

Pulmonary Artery Pressure Monitoring (CardioMEMS)

Policy Number: PG0377
Last Review: 12/01/2023

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

- Professional
- Facility

DESCRIPTION:

The CardioMEMS™HF heart failure system is a wireless implantable hemodynamic monitor that measures pulmonary artery pressure (PAP) and heart rate in patients with heart failure. The system consists of an implantable PAP sensor, a transvenous catheter delivery system, a patient home monitoring electronic system, and a secure Internet-accessible database that allows clinicians to access the patient data. A dime-sized wireless sensor is permanently implanted in the pulmonary artery via fluoroscopy-guided right heart catheterization while the patient is mildly sedated. The CM-IHM home monitoring components comprise a pillow containing the antenna to capture the sensor reading, a bedside monitoring unit to which the pillow is connected via a cable, and a remote button. The system is simple to operate. Each sensor reading captures 18 seconds of data, which are wirelessly transmitted to a secure database that physicians can access and use to optimize heart failure medical management. Currently, there is a lack of evidence on the accuracy and clinical utility of CM-IHM patients with other New York Heart Association (NYHA) functional classifications.

The CardioMEMS™HF device system transmits information to a clinical staff that monitors and manages heart failure. The basis for Pulmonary Artery Pressure Monitoring is that real-time values of cardiac output will supplement the characteristic signs and symptoms and optimize the clinician's medical management ability to intervene early to prevent acute decompensation and potentially reduce the need for Heart Failure related hospitalizations.

POLICY:

Paramount Commercial Insurance Plans

- **Implanted Wireless Pulmonary Artery Sensor (e.g., CardioMEMS™HF System) (33289) is non-covered**

Elite (Medicare Advantage) Plans

- ~~Implanted Wireless Pulmonary Artery Sensor (e.g., CardioMEMS™HF System) (33289) is covered with prior authorization. Prior Authorization Effective Date 1/1/2020.~~
- **Medicare's coverage of CardioMEMS while in a clinical trial ended as of 5/17/2023. Currently, Medicare does not have any LCD or NCD for coverage criteria. Coverage for Medicare will follow Commercial as experimental/investigational.**

COVERAGE CRITERIA:**Paramount Commercial Insurance Plans**

Paramount considers an implanted wireless pulmonary artery pressure sensor (e.g., CardioMEMS™ HF System) (33289) experimental and investigational for heart failure and all other indications.

Currently, the current evidence is insufficient to support the use of ambulatory cardiac hemodynamic monitoring using an implantable pulmonary artery pressure measurement device in individuals with heart failure in an outpatient setting. Data on long-term health benefits (including survival), safety issues, and quality of life are lacking. In addition, there is a lack of evidence on the accuracy and clinical utility of the device for use in other NYHA functional classifications.

Elite (Medicare Advantage) Plans

Medicare's coverage of CardioMEMS while in a clinical trial ended as of 5/17/2023. Currently, Medicare does not have any LCD or NCD for coverage criteria. Coverage for Medicare will follow Commercial as experimental/investigational.

The CardioMEMS implantable hemodynamic monitor (CM-IHM) for managing patients with heart failure continues to be a very low-quality body of evidence that is insufficient to draw conclusions regarding the safety and efficacy of the CM-IHM in adults with NYHA class III HF. Limited evidence suggested management of HF patients with CM-IHM in addition to standard care, reduced the incidence of HF-related hospitalization. In conclusion, the authors found that due to inconsistent findings, short duration of follow-up, and variability in reported outcome measures, substantial uncertainty remains about the comparative effectiveness of CM-IHM with standard monitoring and the impact of CM-IHM on long-term patient's safety, mortality, survival, and quality of life. Thus, due to the uncertainty surrounding the efficacy of CM-IHM, large well-designed comparative studies are needed to provide evidence for the long-term benefits and harms of CM-IHM.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
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, when performed
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
HCPCS CODES	
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
ICD-10 CODES	
I50.1- I50.9	Heart Failure

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 09/23/2016

Date	Explanation & Changes
09/23/2016	<ul style="list-style-type: none"> Policy created to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
06/23/2017	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)

03/22/2018	<ul style="list-style-type: none"> Implanted Wireless Pulmonary Artery Sensor (e.g., CardioMEMS HF System) (C2624, C9741) is covered without prior authorization only for a Medicare-approved clinical trial for Elite per CMS guidelines Policy reviewed and updated to reflect most current clinical evidence per the Technology Assessment Working Group (TAWG)
11/14/2019	<ul style="list-style-type: none"> Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Clinical Work Group, 111419 ODM coverage as of 1/1/2019 per ODM fee schedule Elite allows coverage when part of the clinical study Prior authorization effective 1/1/20, per 30 days prior authorization notice requirement
12/09/2020	<ul style="list-style-type: none"> Medical policy placed on the new Paramount Medical Policy Format
02/28/2023	<ul style="list-style-type: none"> Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
12/01/2023	<ul style="list-style-type: none"> Medical Policy updated to indicate noncoverage for the Medicare plans effective 5/18/2023 Added the coverage to indicate Facility along with Professional coverage

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to <https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>
Industry Standard Review

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review

Medical Policy History – Prior to 01/01/2024

POLICY

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Paramount Commercial Insurance Plans

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Medicare Advantage Plans, and Paramount Advantage Medicaid

Implanted Wireless Pulmonary Artery Sensor (e.g., CardioMEMS™ HF System) (33289) is covered with prior authorization. Prior Authorization Effective Date 1/1/2020.

COVERAGE CRITERIA

Paramount Commercial Insurance Plans

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Paramount Advantage Medicaid

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of Pulmonary Artery Pressure Monitoring (CardioMEMS), The Ohio Department of Medicaid requires coverage for Advantage members.

Clinical Indications:

Implantable hemodynamic monitors (e.g., CardioMEMS™ HF System) for heart failure may be covered when both (#1 and #2) of the following are met:

1. ALL the following clinical criteria must be met:
 - a. Has Congestive Heart Failure (CHF) that is difficult to monitor and treat.
 - b. Documentation that the CHF is not due to medical non-compliance.
 - c. Classified/Diagnosis as NYHA class III heart failure within 14 days of the implanting procedure.
 - d. Has had at least one heart failure hospitalization in the previous 12 months.
 - e. Reduced Ejection Fraction (EF) patients are receiving or have received a beta-blocker for 3 months and an ACE1 or ARB for one month unless the Member is intolerant to medication therapy.
 - f. If the BMI is 35 or greater, the chest circumference at the axillary level must be less than 165 cm (or 65 inches).
 - g. The pulmonary artery branch diameter is 7mm or more (assessed during the right heart catheterization procedure).
 - h. Member must be able to tolerate the right heart catheterization procedure.
 - i. There is documentation of Advance Care Planning including the designation of a Durable Power of Attorney for Healthcare (DPOAHC).
2. Member has NONE of the following:
 - a. Active infection.
 - b. History of recurrent pulmonary embolism or deep vein thrombosis.
 - c. Major cardiovascular event within the previous two months.

- d. Cardiac resynchronization therapy (CRT) is in the next three months or within the previous three months.
- e. Congenital heart disease or mechanical right heart valve that is contraindicated for a right heart catheterization.
- f. Known coagulation disorders.
- g. Hypersensitivity or allergy to aspirin and / or clopidogrel.
- h. Likely to undergo evaluation for heart transplant or VAD implantation within the next six months.

Facility Indications:

Clinical, Provider and Program Requirement – all the following:

1. Physician medical director who:
 - a. devotes more than 40% of their practice in managing advanced heart failure patients
AND
 - b. is board certified or eligible in advanced heart failure management consistent with the ABIM subspecialty requirements.
2. A multi-disciplinary team of professionals dedicated to the management of heart failure patients, including but not limited to a clinical pharmacist and social worker.
3. Comprehensive telemonitoring services are available including remote heart failure monitoring and remote device monitoring.
4. The following outcome measures are monitored with annual reporting:
 - a. Device complication for a minimum of 24 months
 - b. Device failures for a minimum of 24 months
 - c. Heart failure hospitalization rate 12 months
 - d. Heart failure ED visits 12 months
 - e. All-cause mortality 1 year
 - f. Heart failure cause mortality 1 year

Medicare Advantage Plans

An implanted wireless pulmonary artery pressure sensor (e.g., CardioMEMS™HF System) (C2624, C9741) is covered only for a Medicare-approved clinical trial. In February 2018, CMS approved the investigational device exemption (IDE) study titled, “Hemodynamic-GUIDEd Management of Heart Failure” (NCT03387813). [2] Therefore, this service may be covered only if the member is enrolled in a Medicare approved Category B IDE study.