

National Coverage Determination 20.36: Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management

Related CR Release Date: June 20, 2025	MLN Matters Number: MM14000 Revised
Effective Date: January 13, 2025	Related Change Request (CR) Number: CR 14000
Implementation Date: October 6, 2025	Related CR Transmittal Numbers: R13246CP, R13246NCD, R13282CP & R13282NCD

What's Changed? We made no substantive changes to the article other than to update the CR release date, transmittal numbers, and transmittal links.

Affected Providers

- Physicians
- Hospitals
- Other providers billing Medicare Administrative Contractors (MACs) for heart-related services

Action Needed

Make sure your billing staff knows about:

- National coverage of implantable pulmonary artery pressure sensors (IPAPS)
- Criteria for coverage
- Coverage with evidence development (CED) study criteria
- Claims processing requirements

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Background

Heart failure (HF) is a chronic syndrome in which the heart muscle can't pump enough blood to meet the body's needs. HF patients are prone to fluid retention in the body, including the lungs (pulmonary congestion), which results in shortness of breath, fatigue, and limitations of everyday activities, such as walking or climbing stairs. Worsening of these symptoms can lead to acute decompensated HF and hospitalization. A change in blood flow, measured by pulmonary artery (PA) pressure, precedes symptoms of HF.

The purpose of an IPAPS is early detection of the change in blood flow allowing medical intervention intended to prevent:

- Symptom onset
- Further exacerbation
- Hospitalization

Using an IPAPS and external data gathering unit in the patient's home sends the patient's PA pressure trends to their physician and allows for better management of medications, lifestyle adjustments, and office visits to prevent or reduce acute HF episodes.

Key Updates

Nationally Covered Indications

Starting for services performed on or after January 13, 2025, CMS determined the evidence is sufficient to cover IPAPS for HF management under CED when provided according to an FDA market-authorized indication and all the following conditions are met.



Patient Criteria

The patient must meet all the following criteria:

Diagnosis of chronic HF of at least 3 months duration and in New York Health Association (NYHA) functional Class II or III within the past 30 days, prior to pulmonary artery pressure sensor (PAPS) implantation, regardless of left ventricular ejection fraction (LVEF).

- History of HF hospitalization or urgent HF visit (emergency department (ED) or other outpatient (OP) visit requiring intravenous (IV) diuretic therapy) within the past 12 months, or elevated natriuretic peptides within the past 30 days.
- On guideline-directed medical therapy (GDMT) for at least 3 months with the goal of achieving optimal or maximally tolerated GDMT prior to PAPS implantation.
- Evaluated for, and received if appropriate, an implantable cardioverter defibrillator, cardiac resynchronization therapy (CRT)-Pacemaker (CRT-P), or CRT-Defibrillator (CRT-D). Implantation of the device must occur at least 3 months prior to PAPS implantation.
- No major cardiovascular event (for example, unstable angina, myocardial infarction, percutaneous coronary intervention, open heart surgery, or stroke) within the last 3 months prior to PAPS implantation.
- Have access to reliable connectivity to ensure daily collection and submission of IPAPS data.
- Must not have PAPS implantation occur during a hospital admission for an acute HF episode.

Physician Criteria

Practitioners who provide the IPAPS items and services must meet the following criteria, as applicable:

- Physicians referring Medicare patients and managing them post-implantation must be cardiologists with training and experience in HF management
- Physicians implanting an IPAPS must have training and experience in pulmonary arterial catheterization and intervention



CED Study Criteria

The practitioner must provide IPAPS items and services in the context of a CMS-approved CED study. Study protocols must:

- Include only those patients who meet the patient criteria in National Coverage Determination (NCD) 20.36
- Provide items and services only through practitioners who meet the physician criteria in NCD 20.36
- Include the following:
 - Primary outcomes of HF hospitalization (the cumulative number of HF hospital admissions and HF ED or other OP visits requiring IV diuretics), all-cause mortality, or a composite of these, through a minimum of 24 months. The practitioner must individually report each component of a composite outcome.
 - An active comparator.
 - A care management plan that:
 - Identifies members, roles, and responsibilities of the physician-led HF clinical team (for example, physicians, physician assistants, nurse practitioners, and nurses) that performs the follow-up IPAPS patient monitoring and medication management
 - Specifies the medication management protocols the patient and HF clinical team must follow
 - Be designed sufficiently to demonstrate clinical utility of the IPAPS for HF management using direct measures of clinical behavior (for example, counts of patient and physician interactions, counts and type of medication changes, counts of unscheduled outpatient clinic visits, and counts of days within clinician set thresholds) to effectively manage and improve patient outcomes.
 - Be designed sufficiently for subgroup analyses by:
 - CRT-P, CRT-D, or ICD (with hemodynamic monitoring capabilities) status (with or without)
 - Age (75+ years)
 - Sex
 - Race and ethnicity
 - LVEF (by guideline-defined subgroups)
 - NYHA Class II vs III (as appropriate based on the FDA-approved label)
 - Stage IV or greater chronic kidney disease
 - HF hospitalization in the past 12 months vs. elevated natriuretic peptides alone in the last 30 days

CMS-approved CED studies must adhere to the scientific standards (criteria 1–17) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in section VI of our CED guidance document and CR 14000.



Note: Consistent with section 1142 of the <u>Social Security Act</u>, the AHRQ supports clinical research studies that we determine meet all the criteria and standards identified.

Other Uses of IPAPS

- We don't cover IPAPS for HF management for patients outside of a CMS-approved study
- Nothing in this NCD would preclude coverage of IPAPS for HF management through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption Policy

Claims Processing Requirements for Claims with Dates of Service on or After January 13, 2025

Coding

Use the following HCPCS and ICD-10-PCS codes and claims modifiers for billing IPAPS:

- HCPCS code 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
- ICD-10-PCS code 02HQ30Z Insertion of Pressure Sensor Monitoring Device into Right Pulmonary Artery, Percutaneous Approach
- ICD-10-PCS code 02HR30Z Insertion of Pressure Sensor Monitoring Device into Left Pulmonary Artery, Percutaneous Approach
- Modifier Q0 Investigational clinical service provided in a clinical research study that is in an approved clinical research study
- Condition Code 30 Qualified clinical trial
- Value code D4 Clinical trial number (8-digit number)

Note: Only report ICD-10-PCS codes 02HQ30Z and 02HR30Z on institutional claims.

Claims containing HCPCS code 33289, 02HQ30Z, or 02HR30Z must contain ICD-10 diagnosis code Z00.6 and one of the following diagnosis codes: I50.1, I50.22, I50.23, I50.32, I50.33, I50.42, I50.43, I50.82, or I50.812.

Types of Bills

Submit claims for:

- HCPCS code 33289 on types of bills (TOBs) 12X, 13X, or 85X
- ICD-10-PCS codes 02HQ30Z and 02HR30Z on TOB 11X

Your MAC will return any claims you submitted with the wrong TOB, claims without the appropriate condition or value code, or claims not including the clinical trial number.

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Frequency Requirements

We cover IPAPS once in a patient's lifetime.

Note: Your MAC won't search their files for IPAPS claims with dates of service between January 13, 2025, and October 6, 2025; however, they'll adjust any claims that you bring to their attention.

More Information

We issued these transmittals to your MAC as the official instructions for the changes:

- R13246CP
- R13246NCD
- R13282CP adds section 413 to the Medicare Claims Processing Manual, Chapter 32
- R13282NCD adds section 20.36 to the Medicare NCD Manual, Chapter 1, Part 1

For more information, find your MAC's website.

Document History

Date of Change	Description
June 23, 2025	We made no substantive changes to the article other than to update the CR release date, transmittal numbers, and transmittal links.
May 23, 2025	Initial article released.

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