medicare provides coverage for “medically reasonable and necessary” services. Medicare provides guidance through national coverage determinations (NCDs) and local coverage determinations (LCDs). Currently, there is no NCD related to the CardioMEMS HF System. The local MACs provide coverage for the CardioMEMS HF System in the absence of a national policy. The MACs cover the CardioMEMS HF System based on “reasonable and necessary” guidelines. At this time, there are no LCDs in place for CardioMEMS. Providers can implant the pulmonary artery (PA) pressure sensor (CPT± 33289) and provide remote monitoring services (CPT 93264) for

appropriately indicated Medicare patients based on reasonable and medically necessary guidelines. Providers should always document medical necessity of the CardioMEMS HF System for their patients.

Traditional Medicare fee-for-service does not require prior authorization. Providers should continue to prior authorize for Medicare Advantage Plans as these plans are administrated by the commercial payers. In the absence of a local or national Medicare policy, Medicare Advantage Plans may choose to cover (or not cover) the CardioMEMS HF System based on medical necessity. This is the reason why prior authorization continues to be important in obtaining individual case consideration supporting coverage.

COMMERCIAL PAYER POLICIES

Commercial insurers’ coverage policies will vary. Some payers currently maintain non-coverage policies for hemodynamic monitoring. We strongly encourage

healthcare professionals (HCPs) to contact their payer(s) directly with questions regarding medical policies or guidelines for the CardioMEMS™ HF System. In addition, we provide general guidance with respect to private payers. Please contact us at 1-855-569-6430 or at hce@abbott.com.

CARDIOMEMS HF SYSTEM REIMBURSEMENT – WHAT'S NEW?

EXPANDED INDICATION

On February 18, 2022, the Food and Drug Administration (FDA) approved for an expanded indication:

The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

The indication expansion follows the publication of the randomized-control results of the GUIDE-HF trial that demonstrated a 19% reduction in primary endpoint events driven by a 28% reduction in HF hospitalizations in the prespecified “pre-COVID analysis”.⁴ The pre-COVID analysis also showed that hemodynamic monitoring was safe and effective for patients in earlier stages of HF (NYHA Class II patients).

Questions related to the coding, coverage, and payment can be found in the FAQ section of this document.

PATIENT ELECTRONICS UNIT REPLACEMENT

For replacement of the CardioMEMS Patient Electronic System (PES) that falls outside of the manufacturer’s warranty, providers will have the opportunity to furnish replacements based on the medical policies and guidelines for Medicare and/or commercial payers. Please check with your payer.

Unlisted code **L9900: Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS code**, may be utilized for the replacement.⁵

As the replacement PES is reported under the unlisted supply code, there is no defined payment amount. Payment is determined by your payer or MAC, which will require appropriate documentation of medical necessity and an invoice for coverage and payment consideration.

PAYMENT CONSIDERATIONS – PHYSICIAN

Commercial payers may require prior authorization to justify medical necessity for the CardioMEMS HF System implant procedure due to lack of defined coverage policies or existing non-coverage policies. Please note that traditional Medicare does not allow for prior authorization.

Prior authorization requests and claims must be submitted with supporting documentation and may be subject to a medical director review. Supporting documentation varies by payer but generally should include the following:

- A cover letter describing the service rendered, why the service was needed – medical necessity
- Operative report that details the procedure
- Medical necessity for the procedure
- Any complicating circumstances (such as complexity of symptoms and concurrent problems)

The appeals process (e.g., traditional appeal and/or expedited review) provides an opportunity to request a case exception for review of medical necessity of the patient’s claim. For more information or assistance with commercial payer or Medicare appeals or resubmission processes, please contact our Reimbursement Hotline at 1-855-569-6430.

Payers may request technical information about the CardioMEMS HF System and clinical justification for its use either generally or in a particular case. Such requests may be made by “suspending the claim for development” (i.e., placing the processing of the claim on hold, pending receipt of further information), or by issuing a denial of the claim to elicit additional information through the appeals process. Physicians should be prepared to provide well-documented responses to payer questions.

HOSPITAL INPATIENT CODING AND PAYMENT

For FY2022, the CardioMEMS HF System’s implant procedure generally will map to MS-DRG 264 (other circulatory system operating room procedures) when reported with ICD-10-PCS code 02HQ30Z or 02HR30Z. Other criteria may apply to justify an inpatient stay for the implant procedure (e.g., Medicare’s ‘two-midnight rule’).

HOSPITAL OUTPATIENT CODING AND PAYMENT

Comprehensive Ambulatory Payment Classifications (C-APC) 5200 represents the CardioMEMS HF System implant. This C-APC includes a right heart catheterization, implantation of the wireless PA pressure device and associated angiography. A C-APC represents a bundled payment that includes the primary service and all adjunct services to support the delivery of the primary service. As a result, for Medicare claims, both the CPT⁺ code 33289 and

HCP code C2624 should be reported together when implanting the CardioMEMS™ HF System.

HOSPITAL PAYMENT CONSIDERATIONS – PRIVATE INSURERS

Payment to hospitals by private insurers takes many forms. Where there are contracted case rates or negotiated, fixed procedure prices, private insurer payment for the CardioMEMS HF System may follow the Medicare model, with the costs of the procedure included in the cost of some other primary diagnostic or therapeutic intervention. Other private payers may pay hospitals on a charge-related basis with payment based on submitted charges for the CardioMEMS HF System and other procedural inputs. It is best to review the applicable private payer contracts and ensure that the established rates appropriately reflect the device and the procedure.

NON-COVERED SERVICES

Medicare and some private payers will allow the HCP to seek and collect payment from patients for non-covered services, as long as the HCP first obtains the patient's written consent. This may be the case as it relates to non-coverage policies for the CardioMEMS HF System technology. Obtaining this consent helps protect the HCP's right to bill and collect from the patient for services rendered when it is unknown whether the payer will ultimately provide coverage for the procedure. The consent must be signed and dated by the patient or legal guardian prior to the provision of the specific procedure(s) in question.

The written consent generally includes the following:

- The name of the procedure(s) and/or supplies requested for treatment.
- An estimate of the charges for the procedure(s).
- A statement of reason why the HCP believes the procedure(s) may not be covered.
- A statement indicating that if the planned procedure(s) are not covered by the payer, the patient member agrees to be responsible for the charges.

If the HCP does not obtain written consent, the provider must accept full financial liability for the cost of care. General agreements to pay, such as those signed by patients at the time of an office visit, are not considered written consent. A copy of the signed written consent form must be retained in the patient's medical records should questions arise at a later date.

For Medicare, an Advance Beneficiary Notice (ABN) is

required in advance of the service being provided.

Instructions for ABNs can be found at <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html>.

Each payer may have different requirements regarding patient consent, and it is strongly recommended to check with the payer on their specific requirements.

SERVICES REQUIRING PRIOR AUTHORIZATION FOR PRIVATE PAYERS

Prior authorization, sometimes referred to as “pre-certification,” is the process used to verify whether a proposed service or procedure is appropriate and medically necessary. Whenever possible, prior authorization should occur before a procedure is furnished.

Prior authorizations are for certain services and/or procedures that require review and approval prior to being provided. Some services and/or procedures that require prior authorization include inpatient admissions, selected surgical procedures and certain outpatient procedures. When care is performed or coordinated by a primary care physician (for those in the health maintenance organization and point-of-service plans), the network provider is responsible for obtaining prior authorization.

The physician who schedules an admission or orders the procedure is responsible for obtaining prior authorization. Providers should contact the payer to confirm if prior authorization is required.

For questions regarding the prior authorization process, please contact Abbott's reimbursement hotline at 1-855-569-6430.

APPEALING A DENIED CLAIM

An appeal is a request for review of a denied claim or service. Claims may be denied for a variety of reasons, including the result of health plan errors, inaccurate patient or claim information submission, inaccurate coding and/or payer coverage policy. The reason for denial can be found in the denial letter and/or the Provider Remittance Advice.

Depending on the payer, the level of appeal may be considered a reconsideration, redetermination, grievance or appeal. Additionally, each payer may have different administrative requirements for each of these levels based on their own definitions. We suggest contacting the payer directly to verify the appeal requirements, including what forms are required, what supporting documentation is required (including if a letter of medical necessity is required), the time limits for requesting an appeal and an

explanation of the specific appeal process.

If the payer does not have a required appeal form, submit an appeal letter. The appeal letter should be tailored to the reason for the denial. It should clearly articulate why the procedure was medically necessary for the patient. In addition, the appeal letter may include a corrected claim, product information, patient information, clinical data and other requested supporting documentation.

The more complete and detailed the appeal, the more likely it is to be successful in securing payment. The specificity of the medical necessity information and the documentation provided are critical to the success of the appeal. It is also important that the provider attach any medical documentation that may support the medical necessity of the procedure.

Another resource that providers and patients can pursue beyond the appeal process is an expedited external review. An external review is part of the health insurance claims denial process and occurs when an independent third party reviews an individual's claim to determine whether or not the insurance company is obligated to pay. An external review is performed after the appellant has exhausted the insurance company's internal review process without success.

If you have additional questions regarding the process to appeal a denied claim, please contact Abbott's reimbursement hotline from 8 a.m. to 5 p.m. Central Standard Time, Monday through Friday, at 1-855-569-6430.

EXPANDED INDICATION REIMBURSEMENT QUESTIONS

GENERAL QUESTIONS

What are BNP and NT-proBNP and how do they relate to heart failure?

B-type natriuretic peptide (BNP) is a hormone produced by the myocardium. N-terminal (NT)-pro hormone BNP (NT-proBNP) is a non-active prohormone that is released from the same molecule that produces BNP.

Both BNP and NT-proBNP are released in response to changes in pressures inside the heart. These changes can be related to heart failure and other cardiac problems. Levels go up when heart failure develops or gets worse, and levels goes down when heart failure is stable.

Please refer to the CardioMEMS™ HF System IFU for BNP/NT-proBNP thresholds.

COVERAGE FOR EXPANDED INDICATION

Does traditional Medicare fee-for-service cover the new expanded indication?

As stated previously, traditional Medicare provides coverage for “medically reasonable and necessary” services. Currently, there is no NCD related to the CardioMEMS HF System. The local MACs provide coverage for the CardioMEMS HF System in the absence of a national policy. To date, there are no LCDs for CardioMEMS (implant and monitoring) and the MACs cover these services based on general “reasonable and necessary” guidelines. These guidelines apply to the expanded indication as they applied to the original indication.

Will Medicare Advantage Plans and commercial payers who have positive coverage policies for the previous indication apply to the expanded indication?

In the absence of a local or national Medicare policy, Medicare Advantage Plans can choose to cover or not cover the CardioMEMS HF System based on medical necessity. Many plans apply their commercial coverage policies for PAP monitoring to Medicare Advantage enrollees. Some Medicare Advantage plans and commercial payers have positive coverage policies for the previous indication for the CardioMEMS HF System. **However, this does not guarantee that the policy for the prior indication will apply to the expanded indication.** This is the reason why prior authorization continues to be important in obtaining individual case consideration supporting coverage.

CODING FOR EXPANDED INDICATION

Are there any ICD-10-CM diagnosis codes differentiating between NYHA Class II and Class III patients?

Currently, ICD-10-CM does not differentiate heart failure based on NYHA Class.⁶ ICD-10 code set I50.x applies to heart failure patients and should be reflective of the broader heart failure population, some of whom may be indicated for the CardioMEMS™ HF System procedure.

Are there additional procedural codes to support the implant or remote monitoring for the expanded indication?

The current procedure codes for the implant, both inpatient and outpatient, apply to the initial and expanded indications. The remote monitoring codes also may be utilized for all indicated patients. Please refer to Abbott's 2022 CardioMEMS HF System Coding Guide for further information on the requirements of the codes for billing.

Is there a CPT⁺ code for a BNP/NT-proBNP test?

CPT⁺ code **83880: *Natriuretic peptide*** may be utilized for billing purposes.

CODING AND BILLING QUESTIONS – GENERAL

What are the ICD-10-CM diagnosis codes for FDA-approved indications for the CardioMEMS HF System?

ICD-10 codes set I50.x apply to heart failure patients and should be reflective of the broader heart failure population, some of whom may be indicated for the CardioMEMS HF System procedure.

Will CardioMEMS HF System patients have coinsurance responsibility for remote services performed?

It depends on the patient's insurance. Please verify with your patient's health plan.

CODING AND BILLING QUESTIONS – PHYSICIAN

What are the requirements for reporting CPT⁺ code 93264?

According to the 2022 CPT⁺ code manual, additional parentheticals and/or criteria around code 93264 include the following:

- Report 93264, only once per 30 days.
- Do not report 93264 if download(s), interpretation(s), trend analysis, and report(s) do not occur at least weekly during the 30-day time period.
- Do not report 93264 if review does not occur at least weekly during the 30-day time period.
- Do not report 93264 if monitoring period is less than 30 days.

If a patient has multiple devices such as a CardioMEMS PA Sensor for pulmonary artery (PA) pressure monitoring and a device (e.g., CorVue/OptiVol[‡]) for monitoring intrathoracic impedance, can the same provider bill for both remote monitoring periods represented by codes 93264 and 93297/G2066, respectively?

According to the CPT[‡] code instructions, it states, "Do not report 93297 in conjunction with 93264, 93290, 93298." CPT[‡] code 93264 is used specifically for reporting remote monitoring of an implantable wireless PA pressure sensor.

We strongly suggest that clinicians verify with their billers and coders to determine if monitoring for intrathoracic impedance with the CorVue or OptiVol systems constitutes a distinct service that is different than the work done with remote monitoring via PA pressures. The Correct Coding Initiative (CCI) may allow for modifiers to be utilized when

such circumstances exist based on medical necessity and supporting documentation. We advise that you follow up with your coders and payers to determine how they cover and treat the different mechanisms for reporting remote monitoring.

CODING AND BILLING QUESTIONS – INPATIENT AND OUTPATIENT HOSPITAL

Is CPT[‡] code 93264 reimbursed when the technical services (e.g., data acquisitions for and distribution of results) are performed in the outpatient hospital?

Based on the CY2022 Medicare Outpatient Hospital Payment Final Rule, CPT[‡] code 93264 has a status indicator of "M" stating not payable in the outpatient hospital. CPT[‡] code 93264 is for physician reporting of remote monitoring of PA pressures. There is no separate component for the hospital to bill 93264.

If the outpatient hospital acquires the PA pressure data for remote technical support and distribution of results, how should they report this service?

Assuming the hospital meets the requirements of the newly created HCPCS code G2066, they may be able to bill with this code based on medical appropriateness and documentation. G2066 has a site-of-service differential payment when performed in the outpatient hospital versus when performed in the physician's office setting. It is important to verify with your institution's coders and your MAC and private payers. CPT 93264 may not be used for outpatient hospital billing of remote monitoring (outpatient hospital status indicator "M" non-payable).

REFERENCES

1. Hospital Outpatient Prospective Payment-CY2022 Notice of Final Rulemaking with Comment Period (NFRM). CMS-1753-FC: <https://www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientpps/cms-1753-fc>
2. Physician Prospective Payment-Final rule with Comment Period and Final CY2022 Payment Rates. CMS-1751-F: <https://www.cms.gov/medicare/medicare-fee-service-payment/physicianfeeschedpfs-federal-regulation-notices/cms-1751-f>
3. Hospital Inpatient Prospective Payment-Final Rule and Correction Notice. CMS-1752-CN2: <https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ippa-final-rule-home-page>
4. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomised controlled trial. Lancet. 2021;398(10304):991-1001. doi:10.1016/S0140-6736(21)01754-2. PMID: 34461042.
5. CMS 2022 HCPCS Release & Code Sets: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets>
6. CMS 2022 ICD-10-CM: <https://www.cms.gov/medicare/icd-10/2022-icd-10-cm>

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IMPORTANT SAFETY INFORMATION

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

CardioMEMS™ HF System Contraindications: The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product con (when available) or at medical.abott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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