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 the product’s labeling. This guide includes information regarding coverage, coding and payment, as well as general education regarding appealing denied claims and supporting documentation.

In addition, Abbott offers a reimbursement hotline, which provides live coding and billing information from dedicated reimbursement specialists. Hotline support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at 855-569-6430 or email hce@sjm.com. This guide and all supporting documents are available for download at https://www.sjm.com/en/professionals/resources-and-reimbursement/reimbursement-support. Hotline reimbursement assistance is provided subject to the disclaimers set forth in this guide.

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CONTENTS

Coverage for the CardioMEMS™ HF System ................................................................. 3
Payment Considerations–Physician .............................................................................. 3
Hospital Inpatient Coding and Payment ................................................................. 4
Hospital Outpatient Coding and Payment .............................................................. 4
Hospital Payment Considerations–Private Insurers .................................................. 4
Non-Covered Services .................................................................................................. 5
Services Requiring Prior Authorization For Private Payers ..................................... 5
Appealing a Denied Claim ......................................................................................... 6
Coding and Billing Questions–General ...................................................................... 6
Coding and Billing Questions–Physician ................................................................. 7
Coding and Billing Questions–Inpatient and Outpatient Hospital ................................ 7
References .................................................................................................................... 8
**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 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. Check with your local Medicare Administrative Contractor (MAC) regarding any LCDs related to the CardioMEMS™ HF System. The MS DRG New Technology Add On Payment for CardioMEMS™ HF System has expired and CMS has replaced those payments with permanent payment mechanisms in both the inpatient and outpatient hospital settings.

Commercial insurers’ coverage policies will vary, and we are aware of some payers maintaining 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 are able to provide general guidance with respect to private payers. Please contact us at (855) 569-6430 or at hce@sjm.com.

Further, as an unlisted CPT code, it may be appropriate to describe professional services furnished by physicians related to the CardioMEMS HF System. Providers may seek and collect payment from patients for non-covered services, as long as the HCP notifies the patient in advance and obtains the patient’s consent (e.g., advance beneficiary notice (ABN)). Advance notice and consent is required by both Medicare and private payers. Further information on the use of unlisted coding, as well as ABN requirements in the event of non-covered services is detailed below, and may be obtained by calling or emailing the Abbott reimbursement hotline between 8 a.m. and 5 p.m. Central Time, Monday through Friday at (855) 569-6430 and hce@sjm.com.

**PAYMENT CONSIDERATIONS—PHYSICIAN**

Physicians anticipate being paid for services provided to patients that are medically reasonable and necessary. Some non-Medicare payers will reimburse for unlisted procedures where prior authorization was obtained (please note that traditional Medicare does not allow for prior authorization). Please check with your patient’s specific plan regarding the appropriate use and reimbursement of unlisted CPT codes, regardless of site of service setting.

An unlisted procedure code provides the means of reporting and tracking procedures or services that do not have an established CPT code until a more specific code is established. Unlisted codes do not include descriptor language that specifies the components of a particular service. Therefore, prior authorization requests and claims must be submitted with supporting documentation and may be subject to a Medical Director review. Similar codes to the unlisted code will be identified to determine reimbursement. Supporting documentation 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.
- Time, effort and equipment needed to perform the procedure and reference of a comparator CPT code commensurate with performing the CardioMEMS PA Sensor implant.
- Any complicating circumstances (such as complexity of symptoms and concurrent problems).

Unlisted CPT codes do not have an assigned payment rate in Medicare’s physician fee schedule, and private insurers do not have assignment of RVUs to use as a basis for setting physician payment. Payers may therefore request additional information to establish a payment rate.
Often, providing a comparable CPT code assists payers in processing claims that include an unlisted procedure and has evolved in industry practice based on expectations from many U.S. commercial insurers and Medicare Administrative Contractors (MAC). Providing a comparable established CPT code that best approximates the effort associated with the unlisted procedure helps the payer better understand what was performed and value it accordingly. This comparable CPT code should be provided in the accompanying documentation when billing the procedure, including a concise description of an “unlisted procedure code” or a “NOC” code in Box 19 of the physician’s claim form. For instance, SCAI recommendations on Box 19 language when billing an unlisted code includes, “XXX99 (unlisted procedure code) comparable to XXXXX, payment of $XXX.XX expected.” Billing professionals should note this field allows for the entry of 71 characters.

Correct procedure will most likely involve appealing an initial denial since most claims with unlisted codes are automatically rejected by payer claims software which cannot handle the non-specific nature of unlisted codes. The appeals process 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 (855) 569-6430.

By statute, CMS expired the inpatient new technology add-on payment on September 30, 2017. For FY 2018, the CardioMEMS HF System’s implant procedure generally will map to MS-DRG 264 (other circulatory system O.R. procedures) when reported with ICD10PCS code 02HQ30Z or 02HR30Z.

Beginning in CY 2017, CMS created comprehensive APC 5200 to represent the CardioMEMS HF System implant which includes procedures for the right heart catheterization with the wireless pulmonary artery 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, both the HCPCS codes C9741 and C2624 should be reported together when performing the CardioMEMS HF System. The C-APC payment replaced the transitional APC pass-through payment status (TAPTS) that expired by statute on December 31, 2016.

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; however, payment may initially be based on submitted charges for the CardioMEMS HF System.

Private payers seeking additional information are most likely to be interested in how the time and other resource requirements for performing a CardioMEMS HF System procedure compare to similar procedures with established payment rates.
**NON-COVERED SERVICES**

Medicare and some private payers will allow the health care professional (HCP) to seek and collect payment from patients for non-covered services, as long as the HCP first obtains the patient’s written consent. Obtaining this consent helps protect the HCP’s right to collect and bill the patient for services rendered when it is unknown whether or not the payer will 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 if 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 your Primary Care Physician (for those in the HMO and POS 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.

If you have additional questions regarding the prior authorization process, please contact Abbott’s reimbursement hotline at 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 (PRA).

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. Please contact Abbott’s Patient Therapy Access team if you would like more information or assistance with this process.

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 Time, Monday through Friday at 855-569-6430.

CODING AND BILLING QUESTIONS–GENERAL

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

The CardioMEMS™ HF System is approved for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in NYHA Class III heart failure patients who have been hospitalized for heart failure in the previous year. ICD-10 codes set I50.x apply to heart failure patients, and should be reflective of the broader HF population, some of whom may be indicated for the CardioMEMS HF System procedure.
Coding and Billing Questions—Physician

Is there a CPT code that specifically describes the insertion of the CardioMEMS™ Pulmonary Artery (PA) Pressure Sensor?

No. As is common with new technology, a CPT code has not yet been created to describe the implant of the CardioMEMS™ PA Pressure Sensor. In the absence of specific codes, physicians may bill for services using CPT 93799, unlisted cardiovascular service or procedure code. For questions about coverage or using an unlisted code, call the Abbott reimbursement hotline at 855-569-6430, or via email at hce@sjm.com. Insertion of the CardioMEMS PA Pressure Sensor is generally done in conjunction with the procedures listed below. The CPT code and descriptor are listed below for convenience.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>93451-26</td>
<td>Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed</td>
</tr>
<tr>
<td>+93568</td>
<td>Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
</tr>
</tbody>
</table>

* Add-on code; Add-on codes are always performed in addition to the primary procedure and are never reported as a stand-alone code.

Can providers also bill for device monitoring when using the CardioMEMS™ HF System?

Yes. Providers can bill for device monitoring once every 30 days; see the following suggested codes used to report monitoring for the CardioMEMS™ HF System:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>93297</td>
<td>Interrogation device evaluation (remote): physician analysis, review and report</td>
</tr>
<tr>
<td>93299</td>
<td>Interrogation device evaluation (remote): receipt of transmission and technician review, technical support and distribution of results</td>
</tr>
</tbody>
</table>

What are the HCPCS codes for reporting the CardioMEMS™ HF System implant in the hospital outpatient setting?

The HCPCS codes for reporting pulmonary artery sensor implant procedures in the hospital outpatient setting are:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>C9741</td>
<td>Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation and report</td>
</tr>
<tr>
<td>C2624</td>
<td>Implantable wireless pulmonary pressure sensor with delivery catheter, including all system components</td>
</tr>
</tbody>
</table>

For more information, please call Abbott’s Patient Therapy Access reimbursement line at 855-569-6430 or via email at hce@sjm.com, or refer to Abbott’s Cardiac Device Monitoring Physician Reimbursement Guide, available online at https://www.sjm.com/en/professionals/resources-and-reimbursement/reimbursement-support/hf-management.

Is there a defined physician payment rate for the CardioMEMS HF system implant?

Payment to physicians for the CardioMEMS HF System procedure is not defined, and is generally negotiated by the physician. Because CPT unlisted codes are not assigned RVUs, payers do not have a pre-defined reference for establishing payment. Physicians will need to explain the work involved, including the required time and the complexity of the procedure, and practice expense relative to comparable procedures with established RVUs and payment amounts. Over time, payers may establish a fixed payment amount. Should additional information be required, please contact us at 855-569-6430.

Coding and Billing Questions—Inpatient and Outpatient Hospital

Is there an ICD-10-PCS procedure code available for the CardioMEMS™ HF System implant?

Yes. Hospital inpatient procedures may be billed using the ICD-10-PCS code sets:

<table>
<thead>
<tr>
<th>ICD-10-CM Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02HQ30Z</td>
<td>Insertion of Pressure Sensor Monitoring Device, Right Pulmonary Artery, monitoring device with pressure sensor</td>
</tr>
<tr>
<td>02HR30Z</td>
<td>Insertion of Pressure Sensor Monitoring Device, Left Pulmonary Artery, monitoring device with pressure sensor</td>
</tr>
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</tbody>
</table>
2. Hospital Outpatient Prospective Payment- Final Rule with Comment Period and Final CY2018 Payment Rates. CMS-1656-FC: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1656-FC.html
3. CPT Copyright 2017 American Medical Association. All rights reserved.

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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.

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