02.02.22 Noninvasive Heart Failure and Arrythmia Management and Monitoring Systems

Original Effective Date: January 2016

Review Date: February 2026

Revised: January 2025

DISCLAIMER/INSTRUCTIONS FOR USE

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.

Related Policies:

- 02.02.19 Baroreflex Stimulation Device Components and Ancillary Services
- 02.02.17 Cardiac Contractility Modulation Therapy Device Components and Ancillary Services
- 02.02.21 Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

Summary

Description

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.

Summary of Evidence

For individuals with New York Heart Association (NYHA) class II-IV heart failure in outpatient settings who receive non-invasive heart failure and arrhythmia management and monitoring system (µ-Cor™ Heart Failure and Arrhythmia Management System) as an early indicator for heart failure decompensation and arrhythmia detection, the evidence includes studies based on unpublished data to validate the capabilities of the system that were utilized for the device FDA approval and an open-label concurrent-control clinical trial (Boehmer et al 2024) that compared the strategy utilizing data from wearable µ-Cor™ HFMS to manage individuals with a previous HF hospitalization remotely to usual care to avoid hospitalization. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life (QOL), morbid events, hospitalizations, and treatment-related morbidity. While the strategy using HFMS data for HF management in Boehmer et. al 2024 may have been associated with 38% relative risk reduction in 90-day HF hospitalization compared to subjects in the control arm (HR: 0.62; p = 0.03) this is study is not a randomized controlled trial (RCT). Important methodological limitations which may have influenced the outcome of this trial include lack of randomization allowing unbalanced patient populations in the 2 arms regarding baseline characteristics and variations in site practices which may have influenced the outcome of this trial. Also, because this study was started before COVID-19, it is not possible to rule out the possibility that study results may have been influenced by a shift in some centers to a more remote management approach with less face-to-face interactions and it is not possible to determine if COVID-19 affected the primary outcomes of the two study arms. RCTs are still needed to evaluate whether remote monitoring with HFMS improves to earlier intervention in individuals with HF and reduces risk of hospitalization. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable

OBJECTIVE

This evidence review 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.

PRIOR APPROVAL

Not applicable.

POLICY

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

ALL Category III will be considered **investigational** unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.

POLICY GUIDELINES

Category III codes are a set of temporary (T) codes for emerging technologies, services, and procedures that allow for data collection by the American Medical Association's (AMA). If a Category III code is available, providers must use that code instead of an unlisted or deleted Category I code. The services or procedures represented by Category III codes may not have FDA approval, may not be performed by many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

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.

Coding

See the Codes table for details.

BACKGROUND

Chronic Heart Failure

Individuals with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Individuals with a history of acute decompensation have the additional risk of future episodes of decompensation and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.

Management

Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of individuals at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a health care provider, education, and medication adjustments as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable individual but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill individuals and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output, and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating room.

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, μ-Cor™ Heart Failure and Arrhythmia Management System (HFAMS) is a patch-based sensor that 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 brady arrhythmias; or
> 2. requiring fluid management (Product Label Information, 2019).

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 brady arrhythmias; **or**
> 2. requiring fluid management

RATIONALE

This evidence review was created in January 2016 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 2026.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Noninvasive Heart Failure and Arrhythmia Management and Monitoring Systems as Early Indicator for Heart Failure Decompensation

Clinical Context and Test Purpose

The purpose of noninvasive heart failure and arrhythmia management and monitoring systems is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals who have NYHA class II-IV heart failure with fluid management issues in the outpatient setting.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with NYHA class II-IV heart failure in the outpatient setting.

Interventions

The µ-Cor Heart Failure and Arrhythmia Management System is a non-invasive and water-resistant sensor that can be worn by individuals 24 hours a day for monitoring of pulmonary fluids as an early indicator for heart failure decompensation. Once placed on the individuals body this device continuously records and stores patient data including heart rate (HR), heart rhythm (ECG) respiration rate (RR), and thoracic fluid levels. The data provided can then be used to aid medical professionals as they diagnose and identify various clinical conditions, events, and/or trends to improve outcomes and reduce hospitalizations.

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 brady arrhythmias; **or**
2. requiring fluid management.

Comparators

The comparator of interest is standard clinical care without testing. Decisions on guiding volume management are being made based on signs and symptoms.

Individuals with heart failure are managed by cardiologists in an outpatient clinical setting.

Outcomes

The general outcomes of interest are the prevention of decompensation episodes, reduction in hospitalization and mortality, and improvement in QOL.

Study Selection Criteria

Methodologically credible studies were selected using the following principles.

- Comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations will be considered.
- Larger sample size studies and longer duration studies are preferred.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The FDA clearance of the μ-Cor Heart Failure and Arrhythmia Management System 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 40 hemodialysis participants (20 participants in each arm) wearing the μCor 3.0 Heart Failure and Arrhythmia Management System (Study Arm 1 below left axilla; Study Arm 2 upper left pectoral area); 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).

Boehmer et al (2024) conducted a multicenter, multinational, prospective, concurrent-control clinical trial consisting of 2-arms, BMAD-HF (Benefit of Microcor in Ambulatory Decompensated Heart Failure [control arm]; NCT03476187]) and BMAD-TX (Benefit of Microcor in Ambulatory Decompensated Heart Failure [intervention arm]; NCT04096040]). This study used the Zoll Heart Failure Management System (HFMS) (FDA registered name: uCor™ Heart Failure and Arrhythmia Management System). In the control arm (BMAD-HF) the investigators and patients were blinded to the device data and in the intervention arm (BMAD-TX) the device data was shared with the investigators and the data could be shared and reviewed with the patients in the study. The purpose of this study was to compare the strategy utilizing data from wearable HFMS to manage patients remotely with a previous heart failure (HF) hospitalization to usual care to avoid hospitalization. Eligible patients were discharged from the hospital within previous 10 days and had a HF event in the previous 6 months. The impact of HF management with the HFMS was evaluated by Kaplan-Meier analysis of time to first HF hospitalization. A total of 522 subjects were enrolled in the study at 93 sites. A total of 245 subjects in BMAD-HF and 249 in BMAD-TX were eligible for intention-to-treat analysis. There were 276 hospitalizations in 189 subjects at 90 days, of which 108 events were determined to be heart failure related in 82 subjects. The subjects in the arm managed using HFMS data to direct HF therapy had a 38% lower HF rehospitalization rate during the 90 days following a HF hospitalization compared to subjects in the control arm (HR: 0.62; P = 0.03). Limitations of this study included that the lack for randomization resulted in individuals in the BMAD-TX arm being significantly older in age and having great use of angiotensin receptor blockers, angiotensin receptor-neprilysin inhibitors (ARNIs), and sodium-glucose cotransporter 2 (SGLT2) inhibitors. Additionally, variations in site practices between groups may have influenced the outcome of this trial. Also, because this study was started before COVID-19, it is not possible to rule out the possibility that study results may have been

influenced by a shift in some centers to a more remote management approach and less face-to-face interactions.

There is an additional completed/unpublished study (NCT04512703).

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA)

In 2022, the American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) updated their 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

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.
4. 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

5. 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 February 2, 2026
6. 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 February 2, 2026.
7. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. J Amer Coll Cardiol. 2017. Available at: https://www.ahajournals.org/doi/10.1161/cir.0000000000000509. Accessed February 2, 2026.
8. Zoll Medical Corporation. Benefits of Microcor in ambulatory decompensated heart failure (BMAD-TX). NLM Identifier: NCT04096040. Last updated June 1, 2021. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04096040?term=%C2%B5Cor&cond=Heart+Failure&draw=2&rank=2. Accessed February 2, 2026.
9. Zoll Medical Corporation. Benefits of µCor in Ambulatory Decompensated Heart Failure (BMADHF). NLM Identifier NCT03476187. Last updated June 1, 2021. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03476187?term=%C2%B5Cor&cond=Heart+Failure&draw=2&rank=1. Accessed February 2, 2026.
10. 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 February 2, 2026.
11. 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
12. Centers for Disease Control and Prevention. Heart failure. Last updated September 8, 2020. Available at: https://www.cdc.gov/heart-disease/about/heart-failure.html. Accessed February 2, 2026.
13. National Heart, Lung and Blood Institute. Heart failure. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/Hf/HF_WhatIs.html. Accessed February 2, 2026.
14. UpToDate. Overview of the Management of Heart Failure with Reduced Ejection Fraction in Adults. Wilson S. Colucci M.D., Topic last updated September 4, 2025. Also available at https://www.uptodate.com Accessed February 2, 2026.
15. UpToDate. Management of Refractory Heart Failure with Reduced Ejection Fraction. Shannon M. Dunlay M.D., MS, Wilson S. Colucci M.D., Topic last updated August 8, 2025. Also available at https://www.uptodate.com Accessed February 2, 2026.
16. UpToDate. Treatment and Prognosis of Heart Failure with Preservice Ejection Fraction. Barry A. Borlaug M.D., Wilson S. Colucci M.D., Topic last updated October 27, 2025. Also available at https://www.uptodate.com Accessed February 2, 2026.
17. ClinicalTrials.gov Measuring Thoracic Impedance in Hemodialysis Patients with the u-Cor Monitoring System (MaTcH). NCT03072732
18. ClinicalTrials.gov Vital Signs Validation Study of the u-Cor System (ViVUS Validation) NCT02975050
19. ClinicalTrials.gov Benefits of uCor in Ambulatory Decompensated Heart Failure NCT03476187
20. ClinicalTrial.gov Feasibility Study of the uCor Heart Failure and Arrhythmia Management System (PATCH)

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
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 (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
HCPCs		
	None	
Type of Service	Medical	
Place of Service	Outpatient	

POLICY HISTORY

Date	Action	Action
February 2026	Annual Review	Policy Renewed
January 2025	Annual Review	Policy Revised
January 2024	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
January 2022	Annual Review	Policy Revised, Content Moved and 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:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.