FREQUENTLY ASKED QUESTIONS (FAQ)

Implantable Pulmonary Artery Pressure Sensor(s) for Heart Failure Management National Coverage Determination (NCD) including the CardioMEMS™ HF System

GENERAL QUESTIONS

1) What is a National Coverage Determination?
A National Coverage Determination (NCD) is a Medicare policy that covers a specific medical item or service nationally. CMS has issued the NCD for the implantable pulmonary artery pressure sensor(s) including CardioMEMS™ HF System under Coverage with Evidence Determination (CED).[1]

2) What is Coverage with Evidence Development (CED)?
When the available evidence is insufficient to demonstrate items and services are reasonable and necessary for diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member under a certain part of the law, CED has been used to support evidence development for certain items and services that are likely to show benefit for the Medicare population.[3]

3) What is the significance of the NCD for CardioMEMS™ HF System?
The NCD expands access to implantable pulmonary artery pressure sensor(s) including CardioMEMS for more patients when NCD criteria are met.[2]

CED & CLINICAL TRIAL QUESTIONS

1) What is a National Clinical Trial (NCT) number, and why is it important for the CardioMEMS™ HF System CED study?
A National Clinical Trial (NCT) number is a unique identifier that enables the collection of real-world evidence reporting for the CED study. The NCT number and other CED information must be reported on all claim forms to be considered for coverage.[4]

2) Will other implantable pulmonary artery pressure sensors require their own CED study or registry?
Yes. Other remote implantable pulmonary artery pressure sensor(s) will need to sponsor their own CED study or registry for coverage under the NCD.[3]

3) What can I do to enroll my patient in the CED study?
Once CMS approves Abbott's CED study, Abbott will notify physicians and institutions on CED study information and provide education on the requirements for claims. Physicians and facilities will be required to add the CED study information to their claim forms. There will be no additional reporting requirements for the CED outside of standard documentation.[3]

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[1] NCT Final Decision Memo: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=313&fromTracking=Y&

[2] Medicare Coverage Determination: Medicare Coverage Determination Process | CMS

[3] Coverage with Evidence Development: Coverage with Evidence Development | CMS

IMPACT ON PRACTICES AND PATIENTS

1) Once the CED study is approved, how do I enroll patients while Medicare Advantage plans are updating their policies and systems?
The NCD will be effective for CardioMEMS when CMS approves the CardioMEMS CED study. After the CED study approval, implanting sites and physicians may consider using the CardioMEMS™ HF System checklist and submit copies of the CardioMEMS CED approval letter and NCT number with each prior authorization and appeal.[2, 3] Also consider using the Abbott Patient Therapy Access (PTA) support for patient appeals at (877) 706-7426 ext., 3.

2) What should practices do about patients who were previously denied?
Practices can review the updated NCD criteria to determine if previously denied patients may now qualify for CardioMEMS under the new coverage criteria.[2]

3) What are the key patient selection criteria under the NCD?
Read more about the updated coverage criteria under the implantable pulmonary artery pressure sensor(s) NCD including CardioMEMS™ HF System, NCD at the Abbott NCD website.[2]

4) What happens if a Medicare beneficiary under Traditional and Medicare Advantage plan is not enrolled in the CED study?
Medicare requires enrollment in an approved CED registry or study to qualify for coverage. Practices will need to ensure compliance to avoid coverage or payment issues.[3]

5) Will commercial payors follow the NCD criteria?
Many commercial payers tend to follow CMS decisions, and may eventually adopt similar policies, but they take time to do so. Practices will need to check with individual payers for updates.[2]

ADDITIONAL RESOURCES

1) Where can I find more information about the NCD?
You can visit the Abbott NCD website to learn more about the NCD.[2] On the website, you can also find a link to Abbott's Heart Failure Reimbursement and Coding Resource Center where you can find comprehensive information on coding guides, Medicare coverage determinations, and on-demand webinars. Resources for Medical Reimbursement | Abbott

2) What if I have questions that aren't answered in this FAQ?
Please reach out to the Abbott HE&R team that can be contacted at the email: HeartFailureEconomics@abbott.com.

Additionally, you can also contact:

Field HE&R Partner
- Erin Spengeman at (502)-314-2513

Heart Failure HE&R Therapy Leads
- James Hasegawa at (408) 476-5379
- Janet Fike at (248) 303-8234

[2] Medicare Coverage Determination Process: Medicare Coverage Determination Process | CMS
[3] Coverage with Evidence Development: Coverage with Evidence Development | CMS

Important Safety Information

CardioMEMS™ HF System

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.

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.

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