Pulmonary Artery Pressure Monitoring (CardioMEMS™) Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Pulmonary Artery Pressure Monitoring (CardioMEMS)		
MNG #: 128	☒ CCA Senior Care Options (HMO D-SNP) (MA) ☒ CCA One Care (Medicare-Medicaid) (MA) ☒ CCA Medicare Preferred (PPO) (MA & RI) ☒ CCA Medicare Value (PPO) (MA & RI) ☒ CCA Medicare Maximum (HMO D-SNP) (RI) ☐ CCA Medicare Excel (HMO POS) (MI) ☐ CCA Medicare Maximum (HMO D-SNP) (MI) ☐ CCA Medicare Excel (HMO) (CA)	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Benefit Type: ☒ **Medicare** ☒ **Medicaid**	**Approval Date:** 8/8/2024	**Effective Date:** 11/18/2024
Last Revised Date:	**Next Annual Review Date:** 8/8/2025	**Retire Date:**

OVERVIEW:

The CardioMEMS™ HF System is utilized to remotely measure pulmonary artery pressure and heart rate via an implanted wireless sensor, indicated for use in patients with Class II or III heart failure who have been hospitalized for heart failure in the previous year and/or have increased levels of natriuretic peptides that can be indicative of worsening heart failure. Patients are able to transmit their physiologic data to their physician for interpretation of results and determination of need for intervention.

DEFINITIONS:

Ejection Fraction (EF) – A measurement of the amount of blood that the left ventricle pumps out with each contraction, utilized in diagnosing and tracking heart failure. Normal EF is around 70%. Mildly reduced EF is between 40% and 49%. Two designations of heart failure for the purpose of this policy:

- Preserved Ejection Fraction (HFpEF) – Signs and symptoms of heart failure are present, however EF is ≥40%.
- Reduced Ejection Fraction (HFrEF) – Signs and symptoms of heart failure are present due to a reduced EF (EF under 40%).

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Heart Failure (or Congestive Heart Failure) – A condition wherein the heart does not pump blood well enough to meet the body's needs, resulting in compromised blood supply. The New York Heart Association (NYHA) has developed a functional assessment tool to measure the extent of heart failure, based upon limitations of physical activity:

1. Class I - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.
2. Class II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
3. Class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20—100 m). Comfortable only at rest.
4. Class IV - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.
5. No NYHA class listed or unable to determine.

DECISION GUIDELINES:

Clinical Coverage Criteria: Senior Care Options and One Care

Heart Failure with Preserved Ejection Fraction or Reduced Ejection Fraction

Medical necessity for the utilization of CardioMEMS™, as part of treatment for heart failure, may be considered when all of the following criteria (a through j), are met and documented.

a. Under standards established by the NYHA, the member has been diagnosed with Class III or IV heart failure; and
b. The member must have experienced an acute inpatient hospitalization within the past 12 months, with heart failure as a diagnosis contributing to the admission; and
c. The member is not on a waiting list for a heart transplant; and
d. The member is currently not receiving, nor is scheduled to receive, Ventricular Assist Device (VAD) therapy; and
e. Concurrent deep vein thrombosis or pulmonary embolism is not a clinical concern; and
f. The member is able to tolerate a course of dual anti-platelet therapy (aspirin and clopidogrel) following implantation of CardioMEMS™; and
g. The member does not have a mechanical right heart valve; and
h. Given the need for ongoing interaction and management between the clinician and the member, the member must not have had any unexplained "no-shows" with the practice that would be interpreting the data from the CardioMEMS™ system within the previous six months from the date of the request for prior authorization for CardioMEMS™; and
i. The member has the capacity to make fully informed decisions and has consented to the procedure after limitations, risks, and complications of the procedure have been discussed; and
j. Co-morbid medical or mental health disorders are appropriately managed and reasonably controlled.

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LIMITATIONS/EXCLUSIONS: Senior Care Options and One Care

CardioMEMS™ is not considered to be medically necessary under certain circumstances, examples of which include, but are not limited to, the following:

1. Members with Class I or Class II heart failure under standards established by the NYHA.
2. Members with heart failure and a history or risk of pulmonary embolism, deep venous thrombosis, renal failure, mechanical right heart valve, or history of severe bleeding.

DOCUMENTATION: Senior Care Options and One Care

The clinician performing device implantation must submit a request for PA for CardioMEMS™ accompanied by clinical documentation that supports the medical necessity for the procedure, including all of the following:

1. CCA Standard Prior Auth Form, including the additional information (below a-c) from the clinician performing the procedure:
    a. The member meets the clinical criteria for coverage described above; and
    b. The clinician has collaborated with any other health care professionals involved in the member's care, including, but not limited to, the member's primary care clinician; and
    c. The clinician has discussed risks and complications of the proposed procedure and has obtained informed consent from the member.
2. A copy of the assessment performed by an appropriately credentialed and enrolled provider in accordance with the above guidelines, including date of onset and history resulting in the relevant diagnosis and referral(s) for the specific procedures.
3. Progress notes documenting that any co-existing medical or mental health diagnoses are being appropriately managed and are reasonably controlled.

DECISION GUIDELINES:

Clinical Coverage Criteria: Medicare Advantage (MA Medicare Preferred, MA Medicare Value, RI Medicare Preferred, RI Medicare Value, RI Medicare Maximum)

Medical necessity for the utilization of CardioMEMS™, as part of treatment for heart failure, may be considered when all of the following criteria are met and documented.

1. NYHA Class III heart failure member who either:
    a. Has been hospitalized for heart failure in the 12 months; and/or
    b. Has elevated brain natriuretic peptide (BNP) or NT-proBNP level (NT-proBNP level ≥ 1000 pg/mL or a BNP level ≥ 250 pg/mL - thresholds are dependent on left ventricular ejection fraction and body mass index, using a 4% reduction per BMI unit over 25 kg/m2[11]).
2. The member is 18 years of age or older.
3. There is no clinical concern for concurrent deep vein thrombosis or pulmonary embolism.
4. The member is able to tolerate a course of dual anti-platelet therapy (e.g., aspirin and clopidogrel) following implantation of CardioMEMS™.

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5. Co-morbid medical or mental health disorders are appropriately managed and reasonably controlled.
6. Patients with HF with reduced ejection fraction (HFrEF) have been receiving a beta blocker for 3 months and an ACE (angiotensin-converting enzyme) inhibitor or ARB (angiotensin receptor blocker) for 1 month unless the member is intolerant to β-blockers, ACE inhibitors, or ARB.
7. Patients with body mass index >35 kg/m2 have a chest circumference <65 inches measured at the axillary level.
8. The target PA branch for pressure sensor implantation has a diameter ≥7 mm.
9. Given the need for ongoing interaction and management between the clinician and the member, the member must not have had any unexplained "no-shows" with the practice that would be interpreting the data from the CardioMEMS™ system within the previous six months from the date of the request for prior authorization for CardioMEMS™.
10. The member has capacity to make fully informed decisions and has consented to the procedure after limitations, risks, and complications of the procedure have been discussed.
11. The member is willing and able to upload PA pressure information and comply with the follow-up requirements.

LIMITATIONS/EXCLUSIONS: Medicare Advantage (MA Medicare Preferred, MA Medicare Value, RI Medicare Preferred, RI Medicare Value, RI Medicare Maximum)

CardioMEMS™ is not considered to be medically necessary for any of the following:

1. Members with an inability to take dual antiplatelet or anticoagulants for one month post implant
2. History of severe bleeding, with known coagulation disorders and hypersensitivity or allergy to aspirin and/or clopidogrel
3. Members with Class 1, Class II or Class IV heart failure under standards established by the NYHA
4. Nonresponsiveness to diuretic therapy or need for chronic dialysis
5. Members with renal failure
6. Glomerular filtration rate <25 mL/min per 1.73 m2 (obtained within 2 weeks of pressure sensor implant)
7. Inability to tolerate right heart catheterization
8. The member has congenital heart disease
9. The member has a mechanical right heart valve
10. The member has suffered a major cardiovascular event (e.g., myocardial infarction, open heart surgery, stroke) within the previous 2 months
11. The member is receiving Ventricular Assist Device (VAD) therapy, or is anticipated need to undergo heart transplantation or surgical ventricular assist device within the next 6 months
12. Cardiac resynchronization therapy implanted within the previous 3 months
13. History of recurrent (>1) pulmonary embolism
14. Risk of deep venous thrombosis
15. Pregnant or planning to become pregnant in the next 12 months
16. Active infection

17. Unexplained "no-shows" with the practice that would be interpreting the data from the CardioMEMS™ system within the previous six months from the date of the request for prior authorization for CardioMEMS™

DOCUMENTATION: Medicare Advantage (MA Medicare Preferred, MA Medicare Value, RI Medicare Preferred, RI Medicare Value, RI Medicare Maximum)

1. CCA Standard Prior Auth Form, including the additional information (below a-d) from the clinician performing the procedure:
    a. The member meets the clinical criteria for coverage described above; and
    b. The clinician has collaborated with any other health care professionals involved in the member's care, including, but not limited to, the member's primary care clinician; and
    c. The clinician has discussed risks and complications of the proposed procedure and has obtained informed consent from the member; and
    d. The implanting cardiologist has completed special CardioMEMS™ training[10].
2. A copy of the assessment performed by an appropriately credentialed and enrolled provider in accordance with the above guidelines, including date of onset and history resulting in the relevant diagnosis and referral(s) for the specific procedures; and
3. Progress notes documenting that any co-existing medical or mental health diagnoses are being appropriately managed and are reasonably controlled.

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

CPT/HCPCS CODE	CODE DESCRIPTION
C2624	Implantable wireless pulmonary pressure sensor with delivery catheter, including all system components
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
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

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists.

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Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity [(supporting literature (full text preferred) should be attached to the request)], or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

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10. CardioMEMS™ HF System Remote Pulmonary Pressure Monitor, 2024
https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/pulmonary-pressure-monitors/cardiomems/education-and-training.html

11. CardioMEMS™ HF System PATIENT CANDIDATE CONSIDERATIONS
https://www.cardiovascular.abbott/content/dam/cv/cardiovascular/hcp/products/heart-failure/cardiomems/documents/hf-cardiomems-patient-candidate-considerations-tool.pdf

REVISION LOG:

REVISION DATE	DESCRIPTION
8/8/2024	NEW MNG

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APPROVALS:

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Nazlim Hagmann, MD	Chief Medical Officer
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