# Implantable Cardiac Devices for Hemodynamic Management

INDEPENDENT CARE HEALTH PLAN

**Effective Date:** 01/01/2024
**Revision Date:** Click or tap to enter a date.
**Review Date:** Click or tap to enter a date.
**Policy Number:** WI.PA-1045-000
**Line of Business:** Medicare

## Medical Coverage Policy

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## Related Medical/Pharmacy Coverage Policies

None

## Related Documents

**Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.**

**There are no NCD and/or LCDs for the implantable wireless pulmonary artery pressure monitoring device and implantable carotid sinus baroreflex activation system.**

## Description

**Implantable Carotid Sinus Baroreflex Activation Therapy**

Barostim Neo is an **implantable carotid sinus baroreflex activation** system purported to treat resistant hypertension (RHT) or heart failure (HF) in an individual with reduced ejection fraction. This treatment is also known as baroreflex activation therapy (BAT). The device consists of a lead positioned in the carotid sinus wall and a pulse generator implanted in an infraclavicular position. The system delivers electric current to baroreceptors in the carotid sinus and is proposed to initiate systemic blood pressure (BP) lowering responses and to enable the heart to increase blood output.[16,18]

The Barostim Neo is US Food & Drug Administration (FDA) approved for the treatment of heart failure symptoms, including functional status for an individual that remains symptomatic despite treatment with guideline-directed medical therapy (GDMT). The device is indicated for an individual with New York Heart Association (NYHA) Class II or III HF, left ventricular ejection fraction (LVEF) less than or equal to 35% and an NT-proBNP greater than 1600 pg/ml. Individuals indicated for cardiac resynchronization therapy (CRT) according to AHA/ACC/ESC guidelines are excluded from Barostim Neo implantation.[30]

Barostim Neo Legacy System currently has Humanitarian Device Exemption (HDE) for use only in individuals with RHT that have had bilateral implantation of the Rheos Carotid Sinus Leads (which have been discontinued and are obsolete) and were determined responders in the Rheos pivotal clinical study.[27] There are no FDA-approved BAT devices for the treatment of RHT in the United States. Feasibility studies have shown nonclinically significant reductions in systolic blood pressure; however, additional randomized controlled studies are needed to evaluate the safety and effectiveness of the Barostim Neo and clinical utility as compared to medication therapy.[18]

**Wireless Pulmonary Artery Pressure Monitoring**

The CardioMEMS HF system is an implantable **wireless pulmonary artery pressure monitoring** device that is used to measure heart rate and pulmonary artery (PA) pressure in certain individuals with heart failure (HF). Pulmonary artery pressure changes may indicate worsening heart failure. CardioMEMS consists of a small, paper clip-sized sensor that is implanted into the pulmonary artery during a heart catheterization procedure. Once the device is implanted and the individual returns home, the Patient Electronics System uses wireless technology to read the PA pressure measurements and then transmits the information to the healthcare provider. The individual can obtain daily readings with the system that the healthcare provider may use to make medication adjustments. The device recipient must be able to tolerate two types of anticoagulation medication for one month after the implantation procedure.

The FDA-approved indications for CardioMEMS were expanded to include individuals with NYHA Class II or III heart failure who have been hospitalized for HF in the previous year and/or have elevated natriuretic peptides. The hemodynamic data obtained from the CardioMEMS may be used to manage the symptoms and progression of heart failure. Intended benefits of the device include reduced HF-related hospitalization and improved quality of life.[25]

## Coverage Determination

iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:*

**Wireless Pulmonary Artery Pressure Monitoring**

**Wireless pulmonary artery pressure monitoring** will be considered medically reasonable and necessary when the following requirements are met:

- Absence of contraindications[9]; **AND**
- Body Mass Index (BMI) measurement is **EITHER**:
  - Greater than 35 kg/m$^2$ with chest circumference less than 65 inches measured at the axillary line[9]; **OR**
  - Less than 35 kg/m$^2$; **AND**
- Elevated brain natriuretic peptide (BNP or NT-proBNP) level within the last 30 days[5] (adjusted for BMI greater than 25 kg/m$^2$)[1] as defined by **EITHER** of the following:
  - Left ventricular ejection fraction (LVEF) less than or equal to 40%;
    **AND EITHER**:
    - BNP greater than or equal to 250 pg/mL[1]; **OR**
    - NT-proBNP greater than or equal to 1000 pg/mL[1]; **OR**
  - LVEF greater than 40%;
    - BNP greater than or equal to 175 pg/mL[1]; **OR**
    - NT-proBNP greater than or equal to 700 pg/mL[1]; **AND**
- Heart failure (HF) diagnosed greater than 3 months prior to procedure and treated with maximally tolerated guideline-directed medical therapy (GDMT)[9]; **AND**
- History of heart failure hospitalization in the past year[9]; **AND**
- Individual is on maximally tolerated GDMT or has a documented intolerance to GDMT (eg, hemodynamic instability)[1]; **AND**
- New York Heart Association (NYHA) class III heart failure[9]

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically*

*necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

**IMPLANTABLE CAROTID SINUS BAROREFLEX ACTIVATION THERAPY**

**Implantable carotid sinus baroreflex activation therapy** will not be considered medically reasonable and necessary.

A review of the current literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term outcomes establishing the value of this service in clinical management.

**Summary of Evidence**
Feasibility studies (6-month results) from two randomized control trials (RCTs) showed the possibility that Barostim Neo is safe and improves functional status more than optimal medical therapy in individuals with chronic heart failure with reduced EF (HFrEF; LVEF less than or equal to 35%).[12] However, available study results have a moderate risk of bias due to the small nonrandomized controlled (RCT) studies and do not report on mortality or assess hospitalization rates.

A recent systematic review and meta-analysis of the efficacy and safety of BAT for RHT found that although device therapy lowered blood pressure, the evidence was limited by a high risk of bias, small sample size and only one RCT was included in the analysis.[16] Studies do not report the correlation of reduced BP with a reduction in individual risk of cardiovascular death, stroke or kidney failure. There remains a lack of longer-term unbiased RCTs with comparative data between Barostim Neo Legacy and standard care results demonstrating the safety and efficacy of the Barostim Neo Legacy for the treatment of RHT.

A review of the current medical literature indicates a continued lack of randomized, blinded clinical studies examining long-term clinical outcomes that establish the value of Barostim Neo for management of heart failure and resistant hypertension. A low-quality body of evidence suggests that BAT is a potential treatment modality for patients with RHT and HF; however, long-term follow-up from larger randomized, sham-controlled, blinded studies is needed to accurately assess efficacy and safety.[17]

**WIRELESS PULMONARY ARTERY PRESSURE MONITORING**

**Wireless pulmonary artery pressure monitoring** will not be considered medically reasonable and necessary for the following contraindications:

- ACC/AHA Stage D refractory heart failure (including currently receiving or previously received pharmacologic circulatory support with inotropes)[1]; **OR**

- Active, ongoing infection (eg, febrile, elevated white blood cell count, intravenous antibiotic therapy, and/or positive cultures [blood, sputum, urine])[9]; **OR**
- Condition (eg, unexpected severe pulmonary hypertension [trans-pulmonary gradient greater than 15] at right heart catheterization implant and/or history of noncompliance) that would not allow for utilization of the CardioMEMS HF System to manage the individual using information gained from hemodynamic measurements to adjust medications[1]; **OR**
- Congenital heart disease (unrepaired) that would prevent implantation of the CardioMEMS pulmonary artery sensor[1]; **OR**
- Glomerular filtration rate (GFR) less than 25 ml/min (obtained within 2 weeks of implant) in an individual who is non-responsive to diuretic therapy or is on chronic renal dialysis[9]; **OR**
- Heart transplant or ventricular assistive device (VAD) implantation likely within the next 6 months[9]; **OR**
- History of current or recurrent (greater than 1 episode) pulmonary emboli and/or deep vein thromboses[9]; **OR**
- History of major cardiovascular event (eg, myocardial infarction, open heart surgery, percutaneous coronary intervention, stroke, unstable angina) within the previous 3 months[5]; **OR**
- Implanted with cardiac resynchronization therapy (CRT)-pacemaker (CRT-P) or CRT-defibrillator (CRT-D) for less than 90 days[9]; **OR**
- Implanted with mechanical right heart valve(s)[9]; **OR**
- Inability to tolerate or receive dual antiplatelet therapy (DAPT) or anticoagulant therapy (eg, bleeding risk, noncompliance) for one month post implantation[9]; **OR**
- Inability to tolerate a right heart catheterization (eg, allergy or intolerance to contrast material that cannot be pretreated, inability or intolerance to lay flat or at an angle, risk of nephrotoxicity outweighs the benefits of procedure)[9]; **OR**
- Intolerance (hemodynamic instability) to all neurohormonal antagonists (eg, angiotensin converting enzyme inhibitor [ACEi], angiotensin-neprilysin inhibitor [ARNi], angiotensin receptor blocker [ARB], beta blocker, hydralazine/isosorbide dinitrate)[9]; **OR**
- Known coagulation disorder (eg, clotting factor deficiencies, hemophilia, hypercoagulable states, Von Willebrand disease)[9]; **OR**
- Life expectancy anticipated at less than 12 months[9]; **OR**
- NYHA class IV heart failure[25]; **OR**

- Pregnant or planning to become pregnant in the next 12 months[25]; **OR**
- Unrepaired severe valvular disease[25]

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

**Summary of Evidence**

A recent systematic review, one RCT and several retrospective studies found that heart failure (HF) hemodynamic guidance with CardioMEMS monitoring reduced HF-related risks by about 50% at 1 year follow-up in individuals with NYHA Class III heart failure. One RCT including individuals with NYHA Class II and III reported no statistically significant difference in composite 1-year mortality and HF-related hospitalizations rates with or without CardioMEMS.[15]

A review of the current medical literature indicates an overall low-quality body of evidence regarding the safety and efficacy of CardioMEMS monitoring and a continued lack of randomized, blinded clinical studies examining long-term clinical outcomes that establish the value of CardioMEMS for management of heart failure. Long-term follow-up from larger randomized, sham-controlled, blinded studies is needed to accurately assess efficacy and safety.[20]

## Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

| CPT® Code(s) | Description | Comments |
|---|---|---|
| 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 | |
| 93451 | Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed | |

| | | |
|---|---|---|
| 93568 | Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure) | |
| 93799 | Unlisted cardiovascular service or procedure | |
| **CPT® Category III Code(s)** | **Description** | **Comments** |
| 0266T | Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed) | |
| 0267T | Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed) | |
| 0268T | Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed) | |
| 0269T | Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed) | |
| 0270T | Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed) | |
| 0271T | Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed) | |
| 0272T | Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); | |

| | | |
|---|---|---|
| 0273T | Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming | |
| **HCPCS Code(s)** | **Description** | **Comments** |
| C1825 | Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s) | |
| C2624 | Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components | |

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## Appendix

**Appendix A**
**Guideline-directed medical therapy for heart failure[4]**

| Left ventricular ejection fraction (LVEF) | Medication | Duration |
|---|---|---|
| Less than or equal to 40% | • Beta blocker<br>• Diuretic<br>• Mineralocorticoid receptor agonist (MRA)<br>• Sodium-glucose cotransporter-2 inhibitor (SGLT2i)<br>• **One** of the following:<br>  ○ Angiotensin-converting enzyme inhibitor (ACEi)<br>  ○ Angiotensin receptor blocker (ARB)<br>  ○ Angiotensin receptor-neprilysin inhibitor (ARNi) | • 3 months<br>• Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month |
| 41 – 49% | • Beta blocker<br>• Diuretic<br>• Mineralocorticoid receptor agonist (MRA)<br>• Sodium-glucose cotransporter-2 inhibitor (SGLT2i)<br>• **One** of the following:<br>  ○ ACEi<br>  ○ ARB<br>  ○ ARNi | • Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month |
| Greater than or equal to 50% | • Diuretic<br>• Mineralocorticoid receptor agonist (MRA)<br>• Sodium-glucose cotransporter-2 inhibitor (SGLT2i)<br>• **One** of the following:<br>  ○ ACEi<br>  ○ ARB<br>  ○ ARNi | • Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month<br>• Greater than 1 month |

**Appendix B**

**Elevated brain natriuretic peptide (BNP or NT-proBNP) level adjusted for BMI[1]**

Thresholds for NT-proBNP and BNP (for both LVEF less than or equal to 40% and LVEF greater than 40%) are corrected for BMI using a 4%[9] reduction for each BMI unit over 25 kg/m$^2$.

| BMI (kg/m$^2$) | NT-proBNP Threshold (pg/mL) | | BNP Threshold (pg/mL) | |
|---|---|---|---|---|
| | LVEF less than or equal to 40% | LVEF greater than 40% | LVEF less than or equal to 40% | LVEF greater than 40% |
| Less than or equal to 25 | 1000 | 700 | 250 | 175 |
| 26 | 955 | 668 | 238 | 167 |
| 27 | 911 | 638 | 227 | 159 |
| 28 | 870 | 608 | 216 | 151 |
| 29 | 830 | 581 | 206 | 144 |
| 30 | 792 | 554 | 197 | 137 |
| 31 | 756 | 529 | 187 | 130 |
| 32 | 722 | 504 | 178 | 124 |
| 33 | 689 | 481 | 170 | 118 |
| 34 | 657 | 459 | 162 | 112 |
| 35 | 627 | 438 | 154 | 107 |
| 36 | 599 | 418 | 147 | 101 |
| 37 | 571 | 399 | 140 | 96 |
| 38 | 545 | 380 | 133 | 92 |
| 39 | 520 | 363 | 126 | 87 |
| 40 | 496 | 346 | 120 | 83 |
| 41 | 473 | 330 | 114 | 79 |
| 42 | 452 | 315 | 109 | 75 |
| 43 | 431 | 300 | 103 | 71 |
| 44 | 411 | 286 | 98 | 67 |
| 45 | 392 | 273 | 94 | 64 |
| 46 | 374 | 260 | 89 | 60 |
| 47 | 357 | 248 | 84 | 57 |
| 48 | 340 | 236 | 80 | 54 |
| 49 | 324 | 225 | 76 | 51 |
| 50 | 309 | 215 | 72 | 49 |

**Appendix C**
**New York Heart Association (NYHA) Functional Classification System**[4]

| Classification | Symptoms |
|---|---|
| Class I (mild) | Individual with cardiac disease, but without resulting limitations on physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain. |
| Class II (mild) | Individual with cardiac disease resulting in slight limitations on physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain. |
| Class III (moderate) | Individual with cardiac disease resulting in marked limitations on physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain. |
| Class IV (severe) | Individual with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases. |

**Appendix D**
**ACC/AHA Stages of Heart Failure (HF)**[4]

| Stage | Description |
|---|---|
| **A** – At risk for HF | Individual at risk for heart failure but does not yet have symptoms (eg, cough, dyspnea, edema, fatigue, palpitations) or structural or functional heart disease (eg, cardiomyopathy, congenital heart disease, valvular heart disease).<br><br>Risk factors include hypertension, coronary vascular disease, diabetes, obesity, exposure to cardiotoxic agents, genetic variants for cardiomyopathy and family history of cardiomyopathy. |
| **B** – Pre-HF | Individual with no current or previous symptoms of HF (eg, cough, dyspnea, edema, fatigue, palpitations) but with either structural heart disease (eg, cardiomyopathy, congenital heart disease, valvular heart disease), increased filling pressures in the heart or other risk factors. |
| **C** – Symptomatic HF | Individual with current or previous symptoms of HF (eg, cough, dyspnea, edema, fatigue, palpitations). |
| **D** – Advanced HF | Individual with HF symptoms (eg, cough, dyspnea, edema, fatigue, palpitations) that interfere with daily life functions or lead to repeated hospitalizations. |

## Change Summary

- 01/01/2024 New Policy.
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