



CareFirst BlueCross BlueShield and Exosome Diagnostics Announce Evidence Development Collaboration for Molecular Diagnostic Tests

Program designed to accelerate access to ExoDx novel liquid biopsy tests for CareFirst members and is first agreement as part of CareFirst's HealthWorx Program

August 24, 2017 - Baltimore, Md. and Boston, Ma. — CareFirst BlueCross BlueShield (CareFirst) and [Exosome Diagnostics, Inc.](#) (ExoDx) announced today that they have signed an agreement to collaborate on evidence development studies for ExoDx® diagnostic tests. The collaboration is designed to evaluate new products using clinical outcome and cost analyses with the goal of accelerating health plan coverage for products demonstrating measurable benefits for patient care.

The agreement is the first in a series of such agreements through CareFirst's new HealthWorx program, that enables CareFirst to work with small, early stage companies to bring new technologies and care advances to CareFirst's members and providers with the goal of improving health care quality and reducing costs. Under the terms of the agreement, CareFirst will become ExoDx's preferred partner for evidence development studies. CareFirst and ExoDx will mutually agree on the diagnostic tests to be studied, the extent and qualifications of providers participating in these studies, and the study endpoints.

The initial collaboration between ExoDx and CareFirst will center on the company's EPI test ([ExoDx® Prostate IntelliScore](#)). The EPI test is a "rule out" test designed to more accurately predict whether a patient presenting for an initial biopsy does not have high-grade prostate cancer and, thus, could potentially avoid the discomfort, complications and cost of an initial biopsy and, instead, continue to be monitored.

"One of the challenges presented by prostate-specific antigen (PSA) cancer screenings is the relatively high number of false positives detected from PSA results which often fall into a 'gray' zone and require further testing through biopsies," said Dr. Rahul Rajkumar, CareFirst's Chief Medical Officer. "These prostate biopsies often find the false positives to be benign or low-grade cancers for which treatment or intervention is not clinically indicated. Unfortunately, this course of care can lead to medically unnecessary prostate biopsies and avoidable complications for our members. We are excited about the evidence to date and potential for ExoDx's EPI test to better inform physicians and members' decisions on which course of action to pursue when facing a PSA result in the gray zone."

As part of the study, the EPI test will be provided through selected urology group practices in Maryland. The study itself has been designed to provide additional new evidence to guide clinical practice and help CareFirst's members and providers make more informed diagnostic and treatment decisions.

“In developing the EPI test, ExoDx has consistently focused on its value for patient care,” stated Tom McLain, ExoDx Chief Operating Officer. “The opportunity to work with a large health insurer such as CareFirst to demonstrate the clinical utility of our test, assess its benefit in terms of long-term patient outcomes, complete a cost benefit analysis and understand the value of the test from the perspectives of the doctor and patient is invaluable. The information gathered will guide clinical and coverage decisions and help position EPI where it will have the greatest value for patient care.”

ExoDx will work closely with CareFirst in generating evidence to demonstrate the clinical utility of its clinical tests. The technology assessment and coverage determination process have been significant challenges for companies with innovative molecular diagnostic tests. In many instances, it takes years to gain health insurer coverage for new tests. “The collaborative framework established between CareFirst and ExoDx has the potential to speed this process for this test and others,” said CareFirst President & CEO Chet Burrell. “This is the central purpose of the HealthWorx program.”

“We have worked diligently to address the revenue and reimbursement challenges and risk profile that have been associated with other novel molecular diagnostic test companies,” stated John Boyce, CEO of Exosome Diagnostics. “The success of our companion diagnostics business and the launch of our point of care diagnostic system are important components of that strategy. Now our diagnostics business will benefit from CareFirst’s commitment to creating a better way to develop timely and informed decisions about which molecular diagnostic tests bring value for their members and providers. We look forward to working with CareFirst on the launch of future diagnostic and companion diagnostic tests in our pipeline.”

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company’s novel exosome-based technology platform, ExoLution™, and point of care instrument for protein capture and analysis, Shaky™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored. Visit www.exosomedx.com to learn more or follow us on [Twitter](#) and [LinkedIn](#)

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About CareFirst BlueCross BlueShield

In its 79th year of service, CareFirst, an independent licensee of the Blue Cross and Blue Shield Association, is a not-for-profit health care company which, through its affiliates and subsidiaries, offers a comprehensive portfolio of health insurance products and administrative services to 3.2 million individuals and groups in Maryland, the District of Columbia and Northern Virginia. In 2016, CareFirst invested nearly \$43.5 million to improve overall health, and increase the accessibility, affordability, safety and quality of health care throughout its market areas. To learn more about CareFirst BlueCross BlueShield, visit our website at www.carefirst.com or follow us on [Facebook](#), [Twitter](#), [YouTube](#), [LinkedIn](#), [Instagram](#) or [Google+](#).

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