Exosome Diagnostics Announces National Medicare Reimbursement Rate Set at $760 for its Prostate Cancer IntelliScore Test

Approximately 50% of Patients Who Will Benefit from the EPI Test have Medicare for their Primary Insurance Coverage

Medicare Pricing Decision Effective for 2018 through 2020

Boston, MA Nov. 27, 2017 - Exosome Diagnostics, Inc. announced today that the national Medicare price for its prostate cancer risk assessment test, ExoDx® Prostate(IntelliScore), or EPI, has been finalized by the Centers for Medicare and Medicaid Services (CMS). The final pricing decision for EPI’s test specific reimbursement code, 0005U, was set at $760 and has been included on the 2018 Clinical Lab Fee Schedule (CLFS) effective January 1st. The price for this new code was based in part on the median of private payer payments submitted to CMS by diagnostic laboratories as part of the market-based payment reform mandated through Protecting Access to Medicare Act of 2014 (PAMA). EPI’s payment rate will be in effect for a three-year term starting in January 2018 and running through December 2020.

“Being priced by Medicare so quickly after the launch of our EPI test will accelerate other key catalysts including guidelines and private payer coverage,” said Tom McLain, Chief Operating Officer of Exosome Diagnostics. “On its own, being priced on the Clinical Lab Fee Schedule will be significant for driving Medicare coverage and test adoption. We estimate 50% of the patients who will benefit from EPI have Medicare for their primary insurance coverage. In addition, several large private insurers use inclusion on the CLFS to determine their pricing for new diagnostic tests.”

While this achievement will accelerate broader adoption of EPI in the US market for 2018, it also positions the company for future test launches and commercial expansion.

“Exosome Diagnostics is extremely pleased to work with Medicare to have EPI included on Medicare’s Clinical Lab Fee Schedule (CLFS),” stated John Boyce, President and CEO of Exosome Diagnostics. “Exosome Diagnostics has led the field in the development and validation of liquid biopsy diagnostic tests,” Boyce continued. “EPI is the first and only exosomal-based diagnostic test to be included on Medicare’s CLFS. Combined with the company’s announced collaboration with CareFirst BlueCross BlueShield, with regards to the developed channel for evidence based reimbursement for its diagnostic tests, the company is well positioned to improve the lives of patients and deliver much improved diagnostic tools for doctors,” stated Boyce.

About the EPI Test

The EPI test is a completely non-invasive, urine-based test designed to be used along with clinical assessment and other standard of care factors (including age, race and family history) to enable physicians to assess whether an individual patient presenting for an initial biopsy is at greater risk for high-grade prostate cancer. As a “rule out” test, it is 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. EPI, which is intended for use in men 50 years or older with a prostate-specific antigen (PSA) result of 2-10ng/mL presenting for an initial biopsy, involves patients submitting a simple urine sample, without having to first undergo a digital rectal exam (DRE).
This test was evaluated and its performance characteristics determined by Exosome Diagnostics Inc. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. Exosome Diagnostics is certified under the Clinical Laboratory Improvement Amendments (CLIA) act of 1988 as qualified to perform high complexity clinical testing.

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, Shahky™, 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.

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