

Cleerly Launches Cleerly ISCHEMIA Solution for Heart Disease Analysis



FDA cleared, evidence-based AI and machine learning-based algorithm detects heart disease-associated ischemia

Cleerly, the company working to create a new standard of care for the diagnosis of heart disease, today announced the launch of Cleerly ISCHEMIA, which recently received U.S. Food and Drug Administration (FDA) 510(k) medical device clearance. Cleerly ISCHEMIA analysis software is an automated machine learning-based decision support tool, intended as a diagnostic aid for patients undergoing coronary computed tomography angiography (CCTA) analysis using Cleerly LABS software.

Through its AI capability, Cleerly ISCHEMIA determines the likely presence or absence of coronary vessel ischemia based on quantitative measures of atherosclerosis, stenosis, and significant vascular morphology from patients' CCTA images. When utilized by an interpreting healthcare provider, this software in conjunction with the results of Cleerly LABS provides personalized analysis that may be useful in detecting likely ischemia associated with coronary artery disease (CAD).

"We are pleased to have FDA 510(k) clearance for Cleerly ISCHEMIA and offer the software as part of Cleerly Labs to providers to support their diagnosis of patients across the entire heart disease continuum," said James K. Min, MD, FACC, FESC, MSCCT, founder and CEO of Cleerly.

Cleerly ISCHEMIA is rooted in over 20 years of science from landmark multi-center trials and is supported by extensive scientific research and validation through comprehensive studies conducted by leading cardiology experts using study data from the CREDENCE and PACIFIC trials.

"Cleerly ISCHEMIA is a true testament to our unwavering commitment to scientific innovation and research-backed solutions," Dr. Min said. "We are proud to support healthcare professionals personalize patients' heart health journeys. Cleerly ISCHEMIA is a transformative addition poised to reshape the landscape of cardiac care."

A Category 1 CPT code is available for the work performed in association with Cleerly ISCHEMIA analysis. Cleerly ISCHEMIA analysis is only available by prescription. Interested patients should consult with their physician.

Source: [Cleerly](#)

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