PriorityHealth

MEDICAL POLICY
No. 91610-R2

IMPLANTABLE HEART FAILURE MONITORS

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Review Dates: 5/15, 5/16, 5/17, 8/17, 5/18, 5/19
Status: Current

I. POLICY/CRITERIA

Implantable hemodynamic monitors (e.g., CardioMEMS™ HF System) for heart failure may be a covered benefit when **both (A&B)** of the following are met:

A. Clinical Indications, **both 1 & 2:**
   1. **All** of the following:
      a. Diagnosis of NYHA class III within 14 days of implanting procedure
      b. At least one heart failure hospitalization in previous 12 months
      c. Reduced EF patients are/have received beta blocker for 3 months and an ACE-I or ARB for one month unless patient is intolerant to medication therapy
      d. If BMI is greater than or equal to 35, then chest circumference at axillary level must be less than 165cm
      e. Pulmonary artery branch diameter is greater than or equal to 7mm – assessed during the right heart catheterization procedure
      f. Must be able to tolerate right heart catheterization procedure
      g. Documented Advance Care Planning discussion including the designation of a Durable Power of Attorney for Healthcare (DPOAHC)/Patient Advocate

      AND
   2. **None** of the following:
      a. Active infection
      b. History of recurrent pulmonary embolism or deep vein thrombosis
      c. Major cardiovascular event within previous 2 months
      d. Cardiac resynchronization therapy (CRT) likely in next 3 months or within the previous 3 months
      e. Congenital heart disease or mechanical right heart valve that is contraindicated for right heart catheterization
      f. Likely to undergo evaluation for heart transplant or VAD implantation within the next 6 months
      g. Known coagulation disorders
      h. Hypersensitivity or allergy to aspirin, and/or clopidogrel

B. Clinic, Provider and Program Requirements - **all** of the following:
   1. Physician medical director who:
      a. devotes more than 40% of their practice in managing advanced heart failure patients

         AND

      b. is board certified or eligible in advanced heart failure management consistent with the ABIM subspecialty requirements.
   2. A multi-disciplinary team of professionals dedicated to the management of heart failure patients, including but not limited to a clinical pharmacist and social worker.
   3. Comprehensive telemonitoring services are available including remote heart failure monitoring and remote device monitoring.
   4. The following outcome measures are monitored with annual reporting:
      a. Device complication for a minimum of 24 months
      b. Device failures for a minimum of 24 months
      c. Heart failure hospitalization rate 12 months
      d. Heart failure ED visits 12 months
      e. All-cause mortality 1 year
      f. Heart failure cause mortality 1 year

II. MEDICAL NECESSITY REVIEW

☒ Required ☐ Not Required ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***

- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

An implantable heart failure monitor (e.g. CardioMEMS HF System) is a permanently implantable sensor that wirelessly monitors pulmonary artery pressures and other hemodynamic parameters, and transmits data to clinicians managing patients with heart failure.

The best available published evidence for the CardioMEMS HF System is limited to the FDA pivotal CHAMPION trial (Abraham et al., 2011). CHAMPION was a manufacturer-sponsored randomized controlled trial that enrolled patients from 64 U.S. centers with HF management experience. The sponsor monitored, collected, and maintained trial data.

The CHAMPION trial (NCT00531661) enrolled patients with NYHA Class III HF who had been hospitalized for HF within the previous 12 months. The majority of patients were white (73%) and male (~73%). All patients were implanted with the CardioMEMS HF device and then randomly allocated to either the treatment group (n=270) or the control group (n=280). Patients in both groups transmitted data from the monitoring system to the clinician accessible CardioMEMS database. Transmissions to clinicians from control group patients were turned off. Changes in patient management were based on CardioMEMS data in the treatment group, and on patient-reported signs and symptoms in the control group. The primary efficacy endpoint was rate of HF-related hospitalizations during 6 months after sensor insertion, which was significantly lower in the treatment group versus the control group (31% versus 44%). Length of hospital stay for HF-related admissions was significantly shorter in the treatment group versus the control group (2.2 days versus 3.8 days). Significantly more changes were made in HF drug management for patients in the treatment group than for those in the control group (9.1 and 3.8 mean changes per patient, respectively). The 2 primary safety endpoints were device- or system-related complications. Both were met. The CHAMPION trial has been criticized for both conduct and methodological flaws that may have biased published and unpublished outcomes in favor of the treatment group (Loh et al.).

FDA response to criticism of the CHAMPION trial:
In the CHAMPION clinical trial, provision of PA pressures to physicians for patients in the Treatment group led physicians to intensify the use of medications for heart failure (particularly diuretics and nitrates) in these patients far more frequently than in the patients in the Control group. In the Control group, the doses of medications for heart failure were altered 1061 times, based on changes in signs and symptoms of heart failure. In contrast, in the Treatment group, the doses of medications for heart failure were altered 2517 times, based not only on changes in signs and symptoms of heart failure, but also directed by knowledge of PA pressures outside the normal range.

This marked difference in the use of medications for heart failure was accompanied by a highly significant effect on the primary endpoint of the trial: the rate of hospitalizations for heart failure during the first 6 months of the trial. There were 84 hospitalizations for heart failure in the Treatment group, as compared with 120 hospitalizations for heart failure in the Control group. This 28% lower rate of hospitalization for heart failure was highly significant ($p=0.0002$). All pre-specified secondary endpoints were also achieved, and the device fulfilled all pre-specified safety and performance assessments.

During the entire Randomized Access period (Part 1) (mean 17.6 months), there were 182 hospitalizations for heart failure in the Treatment group, as compared with 279 hospitalizations for heart failure in the Control group. This 33% lower rate of hospitalization for heart failure was highly significant ($p=0.0002$), indicating the durability of the treatment effect.

The preliminary finding of a treatment-by-gender interaction for the effect of the device on the rate of hospitalizations for heart failure appears to have been related to (1) the play of chance as a result of the small number of events in women; and (2) the competing risk of an excess of early deaths in women in the Control group. When these limitations were addressed by an analysis of the combined risk of death or hospitalization for heart failure for the entire Randomized Access period, there was neither a qualitative nor quantitative treatment-by-gender interaction, and there was evidence for a treatment effect independent of gender.

The CHAMPION trial was characterized by very frequent and active intervention in the treatment arm of the trial. Principle investigators in the trial consisted of experienced advanced heart failure cardiologists who were quite involved in helping to assure that these interventions were performed. This therefore suggests that achievement of these benefits will require a similar degree of intensive monitoring, frequent contact with the patients and guidance by clinicians experienced in the management of patients with complex heart failure syndromes.

V. CODING INFORMATION

ICD-10 Codes that may apply:

I50.1 Left ventricular failure
I50.20 Unspecified systolic (congestive) heart failure
I50.22 Chronic systolic (congestive) heart failure
I50.23 Acute on chronic systolic (congestive) heart failure
I50.30 Unspecified diastolic (congestive) heart failure
I50.32 Chronic diastolic (congestive) heart failure
I50.40 Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.42 Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43 Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9 Heart failure, unspecified

CPT/HCPCS CODES:

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

93299 Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

C2624 Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components (*OP facility only*)

VI. REFERENCES

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