Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Implantable Pulmonary Artery Pressure Devices (CardioMEMS HF)

Effective: January 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☐ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

CardioMEMS HF (Heart Failure) is an Implantable pulmonary artery pressure monitor system designed with the intent of improving quality of life and reducing morbidity for patients with heart failure by decreasing episodes of acute decompensation. These monitors can assist in identifying physiologic changes that precede clinical symptoms and thus allow for early intervention. FDA (Food and Drug Administration) approved CardioMEMS is a permanent device that is inserted during a right heart catheterization procedure and placed in the left pulmonary artery.

The CardioMEMS HF System allows the hemodynamic data to be transmitted wirelessly to clinical staff. The data is then analyzed to determine if changes in the heart failure plan of care are warranted, with the specific intent to reduce hospitalizations due to heart failure.

The New York Heart Association (NYHA) Functional Classification for heart failure places patients in one of four categories based on physical activity limitations. These four categories are as follows:

- Class I – No limitation during ordinary activity
- Class II – Slight limitation by shortness of breath and/or fatigue during moderate exertion or stress
- Class III – Symptoms with minimal exertion that interfere with normal daily activity
- Class IV – Inability to carry out any physical activity

Clinical Guideline Coverage Criteria

The Plan considers an implantable pulmonary artery pressure device (CardioMEMS) medically necessary as part of treatment for heart failure when **ALL** the following are met:

1. The Member has been diagnosed with **one** of the following:
    a. Class II heart failure under standards established by the New York Heart Association (NYHA) and at least one of the following:
        i. The Member has experienced an acute inpatient hospital admission within the past 12 months, with heart failure as a diagnosis contributing to the admission **OR**
        ii. The Member has a blood test showing elevated levels of biomarkers known as natriuretic peptides, which indicate worsening heart failure
    b. Class III heart failure under standards established by the NYHA; **and**
2. The Member must also meet **ALL** the following:
    a. The Member is not on a waiting list for a heart transplant; **and**
    b. The Member is not receiving and is not scheduled to receive Ventricular Assist Device (VAD) therapy; **and**
    c. There is no clinical concern for concurrent deep vein thrombosis or pulmonary embolism; **and**
    d. The Member is able to tolerate a course of dual anti-platelet therapy following implantation of CardioMEMS; **and**
    e. The Member does not have a mechanical right heart valve; **and**
    f. 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; **and**
    g. The Member must be able and willing to participate in the plan of care and monitoring of the implantable pulmonary artery pressure device (CardioMEMS) ; **and**
    h. The Member is 18 years of age or older; **and**
    i. 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; **and**
    j. Co-morbid medical or mental health disorders are appropriately managed and controlled and are not contraindications to the procedure

Limitations

The Plan considers coverage for implantable pulmonary artery pressure devices not medically necessary for **ANY** of the following indications:

1. Members with Class I and IV heart failure under standards established by the NYHA
2. The Member has a medical contraindication to CardioMEMS

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

Code	Description
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.
C2624	Implantable wireless pulmonary pressure sensor with delivery catheter, including all system components

References:

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2. Adamson PB, Abraham WT, Aaron M, Aranda JM Jr, Magalski A, Reed J, Reynolds D, Stehlik J, Zolty R; CHAMPION Trial Study Group. Mobile health monitoring with long-term implantable sensors is feasible in chronic heart failure

patients: results from the Wireless Pulmonary Artery Pressure Monitoring to Manage Heart Failure (CHAMPION) trial. J Am Heart Assoc. 2019 Jan 22;8(2):e010892. doi: 10.1161/JAHA.118.010892.
3. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the CHAMPION randomised trial. Lancet. 2016;387(10017):453-461. doi:10.1016/S0140-6736(15)00723-0
4. Heywood JT, Jermyn R, Shavelle D, et al. Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patients Implanted With the CardioMEMS Sensor. *Circulation*. 2017;135(16):1509-1517. doi:10.1161/CIRCULATIONAHA.116.026184
5. Ayyadurai P, Alkhawam H, Saad M, et al. An update on the CardioMEMS pulmonary artery pressure sensor. *Ther Adv Cardiovasc Dis*. 2019;13:1753944719826826. doi:10.1177/1753944719826826
6. CardioMEMS HF System Post Approval Study. CTG Labs - NCBI. Accessed November 9, 2023. https://clinicaltrials.gov/study/NCT02279888.
7. CardioMEMS Implantable Hemodynamic Monitor (Abbott) for Managing Patients with Heart Failure Hayesinc.com/login [via subscription only]. Published July 28, 2022. Accessed November 9, 2023.
8. Center for Devices and Radiological Health. CardioMEMS HF system - P100045/S056. U.S. Food and Drug Administration. Accessed November 9, 2023. https://www.fda.gov/medical-devices/recently-approved-devices/cardiomems-hf-system-p100045s056.
9. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): CardioMEMS HF
10. System. 2022; https://www.fda.gov/medical-devices/recently-approved-devices/cardiomems-hf-system-p100045s056. Accessed September 7, 2023.
11. Lindenfeld J, Zile MR, Desai AS, et al. Haemodynamic-guided management of heart failure (GUIDE-HF): a randomized controlled trial. *The Lancet.* 2021;398:991-1001.
12. Guidelines for medical necessity determination for CardioMEMS - Mass.gov. Accessed November 9, 2023. https://www.mass.gov/doc/cardiomems-0/download.
13. Kennel PJ, Rosenblum H, Axsom KM, et al. Remote Cardiac Monitoring in Patients With Heart Failure: A Review. JAMA Cardiol. 2022;7(5):556-564. doi:10.1001/jamacardio.2021.5090
14. WRITING COMMITTEE MEMBERS, Yancy CW, Jessup M, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013;128(16):e240-e327. doi:10.1161/CIR.0b013e31829e8776

Approval And Revision History

November 16, 2023: Reviewed by the Medical Policy Approval Committee (MPAC) as a new coverage guideline for Implantable Pulmonary Artery Pressure Devices (CardioMEMS) with prior authorization effective March 1, 2024.

Subsequent endorsement date(s) and changes:

- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025.
- December 13, 2024: Reviewed by The Utilization Management (UM) Committee, renewed without changes effective January 1, 2025.
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will

govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric Members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.