

CardioMEMS™ Heart Failure (HF) System Reimbursement Guide & FAQ

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 in accordance 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.

Abbott offers a reimbursement hotline that provides live coding and billing information from dedicated reimbursement specialists. Hotline support is available 8 am – 5 pm Central Time, Monday through Friday, at 1-855-569-6430 or email hce@abbott.com. In addition to this guide and the Hotline support, Abbott offers a Patient Therapy Access Program to assist with prior authorizations and appeal support. They can be reached at 877-706-7246, extension #3 or email them at PTA_cardiac@abbott.com.

This guide and all supporting documents are available for download at <u>Heart Failure Resources for Medical</u> Reimbursement | Abbott (cardiovascular.abbott).

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

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CODING	TRADITIONAL MEDICARE	COMMERCIAL INSURERS	<u>APPEALS</u>	EXPANDED INDICATION	CODING & BILLING QUESTIONS	IMPORTANT SAFETY INFORMATION
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Coding

PHYSICIAN

Effective January 1, 2019, providers can utilize CPT‡ codes 33289 and **93264 for reporting Pulmonary Artery** (PA) pressure sensor implant and remote.

PHYSICIAN¹

CPT [‡] Code	Description	Work RVU				
IMPLANT						
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.	6.00				
REMOTE MONI	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, interpretations(s), trend analysis, and report(s) by a physician or other qualified health care professional.	0.70				

HOSPITAL OUTPATIENT AND AMBULATGORY SURGURY CENTER (ASC)

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 including 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 HCPCS code C2624 for device should be reported together on claim when implanting the CardioMEMS HF System.

HOSPITAL OUTPATIENT²

CPT [‡] Code	Description	Status Indicator	APC
IMPLANT			
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.	J1	5200

AMBULATORY SURGICAL CENTER³

CPT [‡] Code	Description	Status Indicator
IMPLANT		
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.	18

CMS added 33289 to the ASC setting in 2024. It is best to review applicable commercial contracts and ensure the established rates appropriately reflect the device and procedure costs.

CODING	TRADITIONAL MEDICARE		COMMERCIAL INSURERS	<u>APPEALS</u>	EXPANDED INDICATION	CODING & BILLING QUESTIONS	IMPORTANT SAFETY INFORMATION
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HOSPITAL INPATIENT CODING

For FY2024, the CardioMEMS HF System's implant procedure maps 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').

INPATIENT CODING4

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	264	

Traditional Medicare⁵

NO PRIOR AUTHORIZATION

Traditional Medicare fee-for-service does not require prior authorization. For appropriately indicated patients, coverage is based on reasonable and medically necessary guidelines whether the implant takes place in the Inpatient, Outpatient or ASC setting depending on clinical appropriateness.

MEDICARE GUIDANCE

Medicare provides coverage for "medically reasonable and necessary" services. Medicare provides guidance through national coverage determinations (NCDs) and / or local coverage determinations (LCDs). Currently, there is no NCD, or LCDs related to CardioMEMS HF System. Providers should always document medical necessity of the CardioMEMS HF System for their patients.

Commercial Insurers

HOSPITAL PAYMENT CONSIDERATIONS

Payment to hospitals by commercial insurers take many forms such as contracted or negotiated case rates and fixed procedure prices. In some cases, commercial payers may follow the Medicare model and may pay hospitals on a charge-related basis, meaning they pay a percent of charges billed. It is best to review the applicable commercial payer contracts and ensure the established rates appropriately reflect the device and the procedure.

PRIOR AUTHORIZATION

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 performed.

Prior authorizations is 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.

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 should include the following:

- A cover letter describing the service rendered, why the service was needed medical necessity.
- Operative report detailing procedure performed.
- Clear written documentation demonstrating medical necessity for the procedure.
- Any complicating circumstances (such as complexity of symptoms and concurrent problems).

MEDICARE ADVANTAGE PLANS⁸

Many commercial insurance companies, including those that offer Medicare Advantage plans (MAPs) can require enrollees to get approval from the plan prior to receiving services such as inpatient care. Some commercial and Medicare Advantage plans maintain non-coverage policies for the CardioMEMS HF System. This is the reason prior authorization continues to be important in obtaining individual case consideration supporting coverage. In some emergent HF hospitalization cases where an insurance company has previous denied a prior authorization, the physician can provide the insurance company additional evidence for the medical necessity of PA pressure monitoring. An urgent reconsideration of the prior denial with a request to implant a CardioMEMS HF Sensor may be authorized.

Please see the illustration below for an example of the process:











The Arithmetic Mean Length of Stay (LOS) for HF admissions range from 3.0 to 5.0 days depending on the presence and severity of comorbidities or complications.¹²

TIME

Patient determined appropriate candidate for CardioMEMS HF System.

- Insurance authorization submitted before HF admission.
- · Request DENIED.

Patient admitted for Heart Failure. MD/hospital requests urgent reconsideration of prior denial with request to implant during current inpatient stay.

- Payer may approve implant.
- Implant occurs during HF stay or at other time.

A PATIENT'S INDIVIDUAL CLINICAL CIRCUMSTANCES SHOULD BE THE PRIMARY CONSIDERATION FOR DETERMINING THE APPROPRIATE SITE OF CARE FOR AN IMPLANT

Appeals⁷

COMMERCIAL, MEDICARE ADVANTAGE & TRADITIONAL MEDICARE

A pre-service or post-service appeal, depending on the payer, is a request for review of a service or claim. 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. Contacting the payer directly may allow you 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, you may 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 specificity of the medical necessity information and the documentation provided are critical to the success of the appeal and securing reimbursement. It is also important the provider attach any medical documentation that may support the medical necessity of the procedure.

Another resource 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 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.

Expanded Indication⁶

On February 18, 2022, the Food and Drug Administration (FDA) approved the CardioMEMS HF System 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.

GENERAL INDICATION QUESTIONS

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.⁵

Will Medicare Advantage Plans and commercial payers who have 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 deny the CardioMEMS HF System based on medical necessity. Many plans apply commercial coverage policies for PAP monitoring to Medicare Advantage enrollees. Some Medicare Advantage plans and commercial payers have positive coverage policies for the initial 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 INDICATION QUESTIONS

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

Currently, ICD-10-CM does not differentiate heart failure based on NYHA Class.¹⁰ 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.

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

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

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 2024 CardioMEMS HF System Coding Guide for further information on the requirements of the codes for billing.

 CODING
 TRADITIONAL MEDICARE
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 CODING & BILLING
 IMPORTANT SAFETY

 QUESTIONS
 INFORMATION

HEALTH ECONOMICS & REIMBURSEMENT

Coding and billing questions

GENERAL QUESTIONS

Can I bill for the patient's electronic system?

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 L code,* may be utilized for the replacement.⁹

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.

What is 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.¹⁰

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.

PHYSICIAN QUESTION

What are the requirements for reporting CPT* code 93264?

According to the 2024 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 weeklyduring the 30-day period.
- Do not report 93264 if review does not occur at leastweekly during the 30-day time period.
- Do not report 93264 if monitoring period is less than 30 days.

I have a CardioMEMS HF System candidate hospitalized for a reason unrelated to HF, should I seek approval for a CardioMEMS HF System implant while they're an inpatient?

If the HCP deems CardioMEMS HF System is an appropriate therapy given the patient's condition, and wants to engage with the insurance company, then the physician will need to provide supporting documentation to support medical necessity.

INPATIENT AND OUTPATIENT HOSPITAL QUESTION

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 CY2024 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.

I did not seek approval for CardioMEMS HF System prior to the inpatient admission but now believe CardioMEMS HF System is necessary for my patient. What are some considerations I need to think about regarding seeking approval now?

While a previous denied prior authorization establishes evidence of your treatment intentions, and contains documentation needed for the payer to process an urgent request to implant during the current stay, if the HCP believes it medically necessary, a de novo prior authorization process can be initiated.

It is important to keep in mind for the hospital, it may be difficult to obtain an approval during the current stay (without a previous prior request) and your patient may be discharged before the request is approved.

TRADITIONAL

MEDICARE

I received a prior authorization, but the patient has already been discharged. Are they still able to be implanted later?

State laws and insurance policies state that prior authorizations are valid for a specified amount of time after the approval has been granted.¹¹ Please review your state's laws and insurance company policies regarding how long prior authorizations are valid.

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.

REFERENCES

- 1. Physician Prospective Payment-Final rule with Comment Period and Final CY2024 Payment Rates. CMS-1784-F: CMS-1784-F
- 2. Hospital Outpatient Prospective Payment-CY2024 Notice of Final Rulemaking with Comment Period (NFRM). CMS-1786-FC: CMS-1786-FC
- 3. Ambulatory Surgery Center Payment-CY2024 Notice of Final Rulemaking with Comment Period (NFRM). CMS-1786-FC: CMS-1786-FC
- 4. Hospital Inpatient Prospective Payment-Final Rule 2024. CMS 1785-F. CMS-1785-F
- Novitas Solutions. Reasonable & Necessary Guidelines. Novitas-Solutions. November 01, 2019. Accessed August 7, 2023. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00099545
- 6. Expanded indication approval Premarket Approval (PMA) (fda.gov)
- Centers for Medicare and Medicaid Services. Prior Authorization and Pre-Claim Review Initiatives. CMS. May 15, 2023. Accessed August 7, 2023. https://www.cms.gov/research-statistics-data-systems/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives
- 8. Jacobson G, Neuman T. Prior Authorization in Medicare Advantage Plans: How Often Is It Used? Kaiser Family Foundation. October 24, 2018. Accessed August 7, 2023. https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans-how-often-is-it-used/
- 9. CMS 2024 HCPCS Release & Code Sets: hcpcs release code sets
- 10. CMS 2024 ICD-10-CM: 2024-icd-10-cm
- 11. American Medical Association. Prior Authorization State Law Chart. AMA-ASSN. Accessed August 7, 2023. https://www.ama-assn.org/system/files/2021-04/pa-state-chart.pdf
- 12. Osenenko K, Burden of hospitalization for heart failure in the United States: a systematic literature review (Length of Stay). JMPC.org. February 2022. Accessed April 20.2024. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10373049/

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