Implantable Pulmonary Artery Pressure Measurement Device

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary implantable pulmonary artery pressure measurement device.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

CardioMEMS™ Heart Failure (HF) System – A wireless pulmonary arterial (PA) pressure monitoring system. It measures PA pressures from a battery free sensor in the distal pulmonary artery. An electronic system transmits the generated data to a secure network where it is available for the interpretation by the treating physician.

PROCEDURES

A prior authorization is required.

The CardioMEMS™ HF System may be considered medically necessary for individuals that meet ALL of the following indications:

- Diagnosis of New York Heart Association (NYHA) Class III HF symptoms predominantly present over the previous months, despite maximally tolerated guideline directed medical and device therapies; and
- At least one (1) HF related hospitalization within the previous 12 months; and
- Able to take dual antiplatelet or anticoagulants for one (1) month post-implant; and
- Greater than or equal to 18 years of age; and
- Diagnosis of HF greater than or equal to three (3) months, with either preserved or reduced left ventricular ejection fraction; and
- PA branch diameter sized between seven (7) mm and 15 mm; and
- Body mass index (BMI) of less than or equal to 35; or
- If BMI is greater than 35, a measurement of chest circumference at axillary level is required. If the chest circumference is greater than 165 cm, the sensor should not be implanted due to poor signal strength.

Monitoring must occur at least once weekly in all individuals implanted with CardioMEMS™. Weekly monitoring is acceptable as long as the individual maintains acceptable PA pressure (opti-volemic).

If PA pressure is not opti-volemic:

- Monitoring must occur at least two (2) to three (3) times per week until opti-volemic in cases where the individual has elevated PA pressure (hyper-volemic) or low PA pressure (hypo-volemic); and
- Monitoring must occur at least two (2) to three (3) times per week until pressure stabilizes in cases where the individual receives medication modifications or exhibits significant deviations in trend data.

Implantable PA pressure monitoring not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Note: Recommendation per FDA label.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Implantable pulmonary artery pressure measurement devices are typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

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CODING REQUIREMENTS

CPT code	Description
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.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

National Institute for Health and Care Excellence – 2018

The National Institute for Health and Care Excellence (NICE) updated their guidelines on chronic heart failure management and did not include outpatient hemodynamic monitoring as a recommendation.

In 2013, the Institute issued guidance on the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure. The recommendations concluded that "Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity."

Heart Failure Society of America – 2018

The Heart Failure Society of America Scientific Statements Committee (2018) published a white paper consensus statement on remote monitoring of patients with heart failure.

The committee concluded that: "Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

American College of Cardiology et al-2017

The American College of Cardiology, the American Heart Association, and the Heart Failure Society of America issued joint guidelines on the management of heart failure that offered no recommendations for the use of ambulatory monitoring devices.

Reference

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POLICY UPDATE HISTORY

10/21/2021	Approved in Medical Policy Committee
12/2021	Approved in QI/UM
10/26/2022	Annual review; approved in Medical Policy Committee
11/2022	Approved in QI/UM