Reading Hospital
TOWER HEALTH
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CLINICAL TRIALS OFFICE
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Full Title	**GUIDE-HF**: Hemodynamic-**GUIDE**d Management of **H**eart **F**ailure
Principal Investigator	Jared Green, MD
Sub-Investigators	Olivera Chandler, MD Eric Elgin, MD Agnieszka Mochon, MD
Study Objectives	To generate scientific evidence supporting the clinical benefit of PA pressure-guided HF management in a broad range of HF patients (NYHA Class II, III, or IV), reflecting contemporary methods of patient selection (elevated BNP) To demonstrate the equivalence of elevated BNP to prior HFHs for selecting the appropriate candidates who will clinically benefit from PA pressure-guided HF management, and to allow for the expansion of the current label to include NYHA Class III HF patients with elevated BNP
Inclusion Criteria	Patients are eligible to be included in the study if they meet all of the following criteria: • Diagnosis and treatment for HF (regardless of LVEF) for > 90 days prior to the date of consent: a. Subjects should be on stable, optimally titrated medical therapy for at least 30 days, as recommended according to current AHA/American College of Cardiology (ACC) guidelines as standard-of-care for HF therapy in the United States, with any intolerance documented. • GUIDE-HF Randomized Arm Only: NYHA Class II, III or IV HF symptoms documented within 30 days prior to consent. • GUIDE-HF Single Arm Only: NYHA Class III HF symptoms documented within 30 days prior to consent. • HFH within 12 months prior to consent and/or elevated BNP within 30 days prior to consent d • ≥ 18 years of age

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- Chest circumference of < 65 inches, if BMI is > 35 kg/m2
- Written informed consent obtained from subject
- Willing and able to upload PA pressure information and comply with the follow-up requirements

Exclusion Criteria

Patients are excluded if they meet any of the following criteria:

- Intolerance to all neuro-hormonal antagonists
- ACC/AHA Stage D refractory HF
- Received or are likely to receive an advanced therapy (e.g., mechanical circulatory support or cardiac transplant) in the next 12 months
- NYHA Class IV HF patients with:
  a. Continuous or chronic use of scheduled intermittent inotropic therapy for HF and an INTERMACS level of ≤ 4, OR
  b. Persistence of fluid overload with maximum (or dose equivalent) diuretic intervention
- Glomerular Filtration Rate (eGFR) < 25 mL/min/1.73m2 and non-responsive to diuretic therapy, or receiving chronic dialysis
- Inability to tolerate or receive dual antiplatelet therapy or anticoagulation therapy for one month post-implantation
- Significant congenital heart disease that has not been repaired and would prevent implantation of the CardioMEMS™ PA Sensor
- Implanted with mechanical right heart valve(s)
- Unrepaired severe valvular disease
- Pregnant or planning to become pregnant in the next 12 months
- An active, ongoing infection, defined as being febrile, an elevated white blood cell count, on intravenous antibiotics, and/or positive cultures (blood, sputum or urine).
- History of current or recurrent (≥ 2 episodes) pulmonary emboli and/or deep vein thromboses
- Major cardiovascular event (e.g., unstable angina, myocardial infarction, percutaneous coronary

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intervention, open heart surgery, or stroke, etc.) within 90 days prior to consent
- Implanted with Cardiac Resynchronization Therapy (CRT)-Pacemaker (CRT-P) or CRT-Defibrillator (CRT-D) for less than 90 days prior to consent
- Enrollment into another trial with an active treatment arm
- Anticipated life expectancy of < 12 months
- Any condition that, in the opinion of the Investigator, would not allow for utilization of the CardioMEMS™ HF System to manage the subject using information gained from hemodynamic measurements to adjust medications, including the presence of unexpectedly severe pulmonary hypertension (e.g., trans-pulmonary gradient >15) at implant RHC, a history of non-compliance, or any condition that would preclude CardioMEMS™ PA Sensor implantation

Affiliations & Sponsors	Abbott
Status	Open to enrollment
Keywords	heart failure, CHF, ADHF, CardioMEMS, cardiology, cardiac