

Cardiac Hemodynamic 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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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 **recipients of the CardioMEMS™ Champion Heart Failure Monitoring System (CPT code 33289 and 93264) who ARE participating in the Medicare-approved Category B IDE study:**

- ✓ Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, [§10.7.2 – Payment for Investigational Device Exemption \(IDE\) Studies](#)

Important Note Regarding Coverage: 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 the Medicare-approved Category B IDE study. For members **not** participating in the Medicare-approved Category B IDE study, see the “Medical Policy Manual” row in this table below.

National Coverage Determinations (NCDs)*

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 (LCAs)*

For **inert gas rebreathing (CPT 93799), left atrial pressure monitoring and pulmonary heart pressure monitoring systems OTHER THAN the CardioMEMS™ system (CPT code 93799 and HCPCS code C2624; e.g., Chronicle®, ImPressure®):**

- ✓ Non-Covered Services ([L35008](#))

There are no left atrial pressure monitoring systems with FDA approval, and only CardioMEMS™ has received FDA-approval as an implantable pulmonary heart pressure monitoring system. According to LCD L35008, “Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by

Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member.” Therefore, any device that has not received FDA-approval would be considered not medically reasonable or necessary.

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.

Medical Policy Manual

Medicare coverage guidance is not available for arterial pressure during Valsalva or for FDA-approved systems for implantable direct pressure monitoring of the pulmonary artery. Therefore, the health plan’s medical policy is applicable.

For *arterial pressure during Valsalva* and *recipients of the CardioMEMS™ system (CPT code 33289 and 93264) who are NOT participating in the Medicare-approved Category B IDE study.*

- ✓ Cardiac Hemodynamic 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

- 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, which is reported with C9741. 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.”^[3] Therefore, 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.” Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. (*MM9014 and Noridian LCD L35008*)
- 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.

CROSS REFERENCES

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), 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](#))
2. Approved IDE Studies listing “*Hemodynamic-GUIDEd Management of Heart Failure*”; Available at: <https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html>
3. MLN Matters® Article MM9014, *January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)*; Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9014.pdf>
[Last cited 05/06/2019]

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
HCPCS	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
	C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report (Code deleted 01/01/2019)

***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.