Guidelines for Medical Necessity Determination for CardioMEMS

This edition of the *Guidelines for Medical Necessity Determination* (Guidelines) identifies the clinical information that MassHealth needs to determine medical necessity for CardioMEMS for treatment of heart failure. The agency evaluates the medical necessity of CardioMEMS as a treatment for other diagnoses on a case-by-case basis. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 415.000: Acute Inpatient Hospital Services, 130 CMR 433.000: Physician Services, 130 CMR 410.000: Outpatient Hospital Services, 130 CMR 450.000: Administrative and Billing Regulations, Subchapter 6 of the Physician Manual, and Subchapter 6 of the Outpatient Hospital Services Manual for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), One Care organization, Senior Care Options (SCO), or a Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for CardioMEMS. MassHealth reviews requests for PA based on medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

1 SECTION I. GENERAL INFORMATION

The "CardioMEMS HF System" uses an implantable pulmonary artery pressure monitor designed with the intent of reducing heart failure hospitalizations. MEMS is an abbreviation for Micro-Electro-Mechanical System. The device is inserted during a right heart catheterization procedure and placed in the left pulmonary artery. After insertion, patients obtain readings with a home sensor every day and wirelessly transmit their physiologic data to the clinician, who interprets the results on an ongoing basis and reaches out to the patient with any need for intervention.

MassHealth considers approval for coverage of CardioMEMS on an individual, case-by-case basis, in accordance with 130 CMR 433.000: *Physician Services* and 130 CMR 450.204: *Medical Necessity*.

Despite advances in medical therapy, heart failure remains a major driver of morbidity, mortality, and acute care utilization in Massachusetts. One of the major challenges with managing heart failure in the ambulatory setting is managing patients who have frequent exacerbations, as it is difficult for clinicians to 'catch' these exacerbations as they develop. This challenge derives in large part from the fact that it is difficult for a clinician to know a patient's physiologic status on a day-to-day basis. Clinicians rely on imprecise information such as changes in the daily weight of a patient or the development of symptoms, both of which may only manifest after the exacerbation is well underway and may already be headed for emergency/inpatient care.

CardioMEMS provides real-time physiologic data as it is implanted in the left pulmonary artery, where it directly obtains physiologic measurements. Each day, patients use a wireless sensor in their homes to obtain measurements from the CardioMEMS device. The sensor wirelessly transmits physiologic data to the clinician, who can recognize an impending exacerbation and take appropriate action (e.g., by altering the patient's medication). Current evidence suggests that exacerbations can take up to several weeks to develop before showing symptoms requiring hospitalization, giving a reasonable timeframe for outpatient intervention with sufficient insight.

CardioMEMS is beneficial for certain patients with heart failure with preserved ejection fraction (HFpEF) as well as heart failure with reduced ejection fraction (HFrEF). It is not beneficial for routine use and shows the most benefit in patients with class III heart failure and some patients with class IV heart failure. This is one of very few interventions that has shown a reduction in hospitalizations for HFpEF and provides a mortality benefit for HFrEF.

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SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for CardioMEMS on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure (if appropriate, including post-operative recovery). The CardioMEMS system, including insertion procedure, device, and sensor will be covered for up to one year from authorization. There is a limit of one insertion procedure during this one-year period.

HEART FAILURE WITH PRESERVED EJECTION FRACTION OR REDUCED EJECTION FRACTION

1. Utilization of CardioMEMS as part of treatment for heart failure may be considered medically necessary when all of the criteria listed in subsections II.A.1.a. through m., below, are met and documented.
    a. The member has been diagnosed with class III or IV heart failure under standards established by the New York Heart Association (NYHA).
    b. The patient must have experienced an acute inpatient hospital admission within the past 12 months, with heart failure as a diagnosis contributing to the admission.
    c. The member is not on a waiting list for a heart transplant.
    d. The member is not receiving and is not scheduled to receive Ventricular Assist Device (VAD) therapy.
    e. There is no clinical concern for concurrent deep vein thrombosis or pulmonary embolism.
    f. The member is able to tolerate a course of dual anti-platelet therapy following implantation of CardioMEMS.
    g. The member does not have a mechanical right heart valve.
    h. Given the need for ongoing interaction and management between the clinician and the member, the member must not have 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.

i. The member is 18 years of age or older.

j. 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.

k. Co-morbid medical or mental health disorders are appropriately managed and reasonably controlled.

ADDITIONAL DIAGNOSES

2. Except as provided in section II.B, below, CardioMEMS as a treatment for any other diagnosis may be considered on a case-by-case basis based on documented medical necessity.

B. NONCOVERAGE

MassHealth does not consider CardioMEMS to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. Members with class 1 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.

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for CardioMEMS must be submitted by the clinician performing device implantation and accompanied by clinical documentation that supports the medical necessity for the procedure. Documentation of medical necessity must include all the following.

1. A copy of the assessment performed by an appropriately credentialed and enrolled provider in accordance with these Guidelines, including date of onset and history resulting in the relevant diagnosis and referral(s) for the specific procedures.
2. Progress notes documenting that any co-existing medical or mental health diagnoses are being appropriately managed and are reasonably controlled.
3. A letter from the clinician performing the procedure must attest to all of the following:
   a. The member meets the clinical criteria for coverage described in Section II.A. of these Guidelines; 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.
4. As noted above, all clinical information must be submitted by the clinician performing the procedure. Providers are strongly encouraged to submit requests electronically. Providers must submit the request for PA and all supporting documentation using the Provider Online Service Center (POSC), or by completing a MassHealth Prior Authorization Request form

(using the PA-1 paper form found at www.mass.gov/masshealth) and attaching all supporting documentation. The PA-1 form and documentation should be mailed to the address on the back of the form. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900.

Select References

1. Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction http://www.onlinejacc.org/content/70/15/1875
2. Wireless Pulmonary Artery Pressure Monitoring Guides Management to Reduce Decompensation in Heart Failure With Preserved Ejection Fraction https://www.ahajournals.org/doi/pdf/10.1161/CIRCHEARTFAILURE.113.001229
3. Cost-Effectiveness of Implantable Pulmonary Artery Pressure Monitoring in Chronic Heart Failure https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4851610/
4. Championing Effectiveness before Cost-Effectiveness https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5459398/
5. CardioMEMS HF System Post Approval Study https://clinicaltrials.gov/ct2/show/NCT02279888

These Guidelines are based on review of the medical literature and current practice in the treatment of heart failure. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

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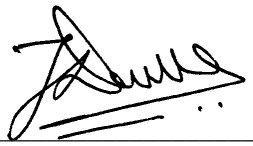
Approved by:



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