CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13246	**Date: May 22, 2025**
	Change Request 14000

SUBJECT: National Coverage Determination (NCD) 20.36 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective January 13, 2025, contractors shall pay claims for implantable pulmonary artery sensors for heart failure management as described in Pub. 100-03, Medicare NCD Manual, Chapter 1, section 20.36.

EFFECTIVE DATE: January 13, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 6, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	Table of Contents
N	1/20.36/Part 1/Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 13246	Date: May 22, 2025	Change Request: 14000

SUBJECT: National Coverage Determination (NCD) 20.36 Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management

EFFECTIVE DATE: January 13, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 6, 2025

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective January 13, 2025, contractors shall pay claims for implantable pulmonary artery sensors for heart failure management as described in Pub. 100-03, Medicare NCD Manual, Chapter 1, section 20.36.

II. GENERAL INFORMATION

A. Background: Heart failure (HF) is a chronic syndrome in which the heart muscle cannot 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 (ADHF) and hospitalization. A change in blood flow, measured by pulmonary artery (PA) pressure, precedes symptoms of HF. The purpose of an implantable PA pressure sensor (IPAPS) is early detection of the change in blood flow, allowing medical intervention intended to prevent symptom onset, further exacerbation and hospitalization. An IPAPS and external data gathering unit are used in the patient's home to send a patient's PA pressure trends to their physician, allowing better management of medications, lifestyle adjustments, and office visits to prevent or reduce acute HF episodes.

B. Policy: Effective for services performed on or after January 13, 2025, the Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover implantable pulmonary artery pressure sensors (IPAPS) for HF management under Coverage with Evidence Development (CED) when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all of the following conditions are met:

1. Patient Criteria

The patient must meet all of the following criteria:

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

b) History of HF hospitalization or urgent HF visit (emergency room (ER) or other outpatient (OP) visit requiring intravenous (IV) diuretic therapy) within the past 12 months, or elevated natriuretic peptides within the past 30 days.

c) 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.

d) Evaluated for, and received if appropriate, an implantable cardioverter defibrillator (ICD), 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.

e) No major cardiovascular event (e.g., unstable angina, myocardial infarction, percutaneous coronary intervention, open heart surgery, or stroke) within the last 3 months prior to PAPS implantation.

f) Have access to reliable connectivity to ensure daily collection and submission of IPAPS data.

g) Must not have PAPS implantation occur during a hospital admission for an acute HF episode.

2. Physician Criteria

The IPAPS items and services are furnished by practitioners who meet the following criteria, as applicable:

a) Physicians referring Medicare patients and managing them post implantation must be cardiologists with training and experience in HF management.

b) Physicians implanting an IPAPS must have training and experience in pulmonary arterial

catheterization and intervention.

3. CED Study Criteria

The IPAPS items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; and include all of the following:

a) Primary outcomes of "HF hospitalization" (the cumulative number of HF hospital admissions, and HF ER or other OP visits requiring IV diuretics), all-cause mortality, or a composite of these, through a minimum of 24 months. Each component of a composite outcome must be individually reported.

b) An active comparator.

c) A care management plan that:

- Identifies members, roles and responsibilities of the physician-led HF clinical team (e.g., physicians, physician assistants, nurse practitioners, nurses) that performs the follow-up IPAPS patient monitoring and medication management; and
- Specifies the medication management protocols the patient and HF clinical team must follow.

d) Design sufficient to demonstrate clinical utility of the IPAPS for HF management using direct measures of clinical behavior (e.g., counts of patient/physician interactions, counts and type of medication changes, counts of unscheduled outpatient clinic visits, counts of days within clinician set thresholds) to effectively manage and improve patient outcomes.

e) Design sufficient for subgroup analyses by:

• CRT-P, CRT-D, or ICD (with hemodynamic monitoring capabilities) status (with/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.

f) CMS-approved CED studies must adhere to the scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI of CMS' Coverage with Evidence Development Guidance Document, published August 7. (***https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38***)

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.

3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors. At a minimum, this includes attention to the intended population's racial and ethnic backgrounds, gender, age, disabilities, important comorbidities, and, dependent on data availability, relevant health related social needs. For instance, more than half of Medicare beneficiaries are women so study designs should, as appropriate, consider the prevalence in women of the condition being studied as well as in the clinical trial and subsequent data reporting and analyses.

7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in

existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and

the health outcomes it is thought to predict.

10. Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting prespecified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).

15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data,

methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with

regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. Other Uses of IPAPS

1. IPAPS for HF management is not covered for patients outside of a CMS-approved study.
2. 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 (IDE) Policy.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
14000 - 03.1	Effective for claims with dates of service on and after January 13, 2025, contractors shall pay claims for implantable pulmonary artery sensors for heart failure management as described in Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 20.36.	X	X							

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)
Coverage Determinations

Table of Contents
(Rev. 13246; Issued: 05-22-25)

Transmittals for Chapter 1, Part 1

20.36 – Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management

20.36 – Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management
(Rev. 13246; Issued: 05-22-25; Effective: 01-13-25; Implementation:10-06-25)

A. General

Heart failure (HF) is a chronic syndrome in which the heart muscle cannot 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 (ADHF) and hospitalization. A change in blood flow, measured by pulmonary artery (PA) pressure, precedes symptoms of HF. The purpose of an implantable PA pressure sensor (IPAPS) is early detection of the change in blood flow, allowing medical intervention intended to prevent symptom onset, further exacerbation and hospitalization. An IPAPS and external data gathering unit are used in the patient's home to send a patient's PA pressure trends to their physician, allowing better management of medications, lifestyle adjustments, and office visits to prevent or reduce acute HF episodes.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers implantable pulmonary artery pressure sensor(s) (IPAPS) for heart failure (HF) management under Coverage with Evidence Development (CED) according to the provisions below:
Coverage Criteria:

Implantation of an IPAPS is covered for HF management when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all of the following conditions are met:

1. Patient Criteria

The patient meets all of the following criteria:

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

b) History of HF hospitalization or urgent HF visit (emergency room (ER) or other outpatient (OP) visit requiring intravenous (IV) diuretic therapy) within the past 12 months, or elevated natriuretic peptides within the past 30 days.

c) 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.

d) Evaluated for, and received if appropriate, an implantable cardioverter defibrillator (ICD), 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.

e) No major cardiovascular event (e.g., unstable angina, myocardial infarction, percutaneous coronary intervention, open heart surgery, or stroke) within the last 3 months prior to PAPS implantation.

f) Have access to reliable connectivity to ensure daily collection and submission of IPAPS data.

g) Must not have PAPS implantation occur during a hospital admission for an acute HF episode.

2. Physician Criteria

The IPAPS items and services are furnished by practitioners who meet the following criteria, as applicable:

a) Physicians referring Medicare patients and managing them post implantation must be cardiologists with training and experience in HF management.

b) Physicians implanting an IPAPS must have training and experience in pulmonary arterial catheterization and intervention.

3. CED Study Criteria

The IPAPS items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; and include all of the following:

a) Primary outcomes of "HF hospitalization" (the cumulative number of HF hospital admissions, and HF ER or other OP visits requiring IV diuretics), all-cause mortality, or a composite of these, through a minimum of 24 months. Each component of a composite outcome must be individually reported.

b) An active comparator.

c) A care management plan that:

- *Identifies members, roles and responsibilities of the physician-led HF clinical team (e.g., physicians, physician assistants, nurse practitioners, nurses) that performs the follow-up IPAPS patient monitoring and medication management; and*
- *Specifies the medication management protocols the patient and HF clinical team must follow.*

d) Design sufficient to demonstrate clinical utility of the IPAPS for HF management using direct measures of clinical behavior (e.g., counts of patient/physician interactions, counts and type of medication changes, counts of unscheduled outpatient clinic visits, counts of days within clinician set thresholds) to effectively manage and improve patient outcomes.

e) Design sufficient for subgroup analyses by:

• CRT-P, CRT-D, or ICD (with hemodynamic monitoring capabilities) status (with/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.

f) CMS-approved CED studies must adhere to the following scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7.
https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.
2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to
ensure timely completion of the CED process.

3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors. At a minimum, this includes attention to the intended population's racial and ethnic backgrounds, gender, age, disabilities, important comorbidities, and, dependent on data availability, relevant health related social needs. For instance, more than half of Medicare beneficiaries are women so study designs should, as appropriate, consider the prevalence in women of the condition being studied as well as in the clinical trial and subsequent data reporting and analyses.

7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and
reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation
studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.

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12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting prespecified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).

15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. Other Uses of IPAPS

1. *IPAPS for HF management is not covered for patients outside of a CMS-approved study.*
2. *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 (IDE) Policy.*

(This NCD last reviewed January 2025.)