# *Medicare Medical Policy*

# Implantable Hemodynamic Monitoring Devices

**MEDICARE MEDICAL POLICY NUMBER:** 417

**Effective Date:** 9/1/2026

**Last Review Date:** 8/2026

**Next Annual Review:** 8/2027



**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

☒ Medicare Only

## MEDICARE COVERAGE CRITERIA

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

| Service | Medicare Guidelines |
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| *Implantable **Pulmonary Artery** Pressure Sensor (IPAPS) for HF Management* | National Coverage Determination (NCD): Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management (20.36)<br><br>**NOTES:**<br>• According to this NCD, coverage is provided under the Coverage with Evidence Development (CED) provision.<br>• In addition, the NCD adds, "Nothing in this NCD would preclude coverage of IPAPS for HF management through… the Investigational Device Exemption (IDE) Policy."<br>• This means services **must** be rendered ***either*** (1) in the context of a Medicare approved CED study or registry ***or*** (2) in the context of a Medicare approved IDE study.<br>• In a accordance with Criterion C.1 of the NCD 20.36, "IPAPS for HF management is not covered for patients outside of a CMS-approved study." Therefore, IPAPS services not provided in the content of either a CED or IDE study will be denied as not medically necessary. |
| *Implantable **Left Atrial** Hemodynamic Monitors (e.g., the HeartPOD™, the Promote® LAP, V-LAP™, and the FIRE1™ Systems) and Long-Term Hemodynamic Monitoring with Implantable Inferior Vena Cava Sensor – **When Rendered in the Context of a Medicare-Approved IDE Study*** | When services are **rendered in a Medicare-approved investigational device exemption (IDE) study:** This service may be considered **medically necessary** for Medicare plan members **if** the services are rendered in the context of a Medicare-approved Category B IDE study. Below are examples of such studies, but others can be found on the CMS IDE website.[1]<br><br>1. *V-LAP™ System:*<br>a. In **January 2024**, CMS approved the IDE study titled, "A Multi-center, National, Open Label, Prospective Study to Evaluate the Safety, Usability and Performance of the V-LAP™ System, for Wirelessly Measuring and Monitoring Left Atrial Pressure (Lap) in Patients With Advanced CHF" |

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| | (NCT06147336). Note this is a **Category A** IDE, so not all charges may be eligible for coverage.<br>2. *FIRE1™ System*:<br>a. In **June 2023**, CMS approved the IDE study for this device, titled "Early Feasibility Study of the FIRE1™ System in Heart Failure Patients" (G2220284).<br><br><u>For services **NOT rendered** in the context of a Medicare-approved IDE study:</u> Apply the Company policy criteria below.<br><br>**NOTES:**<br>• When services are rendered under a Medicare approved IDE study, the Medicare Advantage Plan is the primary payer. The NCT number must be provided in order to confirm an IDE study is Medicare approved. For clinical trials which are **not** IDE or CED studies, Medicare Advantage plans are **not** the primary payer, and coverage would be determined by Original Medicare. |
| **Medicare Coverage Criteria:** "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)<br>• **Medicare Coverage Manuals:** Medicare does not have criteria for implantable hemodynamic monitoring systems in a coverage manual. However, CMS does state that any device that has not received FDA-approval would be considered not medically reasonable or necessary, and many of these devices have not yet received this regulatory approval. *(Medicare Benefit Policy Manual, Chapter 14)*<br>• **National Coverage Determination (NCD):** Medicare does **not** have an active coverage decision for implantable left atrial hemodynamic or inferior vena cava sensor hemodynamic monitoring systems.<br>• **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have current, active LCDs for implantable **left atrial** hemodynamic monitoring systems or **inferior vena cava sensor** hemodynamic monitoring systems.<br>• Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there are no Medicare coverage criteria available specific to these procedures or health systems. However, it should be noted that many of these devices do **not** have FDA approval, and therefore, would not be eligible for coverage, outside the context of clinical trials or registries. *(Medicare Benefit Policy Manual, Chapter 14)*<br>• ***NOTE:** The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].* | |
| *Implantable **Left Atrial** Hemodynamic Monitors (e.g., the HeartPOD™, the Promote® LAP, V-LAP™,* | Company medical policy for Implantable Hemodynamic Monitoring Devices |

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| *and the FIRE1™ Systems) (CPTs 0933T, 0934T)* – ***When NOT Rendered in the Context of a Medicare-Approved IDE Study***<br><br>*Long-Term Hemodynamic Monitoring with Implantable* ***Inferior Vena Cava*** *Sensor (CPTs 0981T-0983T)* – ***When NOT Rendered in the Context of a Medicare-Approved IDE Study*** | I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.* |

**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

## POLICY CROSS REFERENCES

- Clinical Trials, Studies and Registries, MP233
- External Ambulatory Electrocardiography, MP157
- Implantable Loop Recorders, MP343
- Transcatheter Aortic Valve Replacement (TAVR), MP

**The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.**

## POLICY GUIDELINES

**MEDICARE AND MEDICAL NECESSITY**

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for implantable left atrial or vena cava hemodynamic monitoring systems available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied.

## *REGULATORY STATUS*

**U.S. FOOD & DRUG ADMINISTRATION (FDA)**

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

**Implantable Pulmonary Heart Pressure Monitoring Systems**

In 2022, the CardioMEMS™ Champion Heart Failure Monitoring System) received approval from the FDA through the premarket approval (PMA) process.[5] The device is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides.

In 2024, the FDA approved the Cordella Pulmonary Artery Sensor System (CorPASS). It is indicated to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) and have been stable for 30 days on GDMT.[6]

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®).

**Implantable Left Atrial Hemodynamic Monitoring Devices**

Examples of implantable left atrial hemodynamic monitoring systems include, but may not be limited to, the following:

- The HeartPOD™ System - HeartPOD System is not available for commercial use in the U.S.
- The Promote® LAP System - not available for commercial use in the U.S.
- The V-LAP™ System - limited to clinical trial use in the U.S.

## *BILLING GUIDELINES AND CODING*

**GENERAL**

**Implantable Pulmonary Artery Pressure Sensor System**

CPT code 33289 is for **implantation** of the wireless pulmonary artery pressure sensor system.

CPT code 93264 is for **remote monitoring** of the system.

HCPCS code C2624 is for the reporting of the **device** and should be used only by facilities. This code should **not** be used on professional claims. *NOTE: While CMS established a device pass-through category for CardioMEMS and HCPCS code C2624 in 2024, the CMS MLN Matters® Article MM9014 includes a disclaimer which reads, "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."[7] Therefore, this "device pass-through category" does not in itself establish medical necessity for the services under Medicare.*

**Implantable Left Atrial Hemodynamic Monitoring Devices**

Prior to January 1, 2025, there were no specific codes available for left atrial hemodynamic monitoring utilizing implantable device and unlisted code 93799 (Unlisted cardiovascular service or procedure) was used. Effective January 1, 2025, CPT codes 0933T and 0934T were implemented and should be used for this service.

| **CODES*** | | |
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| **CPT** | 0933T | Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation |
| | 0934T | Remote monitoring of a wireless left atrial pressure sensor for up to 30 days, including data from daily uploads of left atrial pressure recordings, interpretation(s) and trend analysis, with adjustments to the diuretics plan, treatment paradigm thresholds, medications or lifestyle modifications, when performed, and report(s) by a physician or other qualified health care professional |

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| | 0981T | Transcatheter implantation of wireless inferior vena cava sensor for long-term hemodynamic monitoring, including deployment of the sensor, radiological supervision and interpretation, right heart catheterization, and inferior vena cava venography, when performed |
| | 0982T | Remote monitoring of implantable inferior vena cava pressure sensor, physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up and patient education on use of equipment |
| | 0983T | Remote monitoring of an implanted inferior vena cava sensor for up to 30 days, including at least weekly downloads of inferior vena cava area recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional |
| | 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 |
| **HCPCS** | C2624 | Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components |
| | G0555 | Provision of replacement patient electronics system (e.g., system pillow, handheld reader) for home pulmonary artery pressure monitoring |

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## *REFERENCES*


1. Centers for Medicare and Medicaid Services (CMS). Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf. Accessed 7/8/2025.

2. Medicare Coverage Database (MCD) Archive Site. RETIRED Novitas LCD for *Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure* (L36419). Retired 07/2020. https://localcoverage.cms.gov/mcd_archive/search.aspx. Accessed 7/8/2025.
3. MCD Archive Site. RETIRED First Coast Service Options LCA for *Noncovered services revision to the Part A and Part B LCD* (A56046). Retired 07/2020. https://localcoverage.cms.gov/mcd_archive/search.aspx. Accessed 7/8/2025.
4. U.S. Food and drug Administration (FDA). Approval Letter for CardioMEMS™ HF System. 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100045S056A.pdf. Accessed 7/8/2025.
5. U.S. FDA. Approval Letter for Cordella Pulmonary Artery Sensor System (CorPASS). 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230040A.pdf. Accessed 7/8/2025.
6. Centers for Medicare and Medicaid Services (CMS). MLN Matters® Article MM9014, January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS). Available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3156cp.pdf. Accessed 7/8/2025.

## *POLICY REVISION HISTORY*

| DATE | REVISION SUMMARY |
|---|---|
| 11/2024 | New Medicare Advantage medical policy |
| 1/2025 | Q1 2025 code updates, add left atrial hemodynamic monitoring to policy |
| 1/13/2025 | Interim update; add Final Decision Memo, which will become an NCD with the same effective date |
| 6/2025 | Interim update; add link to Medicare approved CED studies for implantable pulmonary artery pressure sensors |
| 7/2025 | Q3 2025 code updates, add inferior vena cava hemodynamic monitoring to policy |
| 9/2025 | Annual review; no changes |
| 9/2026 | Annual review; no changes |