Cardiac Hemodynamic and Thoracic Fluid Index Monitoring for the Management of Heart Failure in the Outpatient Setting

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Several approaches have been proposed as techniques for the measurement of cardiac hemodynamics in the outpatient setting, designed with a goal of early identification of patients at imminent risk of heart decompensation. The basis is that real-time values of cardiac output (CO) or left ventricular end diastolic pressure (LVEDP) will supplement the characteristic signs and symptoms and improve the clinician's ability to intervene early to prevent acute decompensation.

Four (4) methods of measurement of cardiac hemodynamics are reviewed in this policy. They are: noninvasive thoracic bioimpedance, inert gas rebreathing, noninvasive arterial waveform during Valsalva, and implantable pressure monitoring devices.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only addresses use of these techniques in ambulatory care and outpatient settings. It does not address the measurement of cardiac hemodynamics in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. In addition, echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound for monitoring cardiac output on an intermittent basis for the more stable patient are also not addressed in this policy.

CMS Coverage Manuals*	For ***left atrial pressure monitoring and pulmonary heart pressure monitoring systems that are NOT FDA-approved (CPT 93799, HCPCS C2624; e.g., Chronicle®, ImPressure®)***: • *According to the Medicare Benefit Policy Manual, Chapter 14, while FDA-approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any device that has not received FDA-approval would be considered not medically reasonable or necessary.*
National Coverage Determinations (NCDs)*	For the implanted pulmonary artery pressure sensor for heart failure (e.g., ***CardioMEMS™; CPT 33289, 93264)***: • Implanted Pulmonary Artery Pressure Sensor for Heart Failure Management (Decision Memo CAG-00466N) *Information about IDE studies can be found in: Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections*, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies For ***thoracic electrical bioimpedance (CPT 93701)***: • Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB) (20.16)
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles	None
Medical Policy Manual	*Medicare coverage guidance is not available for arterial pressure during Valsalva, inert gas rebreathing, thoracic fluid index, or for FDA-approved*

systems for implantable direct pressure monitoring of the pulmonary artery. Therefore, the health plan's medical policy is applicable.

For **all other cardiac hemodynamic and thoracic fluid index monitoring**, including arterial pressure during Valsalva, inert gas rebreathing (CPT 93799), thoracic fluid index monitoring (CPT 0607T, 0608T):

- Cardiac Hemodynamic and Thoracic Fluid Index Monitoring for the Management of Heart Failure in the Outpatient Setting, Medicine, Policy No. 33 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- All medical records and pertinent documentation of the member's medical condition, and indication being treated;
- Planned treatment.
- For CardioMEMS™, documentation regarding the Medicare-approved Category B IDE study, including the National Clinical Trial (NCT) number, must be provided. If this is not provided, it will be determined the member is **not** participating in the Medicare-approved study.

REGULATORY STATUS

The following is a list of applicable devices, with their corresponding Food and Drug Administration approval status. Note, the fact a service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare

covered services or is reasonable and necessary for the Medicare population under §1862(a)(1)(A). *(MM9014)*

- Several impedance plethysmographs and inert gas rebreathing devices received U.S. Food and Drug Administration (FDA) 510(k) approval.
- Several noninvasive LVEDP measurement devices received FDA 510(k) approval, however not all devices have been clinically validated.
- Several wireless abdominal aortic aneurysm (AAA) pressure measurement devices received FDA 510(k) approval for use in monitoring endovascular pressure during AAA repair. However, no device has been cleared for marketing for the indication of determining LVEDP or managing heart failure.
- The FDA approved the CardioMEMS™ Champion Heart Failure Monitoring System through the premarket approval (PMA) process. The device consists of an implantable pulmonary artery sensor, implanted in the distal pulmonary artery, a transvenous delivery system, and an electronic sensor that processes signals from the sensor and transmits pulmonary artery pressure measurements to a secure off-site database. Several additional devices that monitor cardiac output through measurements of pressure changes in the pulmonary artery or right ventricular outflow tract have been investigated in the research setting, but have not received FDA approval (e.g., Chronicle®, ImPressure®);
    - In January, 2015, CMS established a device pass-through category for CardioMEMS and HCPCS code C2624. However, the CMS MLN Matters® Article MM9014 included a disclaimer which read, “The fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it is reasonable and necessary to treat the beneficiary’s condition and whether it is excluded from payment.”[5]
- There are no left atrial pressure monitoring systems (e.g., the HeartPOD™ System or Promote® LAP System) with FDA approved for use outside the clinical trial setting.
- The µCor Heart Failure and Arrhythmia Management System by ZOLL Manufacturing has received 510(k) approval to periodically record, store, and transmit Thoracic Fluid Index and to continuously record and store, and periodically transmit ECG, heart rate, respiration rate, activity and posture data.[6] The µCor Heart Failure and Arrhythmia Management System is indicated in patients 21 years and older who 1. require monitoring for the detection of nonlethal cardiac arrhythmias or 2. require fluid management.

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Intracardiac Ischemia Monitoring, Surgery, Policy No. M-208

REFERENCES

1. NCD for *Plethysmography* (20.14) [Last Cited 12/18/2024] *(This reference can be found on the Medicare Coverage Database website)*
2. Approved IDE Studies listing "*Hemodynamic-GUIDEd Management of Heart Failure*"; Available at: https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html [Last Cited 12/18/2024]
3. Novitas Retired LCD for *Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure* (L36419) [Retired 07/2020] *(This reference can be found on the Medicare Coverage Database website)*
4. First Coast Service Options Retired LCA for *Noncovered services revision to the Part A and Part B LCD* (A56046) [Retired 07/2020] *(This reference can be found on the Medicare Coverage Database website)*
5. MLN Matters® Article MM9014, *January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)*; Available at: MM9014 (codemap.com) [Last cited 12/18/2024]
6. µCor Heart Failure and Arrhythmia Management System [Last cited 12/18/2024]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172510.pdf

CODING

Codes	Number	Description
CPT	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
	93701	Bioimpedance-derived physiologic cardiovascular analysis
	93799	Unlisted cardiovascular service or procedure
	0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment
	0608T	; analysis of data received and transmission of reports to the physician or other qualified health care professional

Codes	Number	Description
HCPCS	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*