ZOLL Heart Failure Management System

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Policy contains: Heart failure; pulmonary edema; remote monitoring; µCor; ZOLL Heart Failure Management System.

AmeriHealth Caritas VIP Care has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas VIP Care's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies, along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation, are considered by AmeriHealth Caritas VIP Care when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas VIP Care's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas VIP Care will update its clinical policies as necessary. AmeriHealth Caritas VIP Care's clinical policies are not guarantees of payment.

Coverage policy

The ZOLL® Heart Failure Management System (ZOLL Manufacturing Corporation, San Jose, California) is investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Guideline-directed care for heart failure.

Background

Heart failure, also called congestive heart failure, occurs when the heart cannot pump enough blood and oxygen to support other body organs. This can result from any structural or functional impairment of ventricular filling or pumping. Heart failure is a leading cause of morbidity and mortality and a substantial burden to health care systems. Racial and ethnic disparities in heart failure-related mortality persist, with non-Hispanic Black patients having the highest death rate per capita (Heidenreich, 2022).

Heart failure is defined clinically in several ways. The American College of Cardiology/American Heart Association's four stages emphasize the development and progression of disease in which advanced stages are associated with reduced survival. The New York Heart Association Classification characterizes patient symptoms and functional capacity, is an independent predictor of mortality, and is used to determine treatment eligibility. Left ventricular ejection fraction reflects differing prognosis and response to treatments and has been used to determine clinical trial eligibility (Heidenreich, 2022).

In the United States, an estimated 6.7 million people live with heart failure. Its prevalence is projected to increase further, affecting more than eight million adults age 18 years and older by 2030 (Martin, 2025). Initial hospitalizations and rehospitalizations (30- and 90-day) account for the largest component of direct medical costs attributed to heart failure diagnoses (Osenenko, 2022).

Current methods to reduce decompensation leading to heart failure hospitalizations include frequent weight monitoring, blood pressure measurements, Holter monitoring, and telehealth platforms for structured assessment of symptoms. However, these methods often reflect later changes in decompensation and are time-consuming and resource-intensive. Remote monitoring devices, broadly categorized as implantable or less invasive wearable options, have been developed to detect impending signs of heart failure decompensation and reduce heart failure hospitalization (Kobe, 2023).

The ZOLL Heart Failure Management System, formerly the µCor Heart Failure and Arrhythmia Management System, is a wearable, patch-based sensor that uses radiofrequency technology to measure the Thoracic Fluid Index for early detection of changes in pulmonary fluid levels. It is intended to continuously record, store, and transmit thoracic fluid data along with heart rate, respiratory rate, activity, posture, and heart rhythm. The U.S. Food and Drug Administration issued 510(k) premarket approval intended for patients who are 21 years of age or older who require either monitoring for the detection of non-lethal cardiac arrhythmia (including, but not limited to, atrial fibrillation, atrial flutter, ventricular ectopy, and bradyarrhythmia) or monitoring fluid management (U.S. Food and Drug Administration, 2018).

Findings

Guidelines

The 2022 American Heart Association/American College of Cardiology/Heart Failure Society of America 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).

A scientific statement by the Heart Failure Society of America lists the ZOLL Heart Failure Management System (herein called "ZOLL") among a number of device-based therapies under investigation that may address an unmet need in the future (Estep, 2024).

Evidence review

The evidence of the effectiveness of the ZOLL device to track pulmonary edema is limited to two validation studies and one concurrent-control trial. While there is an unmet need for early detection of heart failure decompensation to avoid heart failure hospitalization, there is insufficient evidence documenting long-term outcomes and who would most benefit from this technology (e.g., those with or without associated pulmonary edema or on diuretic therapy).

Early validation studies analyzed the ability of the μCor Heart Failure and Arrhythmia Management System to measure a patient's fluid status. In 20 participants with end-stage kidney disease with or without heart failure, 17 exhibited very strong or strong correlations (Pearson's correlation coefficient $r \geq 0.7$) between μCor thoracic fluid measurement and total body fluid removal during dialysis (Connaire, 2020; ClinicalTrials.gov identifier NCT03072732). In another trial of 66 inpatients recently admitted with acute heart failure (predominantly New York Heart Association functional class III to IV) and 54 healthy or stable controls, the diagnostic performances of μCor and computed tomography were similar: sensitivity 70% versus 86%; specificity 82% versus 83%; positive predictive value 82% versus 86%; negative predictive value 69% versus 83%, respectively, and correlation was strong ($r = 0.7$, $P < .001$) (Wheatley-Guy, 2020).

The evidence of clinical benefit is limited to one manufacturer-sponsored, multicenter, prospective, concurrent-control trial (Boehmer, 2024). The control arm (n = 245) was labeled Benefits of Microcor in Ambulatory Decompensated Heart Failure (BMAD-HF), ClinicalTrials.gov identifier NCT03476187), and the intervention arm (n = 249) was labeled Benefits of Microcor in Ambulatory Decompensated Heart Failure (BMAD-TX; ClinicalTrials.gov identifier NCT04096040). The study enrolled participants who had a recent hospitalization within 10 days for heart failure and a heart failure event within the previous six months. Participants in the intervention arm wore the ZOLL patch continuously for 90 days. Using intention-to-treat analysis, the primary endpoint was time to first heart failure hospitalization. Secondary endpoints included a composite heart failure-related events (emergency department visits, hospitalizations, and death) and quality of life as measured with the 12-item Kansas City Cardiomyopathy Questionnaire.

Compared with the control arm, participants using ZOLL lung fluid monitoring had a 37% reduction in heart failure hospitalization (hazard ratio = 0.63, $P = .03$, absolute reduction = 7%), a 38% reduction in the composite outcome of heart failure events ($P = .02$, absolute reduction = 9%), and clinically meaningful improvement in quality of life (12 points higher, $P = .004$). Study limitations included a short follow-up period, lack of randomization, a non-blinded intervention arm, and small but significant baseline differences in the use of angiotensin receptor–neprilysin and sodium glucose cotransporter 2 inhibitors between arms. The effects of COVID-19 on remote management considerations, presence of pulmonary congestion at enrollment, and need for diuretic agents are unclear (Boehmer, 2024).

Extrapolating from the above trial data, Bosworth Smith (2025) estimated ZOLL's cost-effectiveness over a five-year time horizon in the United States context. Compared to the standard of care, an estimated $6,723 reduction in care costs and fewer hospital readmissions (mean, 1.075 versus 1.201 per patient) were projected at five years with ZOLL monitoring. However, there is considerable uncertainty in the model inputs after 90 days, and long-term data are needed to confirm analytical trends.

References

On July 10, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Monitoring, physiologic" (MeSH), "Heart failure" (MeSH), "remote sensing technology," "μCor," "ZOLL," and "heart failure management system." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-

analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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