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

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Next Review: 04/2024
Last Review: 06/2023

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.
**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.

<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>For recipients of the CardioMEMSTM Champion Heart Failure Monitoring System (CPT code 33289 and 93264) who ARE participating in the Medicare-approved Category B investigational device exemption (IDE) study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ In February 2018, CMS approved the IDE study titled, “Hemodynamic-GUIDEd Management of Heart Failure” (NCT03387813). Therefore, this service may be covered by Medicare only if the member is enrolled in the Medicare-approved Category B IDE study. Medicare information regarding IDE studies can be found in the following Medicare reference:</td>
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<tr>
<td>○ Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies</td>
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For members not participating in the Medicare-approved Category B IDE study, see the “Medical Policy Manual” row in this table below.

For left atrial pressure monitoring and pulmonary heart pressure monitoring systems OTHER THAN the CardioMEMSTM system (CPT code 93799 and HCPCS code C2624; e.g., Chronicle®, ImpPressure®):

✓ There are no left atrial pressure monitoring systems with U.S. Food and Drug Administration (FDA) approval and only CardioMEMSTM has received FDA-approval as an implantable pulmonary heart pressure monitoring system. 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 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)* | Note: While the health plan’s local Medicare contractor does not address pulmonary artery pressure measurements using technology such as the CardioMEMS™HF System, the health plan’s Medicare medical policy is consistent with other Medicare Contractors (MACs) with respect to coverage only being allowed when provided under a Medicare-approved Category B IDE study.\(^3,4\) |
| 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 arterial pressure during Valsalva, inert gas rebreathing (CPT code 93799), thoracic fluid index monitoring (Category III codes 0607T and 0608T), 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 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).
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 CardioMEMSTM, 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).

- 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 CardioMEMSTM 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 06/13/2022] (This reference can be found on the Medicare Coverage Database website)
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 05/13/2023]
6. µCor Heart Failure and Arrhythmia Management System [Last cited 06/13/2023]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172510.pdf
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<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>33289</td>
<td>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</td>
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<td>93264</td>
<td>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</td>
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<td>93701</td>
<td>Bioimpedance-derived physiologic cardiovascular analysis</td>
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<td></td>
<td>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
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<td>0607T</td>
<td>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</td>
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<td>0608T</td>
<td>; analysis of data received and transmission of reports to the physician or other qualified health care professional</td>
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<td>HCPCS</td>
<td>C2624</td>
<td>Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components</td>
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*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.*