Non-invasive Heart Failure and Arrythmia Management and Monitoring System

Medical Policy #: 02.02.22
Original Effective Date: January 2016
Reviewed: January 2022
Revised: January 2022

NOTICE: This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

DESCRIPTION

According to the Centers for Disease Control (CDC) and Prevention, nearly 6.2 million Americans are currently diagnosed with heart failure (HF), and more than 960,000 new cases are diagnosed each year (CDC, 2020). Approximately 50% of individuals with HF die within 5 years of diagnosis. As a result of HF, the weakened heart muscle causes inadequate filling of the left ventricle, as well as a backflow of blood into the left atrium, both resulting in decreased cardiac output and increased symptoms for the afflicted individual. Symptoms can include shortness of breath, fatigue, and swelling in the ankles, feet, legs, abdomen and veins in the neck. Currently there is no cure for HF; medical therapy includes a combination of diuretics, digoxin, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta-blockers, and aldosterone antagonists. Some individuals may remain symptomatic despite medical therapy.

Ongoing studies evaluate other treatment options to assist physicians in the management of individuals with severe HF.

Arrhythmias are deviations from the normal cadence of the heartbeat, which cause the heart to pump improperly. More than four million Americans have arrhythmias, most of which pose no significant health threat. As people age, the probability of experiencing an arrhythmia increases. In the United States, arrhythmias are the primary cause of sudden cardiac death, accounting for more than 350,000 deaths each year. The standard initial measure for a diagnosis of arrhythmias involves the use of electrocardiogram (EKG) testing, which allows evaluation of the electrical function of the heart.

μ-Cor Heart Failure and Arrhythmia Management System (HFAMS)
The μ-Cor Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The μ-Cor Heart Failure and Arrhythmia Management System is also intended to continuously record and store, and periodically transmit electrocardiogram (ECG), heart rate (HR), respiration rate (RR), activity and posture, The data provided can then be used to aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends.

The μ-Cor Heart Failure and Arrhythmia Management System is intended for use in clinical and home settings and is indicated for patients who are 21 years of age or older:

1. Who require monitoring for the detection of non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmias; or
2. requiring fluid management

The FDA clearance of the μ-Cor Heart Failure and Arrhythmia Management System e was based on an evaluation of data collected from the unpublished Measuring Thoracic Impedance in Hemodialysis Patients with the μ-Cor Monitoring System (MaTcH study; NCT03072732) study, a prospective, non-significant risk, randomized, 2-arm premarket validation trial. The study enrolled 20 hemodialysis participants wearing the μCor 3.0 Heart Failure and Arrhythmia Management System; all participants also had the ZOE Fluid Status Monitor applied. During dialysis sessions, readings from both devices were recorded simultaneously. The results were summarized as follows: “the μ-Cor 3.0 mean correlation 0.95; ZOE mean correlation 0.211; μ-Cor 3.0 95% confidence interval (CI) [0.92, 0.99].” The Vital Signs Validation Study of the μ-Cor System (ViVUS, NCT02975050) was another prospective, non-significant risk, non-randomized, premarket study used to validate the capability of the μ-Cor 3.0 HFAMS to monitor ECG, HR, RR, posture and activity. This study enrolled 15 healthy volunteers performing activities of breathing, walking, and resting. During these activities the participants’ RR, ECG, HR, activity, and posture were collected for comparison. “Test results confirm that the μ-Cor Heart Failure and Arrhythmia Management System is at least as safe and effective as the predicate devices; therefore, the μ-Cor Heart Failure and Arrhythmia Management System is substantially equivalent to its predicate devices.” (Product Label Information, 2019).

Summary of Evidence
Based on the current evidence the evidence is insufficient to support μ-Cor Heart Failure and Arrhythmia Management System (HFAMS) as an early indicator for heart failure decompensation and arrhythmia detection. Current completed studies, based on unpublished data, intend to validate the capabilities of the system. No evidence is available to assess how the device changes management or affects net health outcomes in the individuals with cardiac disease, as intended by FDA 510(k) clearance indications. Studies include relatively small sample sizes (limiting generalizability) and short follow-up duration; therefore, the long-term complications are unknown. Adequately designed studies of sufficient duration, enrolling participants with established cardiac diseases are needed to confirm longer-term effects of HFAMS on whether health outcomes are significantly improved relative to standard of care for HF management.

Practice Guidelines and Position Statements

American College of Cardiology/American Heart Association/Heart Failure Society of America
In 2017, the American College of Cardiology/American Heart Association/Heart Failure Society of America Focused update of the 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for the Management of Heart Failure does not address the use of non-invasive wireless technology to monitor pulmonary fluid levels as an early indicator for heart failure decompensation or arrhythmia detection.

Regulatory Status
On June 10, 2019, the U.S. Food and Drug Administration (FDA) granted ZOLL® Medical Corporation (Pittsburg, PA), an Asahi Kasei Group Company that manufactures medical devices and related solutions, FDA clearance through the 510(K)-approval process for their μ-Cor™ Heart Failure and Arrhythmia Management System (HFAMS). The patch-based sensor can be worn continuously up to 30 days; the wireless system employs novel radiofrequency technology to monitor pulmonary fluid levels which is an early indicator for heart failure decompensation.

The μ-Cor Heart Failure and Arrhythmia Management System is intended to periodically record, store, and transmit Thoracic Fluid Index. The μ-Cor Heart Failure and Arrhythmia Management System is also intended to continuously record and store, and periodically transmit electrocardiogram (ECG), heart rate (HR), respiration rate (RR), activity and posture, The data provided can then be used to aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends.

> The μ-Cor Heart Failure and Arrhythmia Management System is intended for use in clinical and home settings and is indicated for patients who are 21 years of age or older:

1. Who require monitoring for the detection of non-lethal cardiac arrhythmias, such as, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmias; **or**

2. requiring fluid management

PRIOR APPROVAL

Not Required.

POLICY

See Related Medical Policies

- 02.02.17 Cardiac Contractility Modulation Therapy (CCM)
- 02.02.18 Noninvasive Measurement of Cardiac Bioimpedance in the Outpatient Setting
- 02.2.19 Baroflex Stimulation Devices
- 02.02.21Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

The use of non-invasive heart failure and arrhythmia management and monitoring system, μ-Cor™ Heart Failure and Arrhythmia Management System is considered **investigational** for all indications, because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome

Policy Guidelines

Arrhythmia: Abnormal heart rhythms which may be classified as either atrial or ventricular, depending on the origin in the heart. Individuals with arrhythmias may experience a wide variety of symptoms ranging from palpitations to fainting.

Heart failure: A condition in which the heart no longer adequately functions as a pump. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the lungs and other organs.

New York Heart Association (NYHA) Definitions: The NYHA classification of heart failure is a 4-tier system that categorizes subjects based on subjective impression of the degree of functional compromise; the four NYHA functional classes are as follows:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.

- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate

physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.

- Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.

- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 0607T Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment.

- 0608T Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional.

SELECTED REFERENCES

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POLICY HISTORY		
Date	**Reason**	**Action**
January 2022	Annual Review	Policy Revised, New Medical Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
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