

TEMPUS

New CMS Decision Provides Medicare Coverage for the Clinical Use of the Tempus ECG-AF Device

December 17, 2024

New decision establishes reimbursement for the clinical use of Tempus ECG-AF, reducing the financial burden of using AI to improve early detection of atrial fibrillation

CHICAGO--(BUSINESS WIRE)--Dec. 17, 2024-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced the impact of a new decision by the Centers for Medicare and Medicaid Services (CMS) that will allow reimbursement for assessments of cardiac dysfunction using the Tempus ECG-AF algorithm. ECG-AF is one of just a few FDA-authorized medical technologies in the country to be impacted by the new CMS decision, and this milestone allows Tempus to more broadly support clinicians in identifying patients at increased risk of atrial fibrillation/flutter (AF).

Per the CMS policy to allow payment for certain Software as a Service (SaaS) devices in the Hospital Outpatient setting, CMS has assigned associated procedure codes for assessments with assistive algorithms like Tempus' ECG-AF ([CPT 0764T](#) and [CPT 0765T](#)) to APC 5734, which has a Medicare rate of \$128.90, effective January 1, 2025. This ruling is expected to allow hospitals to receive reimbursement for using Tempus' ECG-AF to help identify patients at increased risk of AF. Earlier this year, Tempus received 510(k) clearance from the FDA for the Tempus ECG-AF device, which was the first FDA clearance for an AF indication in the category known as "cardiovascular machine learning-based notification software" and paved the way for clinicians to use this innovative algorithm in the care of their patients.

Cardiovascular disease remains the leading cause of death globally, making it critical to identify patients at high risk for undiagnosed heart disease much earlier. AF, a common cause of stroke, in particular affects millions of people and can be challenging to diagnose. As a result, nearly one million Americans are believed to have undetected AF, and are missing the opportunity to be treated optimally. Since over 100 million ECGs are performed each year in the U.S.¹ there is an opportunity to make these ECG tests "smarter" by applying machine-learning models that can detect risk of certain heart diseases like AF. Tempus ECG-AF provides a solution to help tackle this problem, giving clinicians an AI-based clinical tool to help them be more proactive about earlier disease identification and management.

"We are incredibly excited by this new Medicare ruling," said Brandon Fornwalt, MD, PhD, Senior Vice President of Cardiology at Tempus. "This, combined with our FDA clearance earlier this year, has substantially lowered the barrier for clinicians to broadly adopt innovative technologies like ECG-AF to tackle undiagnosed cardiovascular disease."

The Tempus ECG-AF algorithm is intended for use to analyze recordings of 12-lead electrocardiogram (ECG) devices and to detect signs associated with a patient experiencing AF within the next 12 months. It is for use on resting 12-lead ECG recordings collected at a healthcare facility from patients 65 years of age or older who do not have a known history of AF or other specified conditions. The device provides clinicians with results that should be interpreted in conjunction with other diagnostic information, including the patient's original ECG recordings and other tests, as well as the patient's symptoms and clinical history. Tempus ECG-AF does not describe a person's overall risk of experiencing AF and should not serve as the sole basis for diagnosis of AF. Results should not be used as the basis for treatment of AF and are not intended to rule out AF follow-up. More details on the Tempus ECG-AF technology can be found [here](#).

About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of multimodal data, and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit [tempus.com](#).

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, about Tempus and Tempus' industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements, including, but not limited to, statements regarding the potential for Tempus' ECG-AF device to support physicians and clinicians in finding patients who are at risk for cardiovascular disease and conditions earlier; the expected benefits of such earlier identification of patients; Tempus' belief that patients at the risk of AF are underdiagnosed and undertreated; and AF-related patient population; and suitability of claim submission for any specific patient; decisions made by CMS regarding coverage, coding, or reimbursement for use of the ECG-AF device. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "going to," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Tempus cautions you that the foregoing may not include all of the forward-looking statements made in this press release.

You should not rely on forward-looking statements as predictions of future events. Tempus has based the forward-looking statements contained in this press release primarily on its current expectations and projections about future events and trends that it believes may affect Tempus' business, financial condition, results of operations and prospects. These forward-looking statements are subject to risks and uncertainties related to: Tempus' financial performance; the ability to attract and retain customers and partners; managing Tempus' growth and future expenses; competition and new market entrants; compliance with new laws, regulations and executive actions, including any evolving regulations in the artificial intelligence space; the ability to maintain, protect and enhance Tempus' intellectual property; the ability to attract and retain qualified team members and key personnel; the ability to repay or refinance outstanding debt, or to access additional financing; future acquisitions, divestitures or investments; the potential adverse impact of climate change, natural disasters, health epidemics, macroeconomic conditions, and war or other armed conflict, as well as risks, uncertainties, and other factors described in the section titled "Risk Factors" in Tempus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 filed with the Securities and Exchange Commission ("SEC") as well as in other filings Tempus may make with the SEC in the future. In addition, any forward-looking statements contained in this press release are based on assumptions that Tempus believes to be reasonable as of this date. Tempus undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this

press release or to reflect new information or the occurrence of unanticipated events, except as required by law.

¹ Tison, G. H., Zhang, J., Delling, F. N., & Deo, R. C. (2019). Automated and Interpretable Patient ECG Profiles for Disease Detection, Tracking, and Discovery. *Circulation: Cardiovascular Quality and Outcomes*, 12(9). <https://doi.org/10.1161/circoutcomes.118.005289>

View source version on [businesswire.com](https://www.businesswire.com/news/home/20241217385462/en/): <https://www.businesswire.com/news/home/20241217385462/en/>

Erin Carron
media@tempus.com
773-612-4414

Source: Tempus AI, Inc.