Anthem

Medical Policy

Subject: Non-invasive Heart Failure and Arrhythmia Management and Monitoring System
Document #: MED.00134
Status: Reviewed
Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses the use of a non-invasive heart failure and arrhythmia management and monitoring system as an early indicator for heart failure decompensation and arrhythmia detection.

Note: Please see the following related document for additional information:

- CG-MED-40 External Ambulatory Cardiac Monitors

Position Statement

Investigational and Not Medically Necessary:

The use of a non-invasive heart failure and arrhythmia management and monitoring system (for example, µ-Cor™ Heart Failure and Arrhythmia Management System) is considered **investigational and not medically necessary** for all indications.

Rationale

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 individuals 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 (Product Label Information, 2019).

The FDA clearance of the device was based on an evaluation of data collected from the unpublished Measuring Thoracic Impedance in Hemodialysis Patients with the µ-Cor Monitoring System (MaTcH; NCT03072732) study, a prospective, non-significant risk,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).

The 2022 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) guideline for the management of heart failure, which replaces the 2017 ACC/AHA/HFSA Focused update of the 2013 American College of Cardiology Foundation (ACCF)/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 (Heidenreich, 2022).

In summary, the current evidence base 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.

Background/Overview

According to the Centers for Disease Control (CDC) and Prevention, nearly 6.2 million Americans are currently diagnosed with 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.

Definitions

510k Clearance: The purpose of a 510(k) submission is to demonstrate that a device is “substantially equivalent” to a predicate device (one that has been cleared by the FDA or marketed before 1976). The 510(k) submitter compares and contrasts the subject and predicate devices, explaining why any differences between them should be acceptable. Human data are usually not required for a 510(k) submission; this decision is made at the discretion of the FDA. The FDA does not “approve” 510(k) submissions. It “clears” them.

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.

Guideline-directed medical therapy (GDMT): The term replaces and is synonymous with “Optimal medical therapy.”

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 (for example, 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.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

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 (eg, 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 (eg, 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

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Bui AL, Horwich TB, Fonarow GC. Epidemiology and risk profile of heart failure, Nat Rev Cardiol. 2011; 8(1):30-41.
2. Desai AS, Stevenson LW. Rehospitalization for heart failure: predict or prevent? Circulation. 2012; 126(4):501-506.
3. Heidenreich PA, Albert NM, Allen LA, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association, Circ Heart Fail. 2013; 6(3):606-619.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022. 145:e895-e1032.
2. January CT, Wann LS, Calkins H, et al. 2019 AHA/ACC/HRS focused update of the 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2019. pii: S0735-1097(19)30209-8.
3. Kyma Medical Technologies. Vital Signs Validation study of the u-Cor System (ViVUS Validation) (ViVUS). NLM Identifier: NCT02975050. Last updated July 7, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02975050?term=NCT02975050&draw=2&rank=1. Accessed on July 3, 2023.

4. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2012; 60(14):1297-1313.
5. U.S. Food and Drug Administration (FDA). . Medical Devices. µ-Cor Heart Failure and Arrhythmia Management System – No. K172510. Rockville, MD: FDA. May 11, 2018. Available at: https://www.accessdata.fda.gov/scripts/cdrh/Cfdocs/cfpmn/pmn.cfm?id=K172510. Accessed on July 3, 2023.
6. Zoll Medical Corporation. Benefits of Microcor in ambulatory decompensated heart failure (BMAD-TX). NLM Identifier: NCT04096040. Last updated May 6, 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04096040?term=%C2%B5Cor&cond=Heart+Failure&draw=2&rank=2. Accessed on July 3, 2023.
7. Zoll Medical Corporation. Benefits of µCor in Ambulatory Decompensated Heart Failure (BMADHF). NLM Identifier NCT03476187. Last updated May 3, 2022. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03476187?term=%C2%B5Cor&cond=Heart+Failure&draw=2&rank=1. Accessed on July 3, 2023.
8. Zoll Medical Corporation. Feasibility Study of the µCor Heart Failure and Arrhythmia Management System (PATCH). Identifier: NCT04512703. Last updated June 3, 2021. Accessed on July 3, 2023. Available at: https://clinicaltrials.gov/study/NCT04512703?cond=heart%20failure&term=%C2%B5Cor&aggFilters=status:not%20rec%20act%20com&rank=2&tab=results.
9. Zoll Medical Corporation. Measuring Thoracic Impedance in Hemodialysis Patients With the u-Cor Monitoring System (MaTcH). NLM Identifier: NCT03072732. Last updated November 4, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03072732?term=NCT03072732&draw=2&rank=1. Accessed on July 3, 2023.

Websites for Additional Information

1. Centers for Disease Control and Prevention. Heart failure. Last reviewed January 5, 2023. Available at:Heart Failure | cdc.gov. Accessed on July 3, 2023.
2. National Heart, Lung and Blood Institute. Heart failure. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/Hf/HF_WhatIs.html. Last updated on March 24, 2022. Accessed on July 3, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee review (MPTAC). Updated Definitions, References and Websites sections.
Reviewed	08/11/2022	MPTAC review. Updated Rationale, References and Websites sections.
Reviewed	08/12/2021	MPTAC review. Updated Rationale, Background, References and Websites sections.
New	08/13/2020	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.