


Cardiac Hemodynamic Monitoring in the Management of Heart Failure (CardioMEMS)

UR Guidelines 028

Policy and Procedure

Department	Medical Management
Purpose	To establish medical necessity guidelines for CardioMEMS
Applicability	All Products/All Panels
Approved	
Approved	Tara Bryant, MD, BSN
Approver Title	Chief Medical Officer
Original Effective Date	7/1/2021
Revision Date	12/19/23
Revision Number	2
Regulatory Requirement	

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Policy: This document applies to VIVA HEALTH, Inc., VIVA HEALTH Administration L.L.C. and Triton Health Systems, L.L.C. hereafter referred to as VIVA HEALTH.

Description:

The CardioMEMS[™] Heart Failure (HF) System is a wireless pulmonary arterial (PA) pressure monitoring system. It measures PA pressures from a battery free sensor in the distal pulmonary artery. An electronic system transmits the generated data to a secure network where it is available for the interpretation by the treating physician.

Clinical Indication:

The CardioMEMS[™] HF System may be considered medically necessary for individuals that meet **ALL** of the following indications:

- Diagnosis of New York Heart Association (NYHA) Class III HF symptoms predominantly present over the previous months, despite maximally tolerated guideline directed medical and device therapies; **and**
- At least one (1) HF related hospitalization within the previous 12 months; **and**
- Able to take dual antiplatelet or anticoagulants for one (1) month post-implant; **and**
- Greater than or equal to 18 years of age; **and**
- Diagnosis of HF greater than or equal to three (3) months, with either preserved or reduced left ventricular ejection fraction; **and**
- Body mass index (BMI) of less than or equal to 35; **or**
- If BMI is greater than 35, a measurement of chest circumference at axillary level is required. If the chest circumference is greater than 165 cm, the sensor should not be implanted due to poor signal strength; **and**
- PA branch diameter sized between 7 mm and 15 mm.

Monitoring must occur at least once weekly in all individuals implanted with CardioMEMS[™]. Weekly monitoring is acceptable as long as the individual maintains acceptable PA pressure (opti-volemic).

If PA pressure is **not** opti-volemic:

- Monitoring must occur **at least** TWO-THREE times per week until opti-volemic in cases where the individual has elevated PA pressure (hyper-volemic) or low PA pressure (hypo-volemic); **and**
- Monitoring must occur **at least** TWO-THREE times per week until pressure stabilizes in cases where the individual receives medication modifications or exhibits significant deviations in trend data.

The CardioMEMS[™] HF System is considered experimental/investigational and, therefore, non-covered for any other indication.

CPT codes covered if selection criteria are met:

Code	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

References

The above policy is based on the following references:

1. National Institute for Health (NIH) and Clinical Excellence (NICE) quality standards. Chronic heart failure in adults. Last updated 2016.
2. Bozhurt B. 2016 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Focused update on new pharmacological therapy for heart failure: An update of the 2013 ACCF/AHA guideline for the management of heart failure. A report of the ACCF/AHA Task Force on clinical practice guidelines and the Heart Failure Society of America. *Circulation*. 2016;134.
3. Barghash MH, Reyentovich A. The use of implantable HF monitoring systems and the CHAMPION trial. *American College of Cardiology*. 2016.
4. Mehta Y, Arora D. Newer methods of cardiac output monitoring. *World Journal of Cardiology*. 2014; 6(9):1022-1029.
5. McDonald, K. Role of monitoring devices in preventing heart failure admissions. *Curr Heart Fail Rep*. 2015;12:269-275.
6. Yandrapalli, S. Ambulatory pulmonary artery pressure monitoring in advanced heart failure patients. *World J Cardiol*. 2017;9(1): 21-26.
7. Sandhu, A. Cost-Effectiveness of implantable pulmonary artery pressure monitoring in chronic heart failure. *JACC Heart Fail*. 2016;4(5): 368-375.
8. Heart Failure Society of America. Evaluation and management of patients with heart failure and preserved left ventricular ejection fraction. *Journal of Cardiac Failure*. 2010;16(6): 126-133.
9. Food and Drug Administration (FDA). Medical Devices Recently Approved. 2022.
10. Ollendorf D, Sandhu A, Pearson, S. CardioMEMS HF for the Management of Heart Failure— Effectiveness and Value. *JAMA Internal Medicine*. 2016;176:1551-3.
11. Emani, S. Remote Monitoring to Reduce Heart Failure Readmissions. *Curr Heart Fail Rep*. 2017; 14;40-47.