Koios Medical Announces FDA Breakthrough Device Designation for Early Cancer Detection AI Software.

Koios Medical announced receiving Breakthrough Device designation from the USFDA for AI software to detect and diagnosis breast and thyroid cancer.

NEW YORK, NY, UNITED STATES, April 11, 2021 /EINPresswire.com/ -- Koios Medical, a US developer of artificial intelligence-based software for physicians, announced receiving Breakthrough Device designation from FDA for the company's Koios DS decision support software platform for accurately interpreting both breast and thyroid ultrasound images. The company's software is the first of its kind proven in several multi-center reader studies to consistently improve cancer detection rates for physicians who use the software while simultaneously reducing costly, avoidable false positive benign biopsies, effectively elevating the quality of care provided to patients.

The Breakthrough Devices Program provides patients and health care providers with timely access to these medical devices by speeding up their development, assessment, and review and offers a new coverage pathway under the Medicare Coverage for Innovative Technology (MCIT). The MCIT rule will provide national Medicare coverage as early as the same day as Food and Drug Administration (FDA) clearance for breakthrough devices and coverage would last for 4 years. The designation offers Medicare patients nation-wide predictable access to new, breakthrough devices to help improve health outcomes.

"Access to care and care inequality are monumental challenges facing millions of Americans every day. Novel but proven technologies can be part of the solution. We could not be more honored to receive Breakthrough Device designation for Koios decision support software for early and accurate diagnosis of breast and thyroid cancer. Billions are spent in the US on overdiagnosis and even more is spent as lives are lost to late stage cancers that could have been found sooner. Removing the hurdle of reimbursement for Medicare patients will mean increased access, meaningful savings with better outcomes," says Koios Medical CEO Chad McClennan.

The Koios DS (decision support) platform met the FDA and CMS combined criteria of offering "an

effective diagnosis of life-threatening or irreversibly debilitating human diseases or conditions". Additional criteria for the designation included being a novel device addressing an emerging or anticipated public health need while being consistent with the U.S. Standard of Care AND offering significant advantages over existing approved or cleared alternatives.

Over 1.6 million breast tissue biopsies are performed annually in the US with nearly 80% of those results being benign. Costs calculated from expenditure data from a major US health care insurance plan estimate the annual national expenditure for false-positive exam results and overdiagnosis of breast cancer was found to be up to $4 billion. For thyroid cancer, over 600,000 thyroid biopsies are performed in the US annually with over 75% (and in some studies close to 9 out of 10) of those results being benign. Overdiagnosis of thyroid cancer, which is defined as “diagnosis of thyroid tumors that would not, if left alone, result in symptoms or death,” has become an issue, accounting for 70-80% of thyroid cancer cases in women and 45% of cases in men in the U.S. The number of thyroid biopsies performed annually has tripled over the last 30 years, yet there has been no reduction in mortality. The added cost burden of benign biopsies also impacts patients, resulting in inconvenience, anxiety, and complications including infection, scarring, and/or lifetime hormone supplementation.

At the same time, cancers continue to be routinely missed. In the case of breast cancer, this occurs often in younger women between the ages of 40 to 49. Despite major advances in mammography achieved via technology, regulation, and reimbursement, over 40% of US women with either dense or heterogeneously dense breast tissue are significantly underserved by the existing risk-stratified standard US screening protocol and insurance coverage rules.

In women with dense breast tissue, mammographic accuracy is reduced dramatically. These women additionally have an up to 5-fold increased risk of developing breast cancer and an 18-fold increased risk of interval cancers, which have a worse prognosis than screen-detected cancers. Ultrasound exams are standard of care, an adjunct to mammography for patients with the promise of AI utilization reducing physician variability and consistently improving physician accuracy.

"AI in radiology will undoubtedly become mainstream given its ability to increase diagnostic efficacy and efficiency in the face of an ever increasing physician workload. Wide-scale physician adoption has been the missing piece of the complex healthcare puzzle that this accelerated reimbursement is designed to address; for the benefit of the patients and the healthcare system overall", says Lev Barinov, PhD VP of Clinical Excellence.

Tonja Haugh
Koios Medical, Inc
+1 716-574-2165
email us here