Prevencio Progresses on Commercialization Plans After Receiving CPT PLA Codes

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NEW YORK – Following the recent receipt of reimbursement codes for three of its cardiovascular disease tests, proteomics firm Prevencio is continuing to make strides in commercializing its assays.

In January, the company announced that the American Medical Association had granted three of its tests – HART CADhs for obstructive coronary artery disease diagnosis; HART CVE for one-year risk of heart attack, stroke, or cardiac death; and HART KD for Kawasaki disease – CPT Proprietary Laboratory Analysis (PLA) codes. PLA codes are specific to a single laboratory-developed test and can be used to submit claims to payors for reimbursement.

According to Rhonda Rhyne, Prevencio's president and CEO, both HART CADhs and HART CVE are currently available as LDTs, while HART KD, which was developed with Seattle Children's Research Institute, is ready to be launched soon.

Most of Prevencio's immunoassays were developed primarily in partnership with Massachusetts General Hospital cardiologist James Januzzi, who had patient blood samples that Prevencio used to build out its machine learning algorithms. As part of a multiyear study called the Catheter Sampled Blood Archive in Cardiovascular Diseases study, Januzzi and his team took blood from 1,251 patients who were undergoing diagnostic coronary angiography in the hospital's catherization lab and followed them for about four years to monitor cardiovascular events.

The samples from Mass General were tested by Prevencio for more than 109 proteins that could potentially be used in final test panels for heart disease. Those proteins were used to train and develop the algorithm for each specific test, Rhyne said. The HART CADhs and HART CVE panels were then internally validated at Mass General on different patients than the training set and externally validated on 750 patients from University Medical Center Hamburg-Eppendorf in Germany and 500 patients from Inova Health System.

The patients from Inova were mostly stable patients referred to the hospitals' catherization labs, while the patients from Hamburg-Eppendorf were ones who had presented with chest pain in the emergency department.

The Kirkland, Washington-based company also looked at more than 250 clinical variables and patient's medical outcomes for up to five years after the cardiac event to further refine the algorithm.

Results from the HART CVE test's validation study using the Mass General samples were published in 2017 in the *American Journal of Cardiology.* In that study, sensitivity for the test was 64 percent,

while specificity was 76 percent, negative predictive value was 93 percent, and the area under the curve of the model, which measures a test's accuracy, was .79. A follow-up external validation study published in 2020 in *Biomarkers in Medicine*, using samples from Hamburg-Eppendorf, found the test's negative predictive value was 99 percent and the area under the curve was .86, an improvement in both metrics.

Meantime, a validation study of HART CADhs also conducted by Januzzi and his team and published in the *Journal of the American Heart Association* in 2020 found the test had an area under the curve of .85, 80 percent sensitivity, 71 percent specificity, and negative predictive value of 66 percent.

For each specific test, the algorithm selects the combination of data with the highest accuracy for the desired diagnosis. It determines the most useful proteins from a massive panel, Rhyne said, narrowing the final test down to three to five proteins.

Prevencio's assays vary in what clinical parameters, if any, they look at, Rhyne added. HART CVE looks only at four proteins – NT-proBNP, Kidney Injury Molecule-1, osteopontin, and TIMP-1 – to determine a 10-point score that indicates the one-year risk of a patient experiencing a heart attack, stroke, or death, while HART CADhs combines three proteins and three clinical parameters to return a five-point score indicating the likelihood of obstruction in a patient's coronary arteries, she said.

In addition to the three tests that have received PLA codes, Prevencio has other tests in various stages of development: HART PAD for peripheral artery disease; HART AKI for predicting acute kidney injury risk; HART AMP for predicting amputation risk; and HART AS for aortic valve stenosis. Rhyne said that the company hasn't yet decided which test will be commercially launched next.

The firm's HART AI platform is also available for customers to develop custom diagnostic tests for specific proteins and clinical parameters, she said.

The PLA codes for the three HART tests will be billable in April, and the firm will be discussing pricing with Medicare this summer, Rhyne noted. Currently, the company is billing patients directly.

She added that Prevencio will be seeking approval from the US Food and Drug Administration for the two HART tests that are already on the market, the HART CADhs and HART CVE. While the focus right now is on the US, the firm does also plan to expand globally, likely starting in Europe and Asia. In 2021, the firm announced a commercialization agreement with Atlas Genomics for its tests.

Rhyne said she sees a variety of uses for the HART tests, including in physician offices, where providers can send samples to Atlas Genomics in Seattle, or in emergency departments or hospitals where the lab can conduct the test itself. While one potentially obvious use case would be for clinicians as a monitoring tool for chronic heart disease and cardiovascular risk, the tests could also be used in COVID-19 patients requiring cardiac monitoring or for insurance companies to determine a patient's risk factors for coverage, Rhyne said.

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