

CardioMEMS™ HF System Clinical Checklist

This form is intended to be used by the treating physician as a guide to help gather information in connection to a heart failure diagnosis. The documentation referenced below may be submitted to the insurance company prior to procedure being performed.

HEALTHCARE PROVIDER INSTRUCTIONS

DO NOT INCLUDE THIS INSTRUCTION PAGE IN YOUR SUBMISSION

1. The Physician completes the CardioMEMS HF System Clinical Checklist, sign and date.
2. The documents below may be submitted to the insurance company for prior authorization.

- ☐ CardioMEMS HF System Clinical Checklist
- ☐ 3-6 months of treatment notes
- ☐ Echocardiogram report
- ☐ Hospitalizations for heart failure including discharge summaries
- ☐ Elevated BNP/NT-proBNP lab values and reports

For questions on the CardioMEMS HF System Clinical Checklist, please contact the Patient Therapy Access Team at PTA_cardiac@abbott.com or the Health Economics Team at heartfailureeconomics@abbott.com.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS HF System 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. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

CardioMEMS™ HF System Contraindications: The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

Reference

2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. <https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000001063>

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Patient Name: _____ Date of Birth: _____

Guideline Directed Medical Therapy

On GDMT with a goal of being on maximally tolerated doses (with optimal device therapy if applicable) per the 2022 ACC/AHA/HFSA/CHF guidelines based on the patient's ejection fraction.

☐ YES. 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.

CURRENT MEDICATION(S)

MEDICATION	CONTRAINDICATION
☐ ACE/ARB/ARNI	
☐ SGLT2i	
☐ MRA	
☐ Beta Blocker	
☐ Diuretic	
☐ Other	

Guideline Recommendations per the 2022 ACC/AHA/HFSA CHF Guidelines based on patient's ejection fraction

For EF $\leq$ 40%: On beta blockers for 3 months, on diuretics, SGLT2i, MRA, ACEi/ARB/ARNI

For EF 41-49%: On diuretic, SGLT2i, MRA, ACEi/ARB/ARNi, beta blockers

For EF greater than or equal to 50% on diuretic, SGLT2i, MRA, ACEI/ARG/ARNI

PATIENT HISTORY

NYHA CLASS (Must be assessed within 30 days prior to implant) ☐ I ☐ II ☐ III Date assessed: _____

☐ No major cardiovascular events within the last 3 months prior to anticipated implant date

Examples: Unstable angina, Myocardial infarction, Percutaneous coronary intervention (PCI), Open heart surgery, Stroke

BNP/NT-proBNP lab value (result within the last 30 days): _____

Ejection Fraction: _____

Actual BMI: _____ KG/m²

If BMI >35, document chest circumference measured at the axillary level: _____

History of heart failure hospitalization within the past 12 months: ☐ YES ☐ NO

Dates of admission(s): _____

DEVICE THERAPY

Evaluated for, and received if appropriate, an ICD/CRT-P/CRT-D ☐ YES ☐ NO

If yes, was the device implanted $\geq$ 3 months ago? ☐ YES ☐ NO

CONNECTIVITY

Has access to reliable connectivity at home ☐ YES ☐ NO

DIAGNOSIS

- | | | |
|--|---|--|
| ☐ I50.1 Left ventricular failure | ☐ I50.32 Chronic diastolic (congestive) heart failure | ☐ I50.43 Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure |
| ☐ I50.22 Chronic systolic (congestive) heart failure | ☐ I50.33 Acute on chronic diastolic (congestive) heart failure | ☐ I50.812 Chronic right heart failure |
| ☐ I50.23 Acute on chronic systolic (congestive) heart failure | ☐ I50.42 Chronic combined systolic (congestive) and diastolic (congestive) heart failure | ☐ I50.82 Bi-ventricular heart failure |

☐ Other: _____

Healthcare Provider Signature: _____

Healthcare Provider Name (Printed): _____

Date: _____