Health Technology Review	
Technology Ref.:	HTA23024
Technology Name:	CARDIOMEMS CM2000 Wireless Pulmonary Hemodynamic Monitoring
Approvals by International Bodies:	FDA Approved
Company name:	Cleveland Clinic Abudhabi
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Short Description of the Technology:	Heart failure (HF) and heart failure admissions area among the leading cause of morbidity and expense to the healthcare systems globally. In the US alone, over 20 billion dollars annually is spent on HF admissions. Admission is usually preceded by congestion, which can be signaled by rises in intracardiac and pulmonary artery pressures, often starting days and weeks before the final event of overt clinical congestion requiring admission. To identify these patients prior to needing admission, implantable systems for chronic monitoring of intra-cardiac and pulmonary artery pressure have been developed. The most studied and developed of these is the CARDIOMEMS system (Abbott Laboratories, Chicago, USA). It consists of a small sensor implanted in the pulmonary artery during a catheterization procedure, a home-based wireless monitoring system, and a hospital-based reporting system. After the initial implant procedure, patient transmits daily wireless recording to system. The responsible physician then gets regular reports on the status of patient's hemodynamics along with alerts on any increased hemodynamics, allowing for earlier intervention and adjustment of medications. This has been well studied in the attached CHAMPION study, which demonstrated a dramatic 37% reduction in HF hospitalizations in patients who had the device activated versus those who didn't. Further cost effectiveness analyses has shown it to be cost-effective for populations of patients similar to the CHAMPION study, and significantly improves quality of life.

Health Technology Assessment Team Recommendation:	**Approved**
Summary of Review:	
The technology is a remote monitoring technology that detects changes in pulmonary artery pressure It is permanently implanted device (about the size of a paper clip). The device is percutaneously implanted in an inferior and later branch of the left pulmonary artery (PA) by putting a small electronic pressure sensor into the pulmonary artery to measure blood pressure for the purpose of ongoing monitoring and management of chronic heart failure. These observations may help to evaluate the disease progression and to make therapeutic solutions, which reduce hospitalizations	

caused by heart failure. The treatment is established procedure that been used in USA and other countries (KSA, Kuwait), The provided two trials (CHAMPION Trial and MONITOR HF Trial/ GUIDE-HF trial (on going)) have shown safety and effectiveness in reducing the HF patient hospitalization rate but did not provide solid proof on the cost effectiveness. The efficacy of the device is depending on the proper readings by the patients and regular review by the specialized concerned healthcare provider. The need to collect additional evidence of continued safety and effectiveness on long term.

Advantages	Disadvantages
Proven reduction in hospital admissions rate for heart failure & improvement in heart failure symptoms management.	The potential risk of device failure, malfunction or migration.
FDA approved device	Local data is required to prove the device efficacy and cost effectiveness in UAE.
The technology empowers patients toward better health & improve patient quality of life.	Evidence on the efficacy of the procedure focuses primarily on reducing hospital admissions.
Use of healthcare resources was reduced as a result of a marked reduction of in-office visits without compromising patient safety.	The cost-effectiveness of CardioMEMS is most sensitive to the duration of effectiveness; therefore, further research on the continued hospitalization trends of patients with the device will be important for future evaluations.
The technology allows easier monitoring of medication management.	Further study of wireless monitoring of the PA pressure by an implantable hemodynamic monitor is needed before they can be recommended for routine clinical care.
Safe and effective method of gathering the data necessary to proactively modify the treatment heart failure preventing disease advancement and subsequently reducing overall heart failure related hospitalizations.	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, haemoptysis, hematoma, nausea, cerebrovascular accident, thrombus
The wireless and remote nature of the technology allow it to be integrated into a framework of rural health and telemedicine, enabling patients to receive a high standard of care without the burden of frequent travel to and from medical centres.	Proper Training/education is required for both the specialized team & patient.
It showed that incorporation of active monitoring led to targeted changes with a higher frequency of medication titration and reduced HF hospitalizations.	The available clinical trials and studies does not show improvements in reducing the mortality

We recommend **approval of using this technology** with the following conditions:

1. Approval on using the CardioMems CM2000.
2. Utilizing the device **is limited to** patients who fall under the specific criteria in medical centers with heart failures services;
   - Class ll or class lll heart failure.
   - Patients with past heart failure hospitalizations or have elevated natriuretic peptides (or

both).

3. Required a proper training and education for both Patients and healthcare providers.
4. Conditional Approval by Abu Dhabi Healthcare Information Security Program until 21/02/2025.
5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
6. Provision of regular updates and reports about the product to DOH upon request.
7. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "CARDIOMEMS CM2000 Wireless Pulmonary Hemodynamic Monitoring"

- **Population/ Intended User**;

CardioMEMS is particularly beneficial to patients with:

- Class ll or class lll heart failure.
- Past heart failure hospitalizations.
- Fluid volumes that are difficult to assess or manage.
- Advanced limitation of physical activity due to fatigue and shortness of breath.

- **To be performed by**:
  - By interventional cardiologist.
- **Clinical Setting:**
  - Medical centers with Heart Failure services.
- **Condition of use:**
  - As per the specific criteria.
- **Exclusion criteria:**
  - The CardioMEMS HF System should not be used in people who are unable to take blood-thinning (anticoagulant) or anti-clotting (antiplatelet) medications for one month after receiving the implant.
  - The following patients may not be appropriate for implantation of the CardioMEMS™ HF System2:

    - Patients with an active infection.
    - Patients with a history of recurrent (> 1) pulmonary embolism or deep vein thrombosis.
    - Patients unable to tolerate right heart catheterization.
    - Patients with a Glomerular Filtration Rate (GFR) < 25 ml/min who are non-responsive to diuretic therapy or who are on chronic renal dialysis.
    - Patients with congenital heart disease or mechanical right heart valve(s).
    - Patients with known coagulation disorders.
    - Patients with a hypersensitivity or allergy to aspirin, and/or clopidogrel.
    - Patients who have undergone implantation of a Cardiac Resynchronization Device (CRT) within the past three months.
    - If the patient's BMI is greater than 35, measure the patient's chest circumference at the axillary level. If the chest circumference is > 165 cm, sensor implantation should not occur.