Heart Failure Monitoring (Formerly Implantable Pulmonary Artery Monitoring Device for Heart Failure Monitoring – CardioMEMS)

Policy Number:	**M20200917101**
Effective Date:	**11/1/2020**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the medical necessity criteria for implantable pulmonary artery monitoring devices, including but not limited to **CardioMEMS HF System**, for **heart failure (HF)** monitoring and the **uCor Heart Failure and Arrhythmia Management System.**

Policy:

Commercial and Self-Funded
Based upon the assessment of peer-reviewed literature, implantable pulmonary monitoring (e.g., CardioMEMS HF system) for the management of heart failure in the outpatient setting has not been proven to be medically necessary and is therefore considered investigational.

Based upon the lack of peer-reviewed literature available, the uCor Heart Failure and Arrhythmia Management System has not been proven to be medically necessary and is therefore considered investigational.

Medicare Advantage
The Centers for Medicare and Medicaid (CMS) does not address wireless pulmonary artery monitoring in either a National or Local Coverage Determination. However, CMS provides coverage for the HCPCS C codes assigned to these devices.

MediSource, MediSource Connect, Essential Plan, Child Health Plus
MediSource, MediSource Connect, Essential Plan, Child Health Plus do not cover implantable pulmonary artery monitoring for heart failure monitoring, i.e., CardioMems or the uCor Heart Failure and Arrhythmia Management System.

Background
HF diagnosis is supported by chest x-ray, echocardiography, and levels of plasma natriuretic peptides. Treatment includes diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor blockers, beta-blockers, aldosterone antagonists, neprilysin inhibitors, sinus node inhibitors, specialized implantable pacemakers/defibrillators and other devices, and correction of the cause(s) of the HF syndrome.

CardioMEMS, a wireless pulmonary artery monitoring device, has been approved by the US Food and Drug Administration to monitor pulmonary artery pressure (PAP) and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year. CardioMEMS is intended to provide measurement of the systolic, diastolic, and mean PAP, which is intended to allow for adjustment of HF medications based upon pressure trends and specified pressure goals. Implantation of CardioMEMS is performed by a cardiac surgeon and may be carried out as an outpatient procedure. The components of the CardioMEMS device include a pillow containing the antenna to capture the sensor reading, a bedside monitoring unit to which the pillow is connected via a cable, and a remote button. Each reading captures 18 seconds of pressure data that are wirelessly transmitted to a secure database. The patient's physician can use this information to optimize medical management and potentially reduce the need for HF-related hospitalizations.

According to the 2016 European Society of Cardiology Guidelines for the diagnosis and treatment of acute and chronic heart failure, CardioMEMS usefulness/efficacy is less well established by evidence/opinion and "may be considered". There is insufficient evidence to establish definitive patient selection criteria for monitoring of HF with a wireless pulmonary artery monitoring device. Additional studies comparing the benefits and harms of pulmonary artery monitoring device with standard HF management are needed. The efficacy of the implantable pulmonary artery monitoring devices has not been established.

According to the manufacturer, Zoll Medical Corp., the µCor™ System is a wearable medical device that is intended to continuously record, store, and transmit medical data to healthcare professionals. After it is placed on the body and activated, the wearable sensor automatically acquires the body's heart rhythm (ECG), Thoracic Fluid Index, heart rate, respiration rate, activity, and posture measurements. The patient can activate a trigger when experiencing symptoms by double tapping the sensor when on the body. The patient's data is automatically transmitted from the sensor to the Gateway, and from there to Zoll for analysis by certified technicians. The certified technicians also prepare reports according

to the defined criteria as requested by the prescribing physician. Data provided in the report aids the prescribing physician in the diagnosis and identification of various clinical conditions, events and/or trends.

According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure states "In selected adult patients with NYHA class III HF and history of a HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated stable doses of GDMT with optimal device therapy, the use-fulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain."

There is a lack of peer-reviewed published data to support the use of the CardioMEMS wireless pulmonary artery monitoring device or the Zoll uCor Heart Failure and Arrhythmia Management System (HFAMS).

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☐ Other ☒

Preauthorization is required for this service for Commercial, Self-Funded, MediSource, MediSource Connect, Essential Plan, and Child Health Plus.

Preauthorization is not required for Medicare Advantage.

Definitions

CardioMEMS is an implantable pulmonary artery monitoring device approved by the United States Food and Drug Administration to monitor pulmonary artery pressure and heart rate in patients with NYHA class III HF who have been hospitalized during the previous year.

Heart failure is a syndrome of left ventricular dysfunction causing shortness of breath and fatigue, and right ventricular failure causes peripheral and abdominal fluid accumulation; the ventricles can be involved together or separately.

uCor Heart Failure and Arrhythmia Management System is a wearable medical device that is intended to continuously record, store, and transmit a patient's medical data to healthcare professionals. Once placed on the body and activated, the wearable Sensor automatically acquires the body's heart rhythm (ECG), Thoracic Fluid Index, Heart Rate, Respiration Rate, Activity, and Posture measurements. A patient can activate a trigger when experiencing symptoms by double tapping the Sensor when it is on the body. Data are automatically transmitted from the Sensor to the Gateway, and from there to ZOLL for analysis by certified technicians. The certified technicians also prepare reports according to the defined criteria as requested by the prescribing physician. Data provided in the report aids the prescribing physician in the diagnosis and identification of various clinical conditions, events and/or trends.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
Abbott [web site]. CardioMEMS HF System. Available at: https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/cardiomems-hf-system.html Accessed February 21, 2023.

Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial [published correction appears in Lancet. 2012 Feb 4;379(9814):412]. Lancet. 2011;377(9766):658-666.

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Merck Manual [web site]. Heart Failure (HF) (Congestive Heart Failure). Revised November 2020. Available at: https://www.merckmanuals.com/professional/cardiovascular-disorders/heart-failure/heart-failure-hf Accessed February 22, 2022.

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Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). Email response 9/11/2020.

United States Food and Drug Administration (FDA) [web site]. Premarket Approval CardioMEMS HF Pressure Measurement System. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100045 Accessed February 21, 2023.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
12/1/2023	Health Care Services	Revised
4/1/2023	Health Care Services	Reviewed
5/1/2022	Health Care Services	Reviewed
5/1/2021	Health Care Services	Revised