Medicare Medical Policy

Implantable Pulmonary Artery Pressure Monitoring

MEDICARE MEDICAL POLICY NUMBER: 417

Effective Date: 11/1/2024

Last Review Date: 8/2024

Next Annual Review: 8/2025

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”).

PRODUCT AND BENEFIT APPLICATION

☒ 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
*Implantable Pulmonary Artery Pressure Sensor for HF Management – Systems **WITH** FDA Approval **and** When Rendered in the Context of a Medicare-Approved IDE study*	**For systems which have been approved by the U.S. Food and Drug Administration (FDA)** (e.g., CardioMEMS™)**:** 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 member is enrolled in one of the following the Medicare-approved Category B IDE studies.[1] 1. *CardioMEMS™ Champion Heart Failure Monitoring System:* In February 2018, CMS approved the IDE study titled, "Hemodynamic-GUIDEd Management of Heart Failure" (GUIDE-HF; NCT03387813). 2. *Cordella™ Pulmonary Artery Sensor System:* a. In **October 2019**, CMS approved the IDE study titled, "A Prospective, Multi-Center, Randomized, Controlled, Single Blind Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients" (NCT04089059). b. In **December 2023**, CMS approved a second IDE study for this device, titled "A Prospective, Multi-Center, Open Label, Randomized Control Clinical Trial Evaluating the Safety and Efficacy of the Cordella™ Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class II Heart Failure Patients" (NCT05934487). Both of these studies are referred to as the "PROACTIVE-HF" study. *For services **NOT rendered** in the context of a Medicare-approved IDE study:* Apply the Company policy criteria below.

	NOTES: • As of the date of the most recent review, CardioMEMS™ is the **only** implantable pulmonary heart pressure monitoring system which has received FDA-approval. • For participation in a Medicare approved **investigational device exemption (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.
*Implantable Pulmonary Artery Pressure Sensor for HF Management – Systems **WITHOUT** FDA Approval*	**For systems which have not been approved by the FDA** (e.g., Chronicle®, ImPressure®)**:** According to the Medicare Benefit Policy Manual, Chapter 14, §10 - Coverage of Medical Devices, while FDA-approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any implantable pulmonary heart pressure monitoring system which has **not** received FDA-approval would be considered **not medically necessary**. **NOTES:** 2. Exceptions may only be considered if the service is rendered in the context of a Medicare-approved trial/study. • For participation in **a non-IDE Medicare approved clinical trial/study**, then **Medicare is the primary payer**. This means the plan is unable to consider payment or reimbursement without the claim first being sent to Medicare, then submitted to the plan with the Medicare explanation of benefits (MEOB). The plan may only consider coverage if Medicare allows and makes payment on the services first. This is according to both CMS guidelines/regulation, as well as member benefit contract language. • For participation in **any clinical trial or study which is not Medicare approved**, coverage would be a direct member benefit exclusion and would not be covered.

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*)

- **Medicare Coverage Manuals:** Medicare does not have criteria for implantable pulmonary heart pressure monitoring systems in a coverage manual.
- **National Coverage Determination (NCD):** As of the date this policy was reviewed, Medicare does **not** have an active NCD for implantable pulmonary heart pressure monitoring systems.
- **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 pulmonary heart pressure monitoring systems.
- 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.

Implantable Pulmonary Artery Pressure Monitoring Systems – ***When Services Are NOT Rendered in the Context of a Medicare-Approved IDE study***	Company medical policy for Implantable Pulmonary Artery Pressure Monitoring 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.

Novitas had an LCD for *Outpatient Wireless Pulmonary Artery Pressure Monitoring for Heart Failure* (L36419) and First Coast Service Options had an LCA for *Noncovered services revision to the Part A and Part B LCD* (A56046)[2,3], both of which addressed this technology; however, both of these Medicare policies were retired in July 2020, and since neither of these MACs have jurisdiction over the plan service area, they would not be used regardless.

Therefore, since there are not fully established coverage criteria for implantable pulmonary heart pressure monitoring systems available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied.

Potential Future NCD

While at the time of the policy's development, there was no active NCD Medicare coverage policy, there is a national coverage analysis (NCA) published by CMS for the CardioMEMS HF System (CAG-00466N). A *proposed* decision memo is not anticipated to be completed prior to October 30, 2024, and a *final* decision memo would not be expected prior to January 2025. If following the formal NCD development process, CMS determines they will develop a NCD for this service, this medical policy will be updated to include the Medicare coverage criteria policy.

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.[4] 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.[5]

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®).

BILLING GUIDELINES AND CODING

GENERAL

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."[6] Therefore, this "device pass-through category" does not in itself establish medical necessity for the services under Medicare.*

CODES*		
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
HCPCS	C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

***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 6/10/2024.
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 6/10/2024.
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 6/10/2024.
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 7/1/2024.
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 7/16/2024.
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 6/10/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2024	New Medicare Advantage medical policy