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News We're Watching: Breakthrough Retinal Scan For CV Disease, InfoBionic's AI-Powered Remote Monitoring, And More

by Reed Miller

Some of the industry news from last week that *Medtech Insight* is tracking: The FDA granted its breakthrough status to Toku's Clair AI technology for finding markers of cardiovascular disease in retinal scans. Dupont is partnering with STMicroelectronics on a new patch sensor technology, ReWalk secures Medicare coverage for its exoskeleton, and more.

Medicare Proposes Preliminary Reimbursement For ReWalk Robotics

ReWalk Robotics announcedyet another milestone in its efforts to solidify Medicare coverage and help more people with spinal cord injuries gain access to its exoskeleton technology.

After announcing that the Centers for Medicare and Medicaid Services ruled that exoskeletons would be covered in the Medicare brace benefit category, the medical device company said that the agency included the ReWalk Personal Prosthetic Exoskeleton system in the agenda for the upcoming Healthcare Common Procedure Coding System (HCPCS) meeting on 29 November and provided a preliminary payment determination of $94,617. (Also see "*Digital Health Roundup: VR, AI Trends In Rehabilitation; Cybersecurity Regulations; Medicare Updates*" - Medtech Insight, 5 Sep, 2023.)

ReWalk CEO Larry Jasinski called the inclusion of the device in the HCPCS agenda and the proposed preliminary pricing “a tremendous step forward in our efforts to ensure broader access to exoskeletons for the substantial percentage of the spinal cord injury community with Medicare coverage.”

According to ReWalk, CMS is open to receiving updated information on pricing that reflects

technological advancements, such as the ability for the system to help people walk on stairs and curbs, which have been implemented since ReWalk's application dating back to 2020. CMS relied on average prices from 2020 market transactions, which it determined to be $125,500, and then resulted in preliminary Medicare pricing of $96,617, the company wrote on 6 November. (Also see "*ReWalk Robotics' Planned Acquisition Of Anti-Gravity Maker AlterG For $19M Paves Way To Profitability*" - Medtech Insight, 10 Aug, 2023.)

"CMS notes that it would welcome materials providing information on updated verifiable market transactions from ReWalk as well as any other makers of similar bilateral lower limb exoskeletons to 'ensure that the Medicare payment amount for this code accurately reflects the full market of devices that would be classified in this code,"' ReWalk said, adding that it will participate in the 29 November meeting to provide more information on current pricing, including for its Personal Exoskeleton.

"The ReWalk team is still reviewing the specific information that it will provide to Medicare at the upcoming HCPCS meeting," Jasinski told Medtech Insight.

The US Food and Drug Administration cleared ReWalk's Personal Exoskeleton in March and gave the device its breakthrough device designation because it is the only commercially available exoskeleton that includes advanced technology to enable paralyzed individuals to navigate real-world environments with stairs and curbs.

The final payment determination is expected in early 2024 with 1 April being the effective date.

FDA Grants Breakthrough Status To Retinal Cardiovascular Risk Assessment

Toku's CLAiR AI technology platform for real-time cardiovascular disease risk assessment has received the US *FDA's breakthrough status*.

CLAiR analyzes images of the tiny blood vessels in the retina to find signals of cardiovascular risk factors, including hypertension and high cholesterol.

The system is designed to be integrated into routine retinal imaging exams performed ophthalmologists, primary care clinics, and pharmacies.

Toku CEO and co-founder Ehsan Vaghefi said, "This designation greatly de-risks our clinical development and regulatory pathway for the technology."

FDA's Breakthrough Devices program provides a prioritized review process for devices that significantly improve patient care or address an unmet need.

InfoBionic Earns Clearance, Funding, And Partnership For AI Remote Monitoring

October was a busy month for InfoBionic, a Boston-based company developing an artificial intelligence-enabled remote cardiac monitoring system.

At the end of October, the US Food and Drug Administration cleared InfoBionic's MoMe ARC wireless ambulatory electrocardiogram (ECG) monitoring and detection system, their third Generation remote-ECG monitoring device, to be paired with their a new Bluetooth diagnostic six-lead sensor designed.

MoMe ARC is indicated to help doctors diagnosis cardiac arrhythmias in patients with a "demonstrated need for cardiac monitoring." It builds on the success of the MoMe Kardia II by providing a decoupled two-channel – six-lead sensor.

MoMe includes a four-in-one Gateway device that lets it seamlessly transition between two-day, extended Holter, event-monitoring and mobile-cardiac telemetry modes remotely. InfoBionic's cloud-based proprietary platform delivers on-demand data and analytics to clinicians. MoMe's new sensor has a new lightweight form with Bluetooth connectivity.

Also at the end of the month, the company announced that it entered a partnership with Mayo Clinic to "incorporate its extensive know-how" into cardiac patient monitoring, AI-ECG, and virtual telemetry.

"This agreement represents our enduring commitment to delivering the most advanced remote monitoring solutions available and continuing our history of industry-leading quality in remote ECG monitoring for caregivers and their patients," says InfoBionic CEO Stuart Long.

On 16 October, the company announced the closure of a series D financing round to support domestic growth and international expansion for MoMe ARC. The company did not announce the value of the deal, but the round includes participation by Security International Investments (SII), Mayo Clinic and Excel Venture Management.

Existing investors Blue Cross Blue Shield of MA (Zaffre Investments), Blue Cross Blue Shield of Kansas and Safeguard Scientifics remain involved with the company.

Dupont Teams Up With STMicroelectronics On Wearables

DuPont's Liveo Healthcare business announced a partnership with STMicroelectronics to develop a new smart wearable technology for remote biosignal monitoring.

The companies have developed a prototype with multifunctional microsensors and control electronics from STM embedded in a flexible patch designed by DuPont.

The patch is smaller, lighter, and more comfortable than existing electrocardiogram/seismocardiogram patches, according to DuPont.

Jennifer Gemo from DuPont Liveo and Oriana Di Marco from STM will present a paper on their patch technology on 14 November at the Medica Trade Fair in Dusseldorf.

NIH Supports AI Brain Imaging at IU

Eleftherios Garyfallidis, a professor and engineer at Indiana University in Bloomington won a $2.3m grant from the National Institutes of Health's Brain 2.0 Initiative to develop artificial intelligence software that will hopefully contribute to breakthrough brain research.

Garyfallidis team is developing community-supported open-source software for computational neuroanatomy to map axon networks based on imaging data. Garyfallidis' *DIPY* software project allows researchers to study how the different brain regions are connected and function.

"A patient takes medicine, but how does a doctor know if it's working?" he said. "How do we know if the targeted parts of the brain are getting better? This project aims to answer those questions."

The next phase of the project builds upon this work to further improve the existing mapping tool and to support the next generation of researchers studying the structure of the brain.

"Open-source scientific software needs to be in the loop with medical practice," he said. "Medical doctors want to learn how AI methods work; they want to understand. We need to stop pushing black-box solutions to the hospitals."

Co-Diagnostics Earns Gates Grant For TB Test

Salt Lake City-based Co-Diagnostics has won a $8.976m award from the Bill & Melinda Gates Foundation to help develop a molecular diagnostics test for tuberculosis (TB).

Co-Diagnostics' Co-Dx polymerase chain reaction (PCR) test for TB is designed to be developed in areas most burdened by the disease. The grant money will be applied to regulatory and clinical validation, improving manufacturing capacity, and additional platform software development, the company announced on 2 November.

The company already has infrastructure and manufacturing capabilities India through a joint venture with Synbiotics Limited called CoSara Diagnostics.

According to the World Health Organization (WHO), about 40% of TB cases are undiagnosed.

“Co-Dx is committed to making point-of-care TB diagnostics more accessible around the world, and we are pleased that this commitment will be supported by the additional proceeds of this new grant as we follow through on our mission to prevent the spread of infectious diseases by increasing the availability of PCR diagnostics worldwide.”