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 *Acute Outpatient Hospital 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, respectively, 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 is a proprietary device made by Abbott that uses an implantable pulmonary artery pressure monitor designed to detect hemodynamic congestion with the intent of reducing heart failure hospitalizations. MEMS is an abbreviation for microelectromechanical 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.

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 manifest only after the exacerbation is well underway and may already be headed for emergency/inpatient care.

CardioMEMS™ provides more precise physiologic measurements, as it is implanted in the left pulmonary artery and is able to transmit to providers in real-time. 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. 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 postoperative 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 the following subsections II.A.1.a. through i. are met and documented.

    a. The member has been diagnosed with class II or class III 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 or elevated natriuretic peptides within the past 30 days.

    c. The member is not on a waiting list for a heart transplant.

    d. There is no clinical concern for concurrent deep vein thrombosis or pulmonary embolism.

    e. The member is able to tolerate a course of dual anti-platelet therapy for one month following implantation of CardioMEMS™.

    f. The member does not have a mechanical right-heart valve.

    g. The member is 18 or older.

h. The member has capacity to make fully informed decisions and has consented to the procedure after the limitations, risks, and complications of the procedure have been discussed.

i. 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 I heart failure under standards established by the NYHA

2. Members with heart failure and a history or risk of current pulmonary embolism; current deep venous thrombosis; renal failure requiring hemodialysis; mechanical right-heart valve; or history of severe bleeding

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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, attesting 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.

Providers must electronically submit PA requests and all supporting documentation using the Provider Online Service Center (POSC), unless the provider has a currently approved electronic claims waiver

(hereinafter, "waiver"). Please see All Provider Bulletin 369 for further waiver information. Questions about POSC access should be directed to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For PA requests that are not submitted using the POSC, providers with currently approved waivers must include the MassHealth Prior Authorization Request (PA-1 Form) and all supporting documentation. The PA1 Form can be found at mass.gov/how-to/request-prior-authorization-for-nonpharmacy-services.

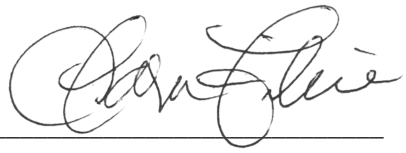
SELECT REFERENCES

1. Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction
2. Wireless Pulmonary Artery Pressure Monitoring Guides Management to Reduce Decompensa-tion in Heart Failure With Preserved Ejection Fraction
3. Cost-Effectiveness of Implantable Pulmonary Artery Pressure Monitoring in Chronic Heart Failure
4. Championing Effectiveness before Cost-Effectiveness
5. CardioMEMS™ HF System Post Approval Study

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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